

**National Park Service**

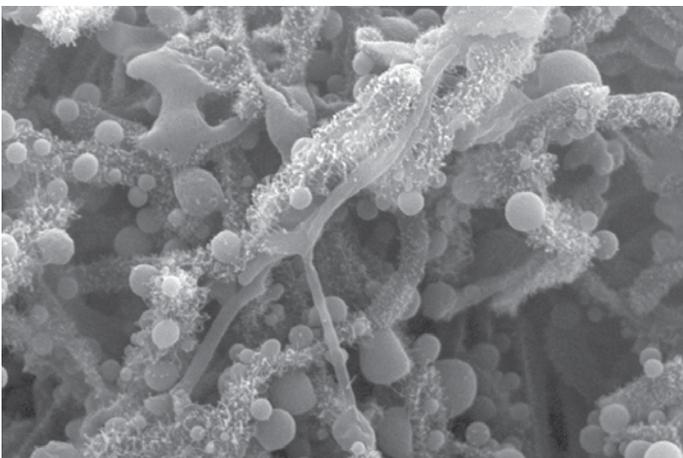
U.S. Department of the Interior



# Benefits-Sharing

## Final Environmental Impact Statement

October 2009



**Service-wide**

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Dear Friends:

Following careful consideration of input received during the public comment process, we are pleased to present the National Park Service (NPS) Benefits-Sharing Final Environmental Impact Statement (FEIS). In completing the FEIS, NPS staff received and reviewed comments submitted by about 9,600 individuals and organizations during the 130-day public review period for the Benefits-Sharing Draft Environmental Impact Statement (September 22, 2006 to January 29, 2007). A range of issues and concerns were identified, many of which have been incorporated into this Benefits-Sharing FEIS.

NPS staff worked to respond to public concerns about the benefits-sharing proposal. We valued hearing from the many commenters who emphasized support for the fundamental purpose of the national park system and the NPS's mandate to conserve park resources and values. By carefully separating the benefits-sharing proposal from the established process parks already used to evaluate applications to perform research in parks, we believe we've met that challenge. Other commenters urged the National Park Service to prevent researchers from studying park resources if their only purpose would be to make commercial discoveries. We listened to your concerns and provided a description of the scientific requirements researchers must meet before they can get an NPS research permit. Additionally, we added language to clarify when and with whom benefits-sharing would be required. Finally, at the public's suggestion, we have also proposed to include more information in the annual report to the public regarding benefits-sharing agreements.

This Benefits-Sharing FEIS presents a range of alternatives and identifies a preferred alternative. Following a required 30-day period of "no action," the National Park Service is expected to sign a "Record of Decision." This Record of Decision will represent the conclusion of the planning process and provide the guidance for parks and researchers about their rights and responsibilities related to research conducted on park resources.

We appreciate the insightful and thought-provoking comments received from the public. Your assistance allowed us to create a better proposal to clarify the rights and responsibilities of both parks and researchers with regard to potential uses of researchers' discoveries.

Sincerely,

The NPS Benefits-Sharing EIS Team

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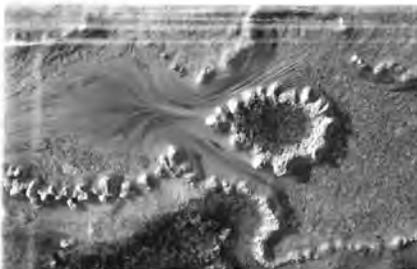
**National Park Service**

U.S. Department of the Interior

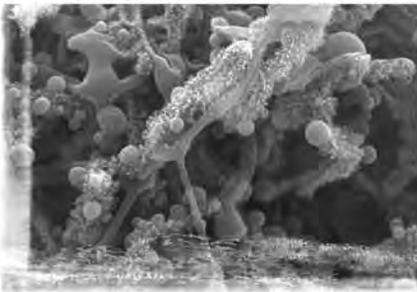


# Benefits-Sharing

## Final Environmental Impact Statement



October 2009



# Service-wide

*Cover photos, clockwise from top left:* filamentous bacteria and algae, Upper Geyser Basin, Yellowstone National Park, NPS/Hirschman; bacterial products, Spider Cave, Carlsbad Caverns National Park, Kenneth Ingham; bacteria from bacterial mats on the walls of Pahoehoe Cave, El Malpais National Monument, Michael N. Spilde and Diana Northup; thermal microbial growth, Monument Geyser Basin, Yellowstone National Park, NPS/Dunmire.

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# National Park Service

## Servicewide Benefits-Sharing Final EIS

This final environmental impact statement (FEIS) contains clarifications and changes made to the draft environmental impact statement released for public review and comment on September 2006.

**Abstract:** The environmental impact statement (EIS) presents and analyzes a servicewide programmatic proposal to clarify the rights and responsibilities of researchers and National Park Service (NPS) management in connection with the use of valuable discoveries, inventions, and other developments that result from research involving specimens lawfully collected from units of the National Park System. The EIS examines the potential environmental impacts of implementing benefits-sharing agreements when information derived from research specimens collected from units of the National Park System results in commercial value. In addition, the EIS examines the potential environmental impacts of continuing the current practice of not requiring benefits-sharing (the “no action” alternative), or barring researchers whose studies might result in commercially-viable products from collecting research specimens in the national parks. The nature of this EIS, whose purpose is essentially to examine the possible effects of implementing certain types of contracts, is such that its affected environment and impact topics relate primarily to administrative functions of the NPS. As a servicewide programmatic EIS, the affected environment and relevant impact topics have the potential to include all units of the National Park System.

A Record of Decision for the EIS can be approved by the National Park Service 30 days after the Environmental Protection Agency publishes a notice in the Federal Register regarding the release of the final EIS. An additional notice will be published in the Federal Register announcing the Record of Decision, concluding the EIS process.

For additional information or to receive a copy of this document (please specify paper copy or CD):

A full electronic copy of this document is available at the NPS’s Planning, Environment and Public Comment (PEPC) website at <http://parkplanning.nps.gov>. Select “Washington Office” under “Choose a park” and then click “Benefits Sharing.”

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Visit our website: [www.nature.nps.gov/benefitssharing/](http://www.nature.nps.gov/benefitssharing/)

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# **Executive Summary**

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## ES.1 Purpose and Need for Action

The National Park Service (NPS) is evaluating the environmental impacts of three alternatives concerning potential implementation of benefits-sharing agreements with scientists who conduct research in National Park System units. This NPS-wide environmental impact statement (EIS) will apply to all of the approximately 400 units of the National Park System.

Benefits-sharing refers to agreements that could occur between the National Park Service and researchers studying material originating as an NPS research specimen. These agreements could return benefits to the park if the results of a scientist's research leads to the development of something commercially valuable. Only researchers who already hold NPS research permits or who obtain research material through NPS Material Transfer Agreements would be engaged in benefits-sharing agreements. Benefits-sharing agreements would not authorize or regulate specimen collection or any other research activities in parks. Researchers who wish to collect specimens from park units would still have to apply for an NPS Scientific Research and Collecting Permit, and parks would continue to evaluate each such application individually in compliance with NEPA and other NPS policies and regulations that protect park visitors and resources.

The outcome of this final EIS (FEIS) is the clarification of the rights and responsibilities of researchers and National Park Service (NPS) managers in connection with the use of valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks. The commercial use or sale of research specimens themselves is prohibited by regulation (*see* 36 CFR 2.1). However, the commercial use of knowledge derived from studying specimens via research is not prohibited. Commercial use of research results has, in the past, been left entirely up to researchers without involvement from the NPS and without any further obligation or responsibilities to the NPS.

In 1998, Congress enacted the National Parks Omnibus Management Act specifically authorizing the NPS to enter into benefits-sharing agreements with researchers. However in 1999, following a legal challenge over a benefits-sharing agreement between Yellowstone and a biotechnology firm named Diversa Corporation, a federal court directed NPS to review the potential impacts of the agreement. (In June 2007, Diversa and another company merged to form Verenum Corporation. To reduce confusion, the EIS will continue to refer to the company as Diversa.) This FEIS responds to the court's directions and examines potential environmental impacts of adopting benefits-sharing throughout the National Park System.

The potential environmental impacts of three alternatives are examined in the FEIS:

**Alternative A:** No Benefits-Sharing/No Action;

**Alternative B:** Implement Benefits-Sharing (*Environmentally Preferred Alternative*) with the following variations:

Alternative B1. Always disclose royalty rate and related information;

Alternative B2. Comply with confidentiality laws regarding disclosure of royalty rate or related information (*Preferred Alternative*); and

Alternative B3. Never disclose royalty rate or related information; and

**Alternative C:** Prohibit Research Specimen Collection for Any Commercially Related Research Purposes.

This FEIS addresses the development of servicewide management practices relating to the implementation of existing NPS policy. A National Environmental Policy Act (NEPA) document of this sort has a broad scope, is general in nature, and is termed a “programmatic EIS.” It describes the conditions under which certain activities may be authorized and provides potential general standards for management. This FEIS evaluates alternative choices for implementing existing policies while evaluating the possible environmental impacts of activities that may be included in any proposal.

Because the description of the potential program at this level is general, the analysis of environmental impacts is conducted at a general level. Thus, the type and amount of data relating to possible impacts is presented at the general level. If Alternative B (Implement Benefits-Sharing) is selected, then NEPA review (environmental impact statement, environmental assessment, or categorical exclusion) of specific benefits-sharing agreements that might be established by individual parks in the future can be tiered from this programmatic EIS. If an individual park proposed site-specific resource management projects using non-monetary or monetary benefits generated by a benefits-sharing program, such projects would receive a separate environmental review for potential project-specific impacts in compliance with NEPA.

### **ES.1.1 The Emerging Need to Define the Role, if Any, of the NPS When Research Involving Study of NPS Specimens Discovers Commercially Valuable Results**

U.S. national parks attract independent researchers in part because they offer opportunities to observe preserved and protected natural resources. At nearly 400 park units and 84.4 million total acres, the National Park System constitutes a vast and complex diversity of ecosystems that represent a large majority of the variety of physical and biological features found within the U.S. today.

Scientific research is encouraged by the NPS, provided that research activities cause no harm to the parks. In order to make well-informed resource management decisions and to inform the public, the NPS collects information derived from research through Investigators’ Annual Reports (IARs), as well as articles published in scientific journals and other publications or reports. Research activities may be conducted by any scientist who qualifies for an NPS research permit without regard to whether that scientist is affiliated with or funded by public or private sources. Every research permit application is reviewed for compliance with National Environmental Policy Act (NEPA) requirements and other laws, regulations, and policies.

Some of the independent research involving study of NPS research specimens will inevitably discover useful applications for research results that could have commercial applications. Advances in research technologies now make it possible to generate substantial scientific and economic benefits from research activities in ways that were not possible—or even conceived of—in the past. Some research results involving study of specimens collected in U.S. national parks already have provided useful and valuable commercial applications. For example, the multimillion-dollar development of the polymerase chain reaction (PCR) process involved study of a microorganism first discovered at Yellowstone National Park.

### **What are research specimens?**

“Research specimens” are those items an authorized researcher has permission to collect from an NPS unit pursuant to an NPS Scientific Research and Collecting Permit (“NPS research permit”) issued by the NPS in accordance with 36 CFR 2.5.

### **What are research results?**

For purposes of this FEIS, “research results” are the data, discoveries, inventions, or other knowledge resulting from “research activities.”

### **What are research activities?**

“Research activities” are the actions taken by researchers or their sponsoring organizations or companies in accordance with an NPS research permit, including research specimen collections and analysis conducted for scientific purposes.

The important distinction between research specimens (“natural products”) and research results is intended to prevent the marketing or other commoditization of NPS resources, while not interfering with the legitimate development of useful and therefore valuable discoveries from research involving NPS research specimens. For example, NPS regulations and policy provide that specimens collected from a national park area cannot be used as raw material in the manufacture of commercial products.<sup>2</sup> In a specific example, ginseng collected under a research permit could not then be used to make a product that is sold commercially that contains the ginseng. However, there is no prohibition against the commercial use of synthetic or other non-naturally occurring compounds whose discovery and development resulted from research that initially involved the biological material collected (ginseng in this example) from a national park pursuant to an NPS research permit.

Currently, an average of more than 200 national parks annually host independent research efforts, authorized under permits generated under current policies and procedures. Research permit policies and procedures focus on potential impacts of proposed research activities on parks and do not fully address the interests of the NPS in the potential results of such research. Research permits control access to park resources, but the NPS does not always take full advantage of opportunities to coordinate research activities between independent scientists and park managers; nor does current policy guarantee that the NPS will eventually share in the benefits from independently conducted research.

The NPS has proposed new management practices (Alternative B) that would require researchers and their institutions to enter into benefits-sharing agreements with the NPS if they wish to commercialize their research results. This EIS will clarify the rights and responsibilities of researchers and NPS managers in connection with the use of valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks.

## **ES.1.2 Public Involvement**

Public involvement for the EIS began in June 2001 with scoping (66 Federal Register [FR] 33712, 33713 and 67 FR 18034, 18035). Two newsletters (mailed to more than 5,000 people), a website, and various newspaper articles invited the public to comment on the issues and alternatives to be addressed. In response, 118 scoping comment messages were received from the public. All of the public’s concerns were considered as described in EIS Sections 1.8 and 1.9.

The Benefits-Sharing Draft Environmental Impact Statement (DEIS) was released for public review on September 26, 2006 (71 FR 184). The comment period was extended (71 FR 241) until January 29, 2007, (due to print omissions and delays in delivering the DEIS) for a total of 130 days. Approximately 12,000 people were notified by mail or email about the availability of the DEIS. Press releases were widely distributed and the DEIS was posted on PEPC, the NPS's web-based public comment system. Additional information about the EIS was posted on the NPS's benefits-sharing website ([www.nature.nps.gov/benefitssharing](http://www.nature.nps.gov/benefitssharing)). More than 450 hard copies or compact disks (CDs) of the DEIS were distributed. All American Indian Tribal Governments and Alaska Native Groups were notified and three Tribes submitted comments.

About 9,600 individuals and organizations responded during the DEIS comment period, and all but 190 submitted form correspondences. As a result, most comments fell into two categories based on information from one of two advocacy group websites. Correspondents motivated by a National Parks and Conservation Association website urged the NPS to adopt benefits-sharing with certain conditions. Correspondents motivated by a website entitled "Parks Not For Sale" responded to an interpretation of potential "commercial bioprospecting" activities and impacts as presented by the former plaintiffs in the court case that precipitated this EIS. The latter correspondences were especially difficult to interpret since they did not reference the actual proposal or content of the DEIS.

For the most part, comments on the DEIS did not contain relevant new information or scientific data that would necessitate notable changes in the final EIS. While letters of this type are not particularly informative to the NEPA process, they are of importance to decision makers as the comments indicated that the majority of correspondents want the national parks to be protected under all circumstances. All of the public's concerns were considered as described in EIS Chapter 5.

### **ES.1.3 Issues and Concerns**

This FEIS is being prepared to provide a programmatic NEPA analysis for benefits-sharing agreements servicewide. In addition, the FEIS will allow the NPS to comply with a court's mandate to evaluate the impacts of a benefits-sharing agreement between Yellowstone National Park and Diversa Corporation: the Yellowstone–Diversa Cooperative Research and Development Agreement (CRADA).

In 1998, Yellowstone National Park finalized a landmark benefits-sharing agreement with the Diversa Corporation of San Diego, California. All of the resource protection restrictions in Diversa's preexisting research permit remained in effect; the research permit authorized Diversa's research activities in Yellowstone, while the benefits-sharing agreement provided for the NPS to share in the economic and scientific research benefits from Diversa research involving specimens collected at Yellowstone.

The Yellowstone–Diversa agreement was challenged in court. The court upheld the agreement and dismissed the plaintiffs' case with prejudice, but required the NPS to complete a NEPA analysis of the agreement.

During scoping, the public and the NPS Interdisciplinary Team (IDT) identified four categories in which impacts could occur:

- NPS Natural Resource Management
- NPS Visitor Experience and Enjoyment
- Social Resources: The Research Community
- Social Resources: NPS Administrative Operations

### **ES.1.4 Issues Not Evaluated Further in this FEIS**

Issues and concerns expressed by the public that are not within the scope of the decision to be made in the Final EIS were not analyzed further. Potential impacts on the following topics were not evaluated in the FEIS.

#### ***Genetic engineering***

The proposal, Alternative B (Implement Benefits-Sharing), would have no impact on genetic engineering. Issues relating to genetic engineering and the safety of any new medicines, agricultural products, or other discoveries that could result from research involving NPS research specimens are regulated by other agencies, such as the Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.

#### ***Intellectual property rights***

The proposal, Alternative B (Implement Benefits-Sharing), would have no impact on intellectual property rights as recognized in U.S. intellectual property rights laws. No federal action within the scope of this FEIS is proposed to modify any existing U.S. intellectual property rights laws.

#### ***Congressional appropriations***

Overall NPS funding is beyond the scope of the analysis of the potential environmental impacts of benefits-sharing. Existing NPS authority to negotiate equitable, efficient benefits-sharing arrangements with the research community is a congressional authorization, not an appropriation.

#### ***Administration of scientific research activities in the NPS***

Authorization to conduct scientific research in national parks is subject to well-established NPS regulations as well as to separate NEPA compliance procedures. Federal actions analyzed in this FEIS would not change the compliance procedures under which research activities could be conducted.

## **ES.2 Alternatives**

The following objectives were identified to help determine the reasonableness of each alternative and to select the preferred alternative.

**OBJECTIVE 1:** Identify the role, if any, of the NPS in the event a researcher wishes to commercialize his/her research results involving study of NPS research specimens.

**OBJECTIVE 2:** Strengthen conservation and protection of resources managed by the NPS by deepening understanding of biodiversity and physical and biological processes.

**OBJECTIVE 3:** Ensure that the NPS research permitting process is independent, objective, and unaffected by actions proposed in this FEIS.

The alternatives were developed based on information provided in comments received from the public and the FEIS Interdisciplinary Team, as well as from the internal scoping process conducted by the NPS for this FEIS. Each alternative meets the objectives described above, though to differing degrees.

**Alternative A:** No Benefits-Sharing/No Action.

**Alternative B:** Implement Benefits-Sharing (*Environmentally Preferred Alternative*) with the following variations:

**Alternative B1:** Always disclose royalty rate and related information;

**Alternative B2:** Comply with confidentiality laws regarding disclosure of royalty rate or related information (*Preferred Alternative*); and

**Alternative B3:** Never disclose royalty rate or related information; and

**Alternative C:** Prohibit Research Specimen Collection for Any Commercially Related Research Purposes.

Two existing government policies that were identified by the public as important during scoping remain unchanged under all of the alternatives in this FEIS:

- 1) Natural products would not be sold. All of the alternatives prevent the sale of research specimens, consistent with existing NPS regulations and policy.
- 2) All research permit applications would continue to be evaluated under NEPA and other NPS regulations.

### **ES.2.1 Alternative A: No Benefits-Sharing/No Action**

For analytical purposes, Alternative A is the “No Action” alternative, because it would leave unchanged the NPS policies and practices regarding commercial use of research results that existed prior to negotiation of the Yellowstone–Diversa CRADA in 1997–1998. Currently, the NPS does not negotiate benefits-sharing agreements. This would continue to be the case under this No Action alternative. Accordingly, the NPS director would issue an order clarifying the *NPS Management Policies* to provide that there is no requirement for negotiation of benefits-sharing agreements, and the NPS research permit condition discussing benefits-sharing would be amended.

Research specimens and material originating as an NPS research specimen would continue to be usable for approved research purposes (including research activities that might lead to discoveries that could be useful in terms of health care, nutrition, agriculture, environmental management, industrial, or other processes with potential commercial or other economic value), whether collected directly by a permitted researcher or obtained from an authorized third-party source such as a culture collection.

## **ES.2.2 Alternative B: Implement Benefits-Sharing (the Environmentally Preferred Alternative)**

The NPS benefits-sharing proposal would apply to research projects involving research specimens collected from units of the National Park System that subsequently resulted in useful discoveries or inventions with some valuable commercial application. A benefits-sharing agreement would provide the terms and conditions for the further development and use of such valuable discoveries, inventions, or other research results. All such researchers would be required to enter into a benefits-sharing agreement with the NPS before using their research results for any commercial purpose. Consistent with the terms of their research permits, researchers would be responsible for initiating benefits-sharing negotiations with the NPS.

Benefits-sharing agreements would not authorize any research activities (or any other activities that require a permit) in parks. A benefits-sharing agreement would be negotiated with researchers who held an NPS research permit only after the permit applicant had met all the regulatory requirements, the park unit had met all resource protection requirements, the permit had been issued, and, usually, after research had already been conducted.

Implementation of benefits-sharing agreements under Alternative B would not circumvent or supersede any NPS planning process, permitting authority, or other regulatory procedure or policy.

Projects, activities, or programs proposed to be conducted in a park as secondary results of implementation of benefits-sharing would receive separate site-specific environmental review as appropriate in compliance with NEPA.

The NPS has identified CRADAs as the appropriate agreement type for implementing benefits-sharing under Alternative B. NPS units that are federal laboratories within the meaning of the Federal Technology Transfer Act (FTTA) are eligible to enter into CRADAs. The FTTA defines the term “laboratory” to mean “a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.” For example, a federal court ruled that Yellowstone National Park is a federal laboratory (see *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DC 2000)).

A standardized CRADA (see example in Appendix A) would provide general terms and conditions to specify the rights and responsibilities of researchers and the NPS in connection with any subsequent development of commercially valuable discoveries, inventions, or other results of research involving study of specimens lawfully collected from units of the National Park System. The standardized CRADA provides a framework that would allow sharing of scientific and monetary benefits resulting from improved cooperation between national parks and the research community. The standardized CRADA (also referred to as the example CRADA in this document) could undergo minor customizations or modifications if necessary once actual use occurs. Specific terms and conditions describing the benefits that would be obligated by a benefits-sharing agreement would be negotiated individually for each agreement.

The NPS has identified four types of non-monetary benefits that could occur under some or all benefits-sharing agreements: knowledge and research relationships, training and education, research-related equipment, and special services (such as laboratory analyses). The particular knowledge and capabilities of the benefits-sharing researcher partner would determine the specific non-monetary benefits generated and managed by each benefits-sharing agreement.

The NPS has identified two types of monetary benefits that could occur under some or all benefits-sharing agreements: 1) up-front funding for research projects that support the park's research activities or 2) performance-based payments paid as a percentage of any CRADA-related income received by a researcher's institution (e.g., from licensing intermediate research results or from selling products developed from the knowledge gained from the research).

All benefits received by the NPS under any type of benefits-sharing agreement would be dedicated to the conservation of resources protected and managed by the NPS. In general, CRADA benefits must be used for scientific purposes. Therefore, this FEIS focuses on the scientific aspect of resource conservation and management.

Alternative B also provides a draft standardized Material Transfer Agreement (MTA) to facilitate compliance with the research permit General Condition that third-party transfer of research specimens or material originating as an NPS research specimen requires written authorization from the NPS. The standardized MTA (also referred to as the example MTA in this document) could undergo minor customizations or modifications if necessary once actual use occurs.

In the absence of any mitigation measures (*see* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5), implementation of Alternative B could result in consideration of separate benefits-sharing issues at the time NPS research permits are issued. For example, some people would allege that some park officials might be inclined to approve a permit based on the applicant's representation that valuable research results were likely, whereas other park officials might be inclined to disapprove permit applications involving commercial research firms for reasons not related to the scientific merits of the proposed research activity. Mitigation efforts would use management controls to manage the risk that benefits-sharing might inappropriately influence research permitting decisions.

There are three different ways that the NPS could treat financial information such as royalty rates in benefits-sharing agreements. Under each of these three variations, the NPS would provide Congress and the public with an annual report summarizing the non-monetary and monetary benefits the NPS received under benefits-sharing agreements. However, the three variations described below (Alternatives B1, B2, and B3) differ regarding the way additional financial details would be disclosed to the public.

If Alternative B is selected, one of the following approaches to the disclosure of agreement royalty rate and related information will also be selected:

***Alternative B1: Implement benefits-sharing agreements and always disclose royalty rate and related information***

During scoping, some members of the public advised the NPS to design a benefits-sharing

program that includes full disclosure of all terms and conditions of benefits-sharing agreements, including all financial details. Alternative B1 is responsive to that request.

Under Alternative B1, the full terms and conditions in all benefits-sharing agreements, including royalty rates and other financial information, would be released to the public upon request. Potential parties to benefits-sharing agreements would be so advised.

***Alternative B2: Implement benefits-sharing agreements and comply with confidentiality laws regarding disclosure of royalty rate or related information (Preferred Alternative)***

Under Alternative B2, the NPS would honor confidentiality and unfair business practice laws which protect certain business or commercial information potentially received from benefits-sharing partners. All benefits-sharing agreements would be made available to the public in their entirety upon request unless one or more parties to an agreement objected to the release of any specific information for reasons satisfying one or more of the statutory disclosure exemptions provided under the federal Freedom of Information Act (FOIA) or other laws protecting confidential business information. An objecting party would be required to demonstrate that the information was proprietary or that disclosure would harm an interest protected by FOIA. In such cases, a summary of such information, including the total monetary benefits and a description of non-monetary benefits generated by the agreement, would be prepared and released to the public upon request.

***Alternative B3: Implement benefits-sharing agreements and never disclose royalty rate or related information***

Under Alternative B3, all benefits-sharing agreements would be made available to the public in their entirety upon request, but no royalty rate or related financial information would be released under any circumstances. A summary of such information, including the total monetary benefits and a description of non-monetary benefits generated by the agreement, would be prepared and released to the public upon request.

### **ES.2.3 Alternative C: Prohibit Specimen Collection for Any Commercially Related Research Purposes**

Under Alternative C, the NPS would prohibit research specimen collection for research involving any potential commercial applications in all units of the National Park System. Researchers requesting NPS research permits who were qualified in all respects pursuant to 36 CFR 1.6 and 2.5, but identified or acknowledged their proposed specimen collections as being associated with the potential development of commercial products or services, would be denied permits. Alternative C is responsive to some public comments urging the NPS to prohibit commercialization of NPS-related research.

Under Alternative C, the NPS would prepare a new subsection amending the NPS's research specimen collection regulation (36 CFR 2.5) to prohibit research specimen collection for research involving any potential commercial applications. In addition, the NPS director would issue an order clarifying *NPS Management Policies* to provide that the collection of specimens for research that is identified or acknowledged by the researcher to have potential for commercial development is prohibited, which would make negotiation of benefits-sharing agreements moot.

Research specimens collected from national parks would continue to be usable for approved research purposes. However, these would not include research activities that the researcher identified or acknowledged could be expected to lead to discoveries that could be commercialized because they were useful in terms of health care, nutrition, agriculture, environmental management, industrial, or other processes with potential commercial or other economic value, whether collected directly by a permitted researcher or obtained from an authorized third-party source such as a culture collection.

The development of any inadvertent or other discoveries resulting from research involving NPS research specimens that could have some valuable commercial application would not be authorized unless the NPS director determined, in writing, that such development was in the public interest. Such a determination would be based on a finding by the director that refusal to authorize such development could be harmful to public health or other overriding public interest (such as discovery and development of an important new medicine). The Director's Order clarifying the *NPS Management Policies* would include these details.

Some NPS research permits signed prior to the time of Alternative C's regulatory change would have contained a requirement that negotiation of a benefits-sharing agreement must occur prior to commercial use of any research results when the research involved study of specimens originating in a park. For those permittees, under Alternative C, the NPS would not prohibit the commercial development of research results and would not make such development contingent on any benefits-sharing obligations. However, all such permittees would be prohibited from acquiring any additional NPS research specimens, because their commercial purpose would be foreseeable.

Alternative C also provides a draft standardized Material Transfer Agreement (MTA) to facilitate compliance with the research permit General Condition that third-party transfer of research specimens and material originating as an NPS research specimen requires written authorization from the NPS. By agreeing to the terms of the MTA, third-party recipient researchers would specifically acknowledge and agree to the same terms and conditions relating to use of research specimens and material originating as an NPS research specimen that apply to all permitted researchers who collect research specimens directly from units of the National Park System.

## **ES.3 Affected Environment**

During scoping, the public and the NPS Interdisciplinary Team (IDT) identified four categories in which impacts could occur:

- NPS Natural Resource Management
- NPS Visitor Experience and Enjoyment
- Social Resources: The Research Community
- Social Resources: NPS Administrative Operations

### **ES.3.1 Natural Resource Management**

A thorough understanding of natural resources is essential to the effective management

and long-term preservation of national parks, and requires a sound scientific basis. Scoping respondents advised the NPS to ensure that the information discovered during park research would be available to park managers. Comments were received supporting scientific endeavors in parks, and warning against any action that might chill research activities that could improve understanding of park resources. This FEIS analyzes the potential impacts to natural resource management by considering the availability of “science for parks” under each alternative.

Two financial metrics were used to evaluate potential impacts of monetary benefits that could be generated under Alternative B (Implement Benefits-Sharing). These metrics are the funding needed for natural resource management operations as described in NPS Business Plans and the FY2007 congressional appropriation (funding) for the NPS Natural Resource Challenge. In part, this FEIS analyzes the availability of science for parks by comparing these quantitative metrics to available information about the income derived by academic and federal research institutions from licensing intermediate research results to other institutions for further research, development, and eventual commercialization. Potential non-monetary benefits are also taken into account.

### **ES.3.2 Visitor Experience and Enjoyment**

The quality of many visitors’ experiences in and enjoyment of most parks is enhanced by an understanding of natural resources. Such understanding is further enhanced by the interpretive services offered to visitors. Visitor enjoyment could be affected by any change in the quality of park interpretation.

Interpretation can also affect visitor behavior in ways that improve the park’s ability to reach natural resource management goals. Visitors could also be affected by changes to natural resources through the alternatives’ impact on natural resource management, including the impact of interpretive services designed specifically to meet natural resource management goals.

The availability of “science for parks” can affect the quality of interpretation and, therefore, visitor experience and enjoyment of parks. This FEIS analyzes the potential impacts to visitor experience and enjoyment by considering the availability of “science for parks” under each alternative.

### **ES.3.3 Social Resources: The Research Community**

Thousands of researchers work on park-related studies every year under the authority of an NPS research permit. Most researchers are independent of the NPS and most research is biological, usually including study of research specimens.

Scientific research and specimen collection activities in national parks are governed by NPS regulations, and all research permit applications are evaluated under NEPA. All researchers who obtain NPS research permits—whether associated with private or public research entities—are subject to the same laws, regulations, policies, and guidelines. The NPS has not historically prohibited researchers from developing any valuable inventions or other scientific discoveries for any lawful purpose.

This FEIS uses the term “bioprospecting” to describe biological research that could result in a discovery with some commercial application. Although any researcher might unexpectedly make a discovery with potential for commercial development, all known past, present, and proposed commercial uses of research results involving the study of NPS specimens involved biological specimens. Accordingly, researchers who discover or seek to discover useful scientific information from study of biological research specimens would be those most likely to be affected by the alternatives.

Researchers who perform research involving study of material originating as an NPS specimen have been divided into categories for impact analysis:

- Researchers who have identified an imminent commercial application for their research results and have informed the NPS about such use are termed “declared bioprospectors.”
- Researchers who unexpectedly discover some potential commercial application for their research results are termed “inadvertent bioprospectors.” When inadvertent bioprospectors recognize a commercial use for their research results and inform the NPS, they are reclassified as declared bioprospectors.
- Researchers in fields known to be particularly likely for commercial application but who consider their research to be strictly “basic research,” having no clear route for developing their research into commercial products unless and until they actually discover some valuable research result, are termed “undeclared bioprospectors.” When undeclared bioprospectors recognize a commercial use for their research results and inform the NPS, they are reclassified as declared bioprospectors.
- Researchers who have obtained material originating as an NPS research specimen from permitted researchers, non-permitted researchers, or other third-party entities such as culture collections are termed “third-party researchers.”
- All other researchers.

Income or other benefits are not realized from every bioprospecting research project. Following the initial discovery of a potentially useful research result, bioprospecting can include additional research, evaluation, and development activities including protection of intellectual property, product development, manufacturing, and marketing. The greatest benefit from the initial discovery is developed at these subsequent stages of the research process.

Only a small proportion of NPS research permittees are expected to be affected by the alternatives. For example, in 2001, 13 research projects involving 24 researchers (representing 0.5% of all researchers named in NPS research permits servicewide) provided the NPS with information that indicated that their research results could possibly have commercial uses. This FEIS analyzes the potential impacts to the research community by evaluating the likelihood for researchers to be affected by changes in the administrative burden, potential economic gains, or research specimen collection authorization realized under each alternative.

### **ES.3.4 Social Resources: NPS Administrative Operations**

NPS administration of agreements and research permits could both be affected by the alternatives.

Although any park could be affected by the alternatives, parks that are most likely to be affected are Yellowstone National Park and other parks that are already aware of current or potential bioprospectors (30 parks) as well as parks that have already hosted independent research activities (270 parks). This FEIS analyzes the impact to NPS administrative operations by comparing the administrative effort required to implement the alternatives with the administrative resources currently available in parks.

## **ES.4 Environmental Consequences**

### **ES.4.1 Natural Resource Management**

The alternatives in this FEIS have the potential to affect natural resource management in the NPS by influencing the availability of useful scientific knowledge (“science for parks”). Potential impacts were analyzed in terms of three contexts: servicewide, Yellowstone National Park, and other individual parks.

#### ***ES.4.1.1 Alternative A (No Benefits-Sharing/No Action)***

Generally, the No Action alternative (Alternative A) provides the baseline against which the impacts of Alternatives B and C to natural resource management are measured. One action of Alternative A, the nullification of the Yellowstone–Diversa CRADA, would have a negligible adverse impact on Yellowstone National Park. Servicewide and in other individual parks, Alternative A would have no impact on natural resource management.

#### ***ES.4.1.2 Alternative B (Implement Benefits-Sharing)***

Alternative B could have a beneficial impact on natural resource management in the NPS by increasing the availability of useful scientific knowledge (“science for parks”).

Non-monetary benefits derived from CRADAs (knowledge and research relationships, training and education, research-related equipment, and special services such as laboratory analyses) would provide the primary impacts to park natural resource management programs. Non-monetary benefits would increase the availability of scientific knowledge useful to natural resource managers, which would improve natural resource management in parks. Monetary benefits from CRADAs could also be used by parks to increase their scientific knowledge. A single CRADA is estimated to yield between \$0 and \$24,000 annually in the short term, and between \$0 and \$155,000 (and, though unlikely, could yield more than \$1 million) annually in the long term. CRADAs are estimated to be more likely to provide small monetary benefits than large ones. These non-monetary and monetary benefits would result in negligible-to-major beneficial impacts to natural resource management servicewide, in Yellowstone National Park, and in other individual parks with CRADAs.

If Alternative B is selected, one of three variations in the way the NPS would treat confidentiality of certain financial information would also be selected, which could affect the intensity of the potential beneficial impacts of this alternative. Under Alternative B1, the NPS would treat royalty rates and related financial information as public information. Because the NPS would not be privy to any financial information the researcher wished to keep confidential, and because researchers might not want to expose themselves to potentially substantial economic and competitive harm resulting from mandatory disclosure of sensitive

information normally considered to be proprietary financial information, Alternative B1 could have five effects. It could (1) limit payment equitability, (2) create an artificial “rate ceiling,” (3) expose the NPS to litigation or other penalties, (4) discourage some research, and (5) discourage establishment of benefits-sharing agreements. Alternative B1 could result in fewer CRADAs and could also compromise the NPS’s ability to negotiate the most favorable terms possible for monetary benefits. Therefore, Alternative B1 could result in less intensely beneficial impacts to natural resource management in the NPS than Alternatives B2 or B3.

Under Alternative B2, royalty rates and related financial information could be identified by CRADA participants as confidential business proprietary information and withheld from the public. Under Alternative B3, such information would always be withheld. Implementation of Alternatives B2 or B3 would avoid the five effects of Alternative B1: they would not limit payment equitability, create an artificial “rate ceiling,” expose the NPS to litigation or other penalties, discourage some research, or discourage establishment of benefits-sharing agreements. Consequently, Alternatives B2 or B3 could result in more CRADAs, and these CRADAs could be more favorable to the NPS than those resulting from Alternative B1.

#### ***ES.4.1.3 Alternative C (Prohibit Specimen Collection for Any Commercially Related Research Purposes)***

Alternative C could have an adverse impact on natural resource management in the NPS by decreasing the availability of useful scientific knowledge (“science for parks”). Although the ratio of bioprospectors to all researchers who study park resources is very small, Alternative C could cause some loss of potential research discoveries and scientific data that could have improved understanding of the natural resources that the NPS protects and manages. Servicewide, the loss of a few current and potential future research projects would have negligible adverse impacts on natural resource management. In Yellowstone National Park and in other individual parks, the potential loss of even a single scientific study revealing important new information about natural resources could be negligible-to-major.

### **ES.4.2 Visitor Experience and Enjoyment**

The alternatives in this FEIS have the potential to affect visitor experience and enjoyment in the NPS through potential impacts to NPS interpretive services by influencing the availability of useful scientific knowledge (“science for parks”). Potential impacts were analyzed in terms of three contexts: servicewide, Yellowstone National Park, and other individual parks.

#### ***ES.4.2.1 Alternative A (No Benefits-Sharing/No Action)***

The No Action alternative (Alternative A) provides the baseline against which the impacts of Alternatives B and C to visitor experience and enjoyment are measured. In all contexts, choosing not to implement benefits-sharing under Alternative A would result in no change in the availability of scientific knowledge for interpretive services, and therefore no impact on visitor experience and enjoyment.

#### ***ES.4.2.2 Alternative B (Implement Benefits-Sharing)***

Beneficial impacts to visitor experience and enjoyment under Alternative B could result primarily from non-monetary benefits that could be used to improve interpretive services, primarily in parks that entered into benefits-sharing agreements. These non-monetary

benefits would include additional knowledge and information about park resources and increased recognition of the societal value associated with scientific research.

Service-wide, the beneficial impact to visitor experience and enjoyment could be negligible and possibly minor. In Yellowstone, the beneficial impact could be negligible-to-minor. Other individual parks with CRADAs could experience negligible-to-moderate beneficial impacts. As described in Section ES.4.1.2 of this document, Alternative B1 could result in less-intense beneficial impacts than Alternatives B2 or B3.

### ***ES.4.2.3 Alternative C (Prohibit Specimen Collection for Any Commercially Related Research Purposes)***

Alternative C could have an adverse impact on visitor experience and enjoyment in the NPS by decreasing the availability of scientific knowledge (“science for parks”). Although the ratio of bioprospectors to all researchers who study park resources is very small, Alternative C could cause some loss of potential research discoveries and scientific data that could have been useful for the development of interpretive services.

Service-wide, the loss of a few current and potential future research projects would have negligible adverse impacts on visitor experience and enjoyment. In Yellowstone, the adverse impacts could be negligible-to-minor. Other individual parks that lose a current or potential future research project could experience negligible-to-major adverse impacts.

## **ES.4.3 Social Resources: The Research Community**

The alternatives in this FEIS have the potential to affect a small proportion of NPS research permittees (*see* Section ES.3.3). Potential impacts were analyzed in terms of five contexts: declared bioprospectors, inadvertent bioprospectors, undeclared bioprospectors, third-party researchers, and all other researchers.

### ***ES.4.3.1 Alternative A (No Benefits-Sharing/No Action)***

Under Alternative A, the revocation of the current requirement in each research permit to enter into a benefits-sharing agreement would have beneficial impacts on researchers who make valuable discoveries from research involving NPS specimens. Because the benefits obligated by each CRADA are not expected to rise above a negligible impact if benefits-sharing were implemented, the beneficial impact of revoking this requirement would be negligible (*see also* Section ES.4.3.2).

Because Alternative A would not provide a service-wide standardized MTA, third-party researchers and any researchers who wish to supply third-party researchers with research specimens or material originating as an NPS research specimen would continue to work with the different forms, processes, and requirements unique to each park, and would therefore experience negligible adverse impacts.

### ***ES.4.3.2 Alternative B (Implement Benefits-Sharing)***

Under Alternative B, implementation of benefits-sharing through CRADAs would have adverse impacts on researchers who make valuable discoveries from research involving NPS specimens. Because the NPS proposal provides that the non-monetary and monetary benefits

obligated by benefits-sharing agreements would be negotiated and mutually agreeable to both parties, it is reasonable to expect that the potential economic impacts of an agreement would not rise above a negligible adverse effect on researchers or their institutions.

Because Alternative B would provide a servicewide standardized MTA, third-party researchers and any researchers who wish to supply third-party researchers with research specimens or material originating as an NPS research specimen would not have to continue to work with the different forms, processes, and requirements unique to each park, and would therefore experience negligible beneficial impacts.

If Alternative B is selected, one of three variations in the way the NPS would treat confidentiality of certain financial information would also be selected, which could affect the intensity of the potential adverse impacts of this alternative. Under Alternative B1, the NPS would treat royalty rates and related financial information as public information. Because there could be potential economic and competitive impacts to researchers whose proprietary financial information was disclosed, and some researchers may abandon or never begin studies involving NPS-related research specimens to avoid potential disclosure, impacts would be more adverse under Alternative B1 than under Alternatives B2 or B3. Under Alternative B2, royalty rates and related financial information could be identified by CRADA participants as confidential business proprietary information and withheld from the public. Under Alternative B3, such information would always be withheld. Implementation of Alternatives B2 or B3 would avoid the additional adverse impacts of Alternative B1.

Most NPS research permittees are not bioprospectors or material transfer participants, and would experience no impacts from Alternative B.

#### ***ES.4.3.3 Alternative C (Prohibit Specimen Collection for Any Commercially Related Research Purposes)***

Alternative C's prohibition of specimen collection to declared bioprospectors would have a minor-to-moderate adverse impact on these researchers, depending on how difficult it would be for them to acquire suitable research specimens elsewhere.

Under Alternative C, the NPS would not authorize commercial use of research results except when the director determined, in writing, that such use was in the public interest. Inadvertent bioprospectors would be prevented from having beneficial impacts from commercialization of their research results. Depending on how difficult it would be for them to acquire suitable research specimens elsewhere, undeclared or inadvertent bioprospectors could experience a negligible-to-major adverse impact if they had to discontinue study of NPS specimens when they recognized and acknowledged a foreseeable commercial use for their research results.

Because Alternative C would provide a servicewide standardized Material Transfer Agreement, third-party researchers and any researchers who wished to supply third-party researchers with research specimens or material originating as an NPS research specimen would not have to continue to work with the different forms, processes, and requirements unique to each park, and would therefore experience negligible beneficial impacts.

Most NPS research permittees are not bioprospectors or material transfer participants and would experience no impacts from Alternative C.

## **ES.4.4 Social Resources: NPS Administrative Operations**

The alternatives in this FEIS have the potential to affect administrative operations in parks that enter into CRADAs or use MTAs. Impacts to NPS administrative operations were determined by examining staffing (expressed in FTE) needed to administer each alternative. Potential impacts were analyzed in terms of three contexts: servicewide, Yellowstone National Park, and other individual parks.

### ***ES.4.4.1 Alternative A (No Benefits-Sharing/No Action)***

Alternative A would not implement benefits-sharing and would therefore result in no CRADAs and no impact from administering CRADAs.

Because Alternative A would not provide a servicewide standardized MTA for park use, it would not resolve the confusion some parks encounter regarding when to request specimen transfer authorizations and how to act upon such requests. Servicewide and individual parks other than Yellowstone National Park would experience a negligible adverse impact. Yellowstone would experience no impact because it already uses a standardized MTA.

### ***ES.4.4.2 Alternative B (Implement Benefits-Sharing)***

The estimated 0.18 FTE required per CRADA would result in negligible adverse impacts in all contexts. Although each CRADA would be monitored throughout the entire period of time studied in this FEIS, almost all of the FTE required to administer a CRADA would be used during the first year, while the CRADA was being negotiated. Therefore, as established CRADAs accumulated, the vast majority of FTE would still be used to negotiate the estimated two to nine new CRADAs annually.

Implementation of mitigation measures (*see* EIS sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5) such as technical assistance to parks and administrative cost recovery as authorized by the FTTA could prevent adverse impacts from rising above a negligible level, even for parks with small staffs.

Because Alternative B would provide a servicewide standardized MTA, it would resolve the confusion some parks encounter regarding when to request specimen transfer authorizations and how to act upon such requests. Provision of the MTA would result in negligible beneficial impacts servicewide and in individual parks other than Yellowstone National Park. Because Yellowstone already uses a standardized MTA, it would experience no impact.

If Alternative B is selected, one of three variations described in Section ES.2.2 would also be selected. Under Alternative B1, the NPS could enter into fewer CRADAs than under Alternatives B2 or B3. The adverse impacts to administrative operations servicewide and to Yellowstone National Park would remain negligible for each variation. Under Alternative B1, fewer individual parks would enter into CRADAs and experience the associated adverse impacts to their administrative operations than under Alternatives B2 or B3.

### ***ES.4.4.3 Alternative C (Prohibit Specimen Collection for Any Commercially Related Research Purposes)***

Alternative C could have a negligible beneficial impact on NPS administrative operations

in all contexts by decreasing the number of research permit applications submitted for evaluation and by providing a servicewide standardized MTA.

By reducing the number of researchers working in parks, Alternative C would have a negligible beneficial impact on the administrative burden associated with managing research permits in individual parks. Servicewide, approximately 0.5% of researchers could drop plans for conducting studies under NPS research permits. In Yellowstone National Park, if somewhat more than 3% of park researchers abandoned or did not begin park-related studies, Yellowstone could save approximately 0.2% of its available FTE. Other individual parks studied for this FEIS that avoided processing a research permit could save, at most, 0.6% of their available FTE.

Because Alternative C would provide a servicewide standardized MTA, it would resolve the confusion some parks encounter regarding when to request specimen transfer authorizations and how to act upon such requests. Provision of the MTA would result in negligible beneficial impacts servicewide and in individual parks other than Yellowstone National Park. Because Yellowstone already uses a standardized MTA, it would experience no impact.

Table ES-1 summarizes the environmental impacts of the alternatives.

**Table ES-1. Summary of Effects\***

Natural Resource Management				
Alternative A No Benefits-Sharing/No Action	Alternative B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
<b>All contexts</b> <ul style="list-style-type: none"> <li>Choosing not to implement benefits-sharing would result in no change in the availability of "science for parks."</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>Increased availability of "science for parks" provided by non-monetary and monetary benefits from benefits-sharing agreements would have a beneficial impact. However, B1 could discourage researchers and benefits-sharing partners and compromise NPS's ability to negotiate.</li> </ul>		<b>All contexts</b> <ul style="list-style-type: none"> <li>Increased availability of "science for parks" provided by non-monetary and monetary benefits from benefits-sharing agreements would have a beneficial impact. Impacts in all contexts would be the same as for Alternative B2.</li> </ul>	
<b>Servicewide</b> <ul style="list-style-type: none"> <li>No impact.</li> </ul>	<b>Servicewide and Yellowstone</b> <ul style="list-style-type: none"> <li>Impacts would be somewhat less beneficial than Alternative B2, because there would be fewer benefits-sharing agreements than under Alternative B2 and those agreements could be less favorable to the NPS than those negotiated under Alternative B2.</li> </ul>	<b>Servicewide</b> <ul style="list-style-type: none"> <li>Non-monetary benefits could have negligible-to-major beneficial impacts.</li> <li>Short-term beneficial impacts of monetary benefits could be negligible.</li> <li>Long-term beneficial impacts of monetary benefits could range from negligible to minor.</li> </ul>		<b>Servicewide</b> <ul style="list-style-type: none"> <li>The loss of a few current and potential future research projects would have negligible adverse impacts to the NPS.</li> </ul>
<b>Yellowstone</b> <ul style="list-style-type: none"> <li>The return of all monetary benefits provided to Yellowstone by Diversa would have a negligible adverse impact.</li> </ul>		<b>Yellowstone</b> <ul style="list-style-type: none"> <li>Non-monetary benefits could have minor-to-major beneficial impacts.</li> <li>Monetary benefits could have short-term negligible beneficial impacts.</li> <li>Monetary benefits could have long-term negligible-to-major beneficial impacts.</li> </ul>		<b>Yellowstone</b> <ul style="list-style-type: none"> <li>The potential loss of at least 3% of independent research projects would have negligible adverse impacts.</li> <li>The potential loss of a single scientific study revealing important new information about Yellowstone's natural resources could be negligible-to-major.</li> </ul>
<b>Individual parks</b> <ul style="list-style-type: none"> <li>No impact.</li> </ul>	<b>Individual parks</b> <ul style="list-style-type: none"> <li>Fewer parks would experience the beneficial impacts of Alternative B2.</li> </ul>	<b>Individual parks</b> <ul style="list-style-type: none"> <li>Beneficial impacts to parks that receive non-monetary benefits could be negligible-to-major.</li> <li>Beneficial impacts to parks that receive monetary benefits during the immediate benefits period could be negligible-to-major, with the majority of parks studied experiencing no more than negligible impacts.</li> <li>Beneficial impacts to parks that receive monetary benefits during the deferred benefits period could range from negligible to major.</li> </ul>		<b>Individual parks</b> <ul style="list-style-type: none"> <li>The impacts of a potential loss of knowledge from abandoned or never-begun research could be long-term, adverse, and negligible-to-major.</li> </ul>

**Table ES-1. Summary of Effects, continued**

Visitor Experience and Enjoyment				
Alternative A No Benefits-Sharing/No Action	Alternative B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
<b>All contexts</b> <ul style="list-style-type: none"> <li>No impact. Choosing not to implement benefits-sharing would result in no change in the availability of “science for parks” (scientific knowledge and assistance) for interpretation, and therefore no change in visitor experience and enjoyment.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>Increased availability of “science for parks” would have a beneficial impact. However, B1 could discourage researchers and benefits-sharing partners and compromise the NPS’s ability to negotiate.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>Increased availability of “science for parks” would have a beneficial impact in all contexts.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>Increased availability of “science for parks” would have a beneficial impact.</li> <li>Impacts in all contexts would be the same as for Alternative B2.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>Decreased availability of “science for parks” could have adverse impacts in all contexts.</li> </ul>
	<b>Servicewide and Yellowstone</b> <ul style="list-style-type: none"> <li>Impacts would be somewhat less beneficial than Alternative B2, because there would be fewer benefits-sharing agreements than under Alternative B2 and those agreements could be less favorable to the NPS than those negotiated under Alternative B2.</li> </ul>	<b>Servicewide</b> <ul style="list-style-type: none"> <li>At least negligible and possibly minor impacts.</li> </ul>		<b>Servicewide</b> <ul style="list-style-type: none"> <li>Negligible impact.</li> </ul>
		<b>Yellowstone</b> <ul style="list-style-type: none"> <li>Negligible-to-minor impacts.</li> </ul>		<b>Yellowstone</b> <ul style="list-style-type: none"> <li>Negligible-to-minor impacts.</li> </ul>
	<b>Individual parks</b> <ul style="list-style-type: none"> <li>Fewer parks would experience the beneficial impacts of Alternative B2.</li> </ul>	<b>Individual parks</b> <ul style="list-style-type: none"> <li>Negligible-to-moderate impacts.</li> </ul>		<b>Individual parks</b> <ul style="list-style-type: none"> <li>Negligible-to-major impacts.</li> </ul>

**Table ES-1. Summary of Effects, continued**

<b>Social Resources: The Research Community</b>				
<b>Alternative A No Benefits-Sharing/No Action</b>	<b>Alternative B. Implement Benefits-Sharing</b>			<b>Alternative C Prohibit Specimen Collection for Commercially Related Research</b>
	<b>Alternative B1 Always Disclose Royalty Rate and Related Information</b>	<b>Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information</b>	<b>Alternative B3 Never Disclose Royalty Rate or Related Information</b>	
	<p><b>Declared bioprospectors</b></p> <ul style="list-style-type: none"> <li>The obligation to share benefits would have a long-term negligible adverse impact.</li> <li>Because there would be potential economic and competitive impacts to researchers whose proprietary financial information was disclosed, and some researchers may abandon or never begin studies involving NPS-related research specimens to avoid potential disclosure, impacts would be more adverse than Alternative B2.</li> </ul>	<p><b>Declared bioprospectors</b></p> <ul style="list-style-type: none"> <li>The obligation to share benefits would have a long-term negligible adverse impact.</li> </ul>	<p><b>All contexts</b></p> <ul style="list-style-type: none"> <li>Impacts in all contexts would be the same as for Alternative B2.</li> </ul>	<p><b>Declared bioprospectors</b></p> <ul style="list-style-type: none"> <li>Denial of permission to collect research specimens would have a minor-to-moderate adverse impact.</li> </ul>
				<p><b>Inadvertent and undeclared bioprospectors</b></p> <ul style="list-style-type: none"> <li>Denial of authorization to use research results for commercial purposes could prevent potential beneficial impacts.</li> <li>Those who abandon or never begin park-related research would have negligible-to-major adverse impacts.</li> </ul>
<p><b>Third-party researchers</b></p> <ul style="list-style-type: none"> <li>Third-party researchers and any researchers who wish to supply third-party researchers with research specimens would have long-term negligible adverse impacts, because Alternative A would not provide a servicewide standardized Material Transfer Agreement.</li> </ul>		<p><b>Third-party researchers</b></p> <ul style="list-style-type: none"> <li>The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.</li> </ul>		<p><b>Third-party researchers</b></p> <ul style="list-style-type: none"> <li>The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.</li> <li>If third-party researcher is a bioprospector, see declared, and inadvertent and undeclared bioprospectors above.</li> </ul>
<p><b>All other contexts</b></p> <ul style="list-style-type: none"> <li>Researchers who make valuable discoveries from research involving NPS specimens would have long-term, negligible beneficial impacts.</li> </ul>	<p><b>All other contexts</b></p> <ul style="list-style-type: none"> <li>Impacts to all other researchers would be the same as for Alternative B2.</li> </ul>	<p><b>All other contexts</b></p> <ul style="list-style-type: none"> <li>99% of researchers would experience no adverse impacts.</li> </ul>		<p><b>Other researchers</b></p> <ul style="list-style-type: none"> <li>99% of researchers would experience no adverse impacts.</li> </ul>

**Table ES-1. Summary of Effects, continued**

<b>Social Resources: NPS Administrative Operations</b>				
<b>Alternative A No Benefits-Sharing/No Action</b>	<b>Alternative B. Implement Benefits-Sharing</b>			<b>Alternative C Prohibit Specimen Collection for Commercially-Related Research</b>
	<b>Alternative B1 Always Disclose Royalty Rate and Related Information</b>	<b>Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information</b>	<b>Alternative B3 Never Disclose Royalty Rate or Related Information</b>	
<p><b>Servicewide and individual parks</b></p> <ul style="list-style-type: none"> <li>• Not having any benefits-sharing agreements to administer would result in no impact.</li> <li>• Not providing a standardized Material Transfer Agreement would result in adverse, negligible impacts.</li> </ul>	<p><b>All contexts</b></p> <ul style="list-style-type: none"> <li>• Fewer benefits-sharing agreements would result in less adverse impacts than Alternative B2.</li> </ul>	<p><b>All contexts</b></p> <ul style="list-style-type: none"> <li>• The institution of Material Transfer Agreements would have a beneficial impact.</li> <li>• The need to administer benefits-sharing agreements would have an adverse impact.</li> <li>• Impacts would be negligible in all contexts.</li> </ul>	<p><b>All contexts</b></p> <ul style="list-style-type: none"> <li>• Impacts would be the same as Alternative B2.</li> </ul>	<p><b>All contexts</b></p> <ul style="list-style-type: none"> <li>• A reduction in the number of submitted research proposals and the institution of Material Transfer Agreements would have negligible beneficial impacts in all contexts.</li> </ul>
<p><b>Yellowstone</b></p> <ul style="list-style-type: none"> <li>• Not having any benefits-sharing agreements to administer would result in no impact.</li> <li>• Not providing a standardized Material Transfer Agreement would result in no impact.</li> </ul>				

\*Table A-1 summarizes the key impacts that could result from each of the alternatives, including the No Action Alternative. Detailed descriptions of these impacts are provided in Chapter 4. Summary statements are abbreviated and taken out of context to provide a quick comparison by element. The reader is encouraged to review the supporting analysis in Chapter 4. All impacts are estimated in the long term, over the 20-year period following implementation of the alternative, unless otherwise noted. Short-term impacts, when addressed, are estimated for the five-year period after the EIS decision is reached.

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# **Chapter 1**

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## **Purpose and Need for Action**

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# 1.1 Introduction

## 1.1.1 The Emerging Need to Define the Role, If Any, of the National Park Service When Research Involving Study of NPS Specimens Discovers Commercially Valuable Results

The outcome of this final EIS (FEIS) is the clarification of the rights and responsibilities of researchers and National Park Service (NPS) managers in connection with the use of valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks.<sup>1</sup> The commercial use or sale of research specimens themselves is prohibited by regulation (*see* 36 CFR 2.1). However, the commercial use of knowledge derived from specimens via research is not prohibited. Commercial use of research results has, in the past, been left entirely up to researchers without involvement from the NPS.

In Chapter 2 of this FEIS, the NPS proposes new management practices that would require researchers and their institutions to enter into benefits-sharing agreements with the NPS in the event that they wish to commercialize their research results. The NPS is using the analyses presented in this FEIS to evaluate the proposed implementation of benefits-sharing as well as reasonable alternatives to it. This FEIS reveals the possible environmental impacts of choosing whether or not to implement a certain type of contract; hence, the nature of this FEIS is such that its affected environment and impact topics relate primarily to administrative functions of the NPS.

### **What are research specimens?**

“Research specimens” are those items an authorized researcher has permission to collect from an NPS unit pursuant to an NPS Scientific Research and Collecting Permit (“NPS research permit”) issued by the NPS in accordance with 36 CFR 2.5.

### **What are research results?**

For purposes of this FEIS, “research results” are the data, discoveries, inventions, or other knowledge resulting from “research activities.”

### **What are research activities?**

“Research activities” are the actions taken by researchers or their sponsoring organizations or companies in accordance with an NPS research permit, including research specimen collections and analysis conducted for scientific purposes.

The important distinction between research specimens (“natural products”) and research results is intended to prevent the marketing or other commoditization of NPS resources, while not interfering with the legitimate development of useful and therefore valuable discoveries from research involving NPS research specimens. For example, NPS regulations and policy provide that specimens collected from a national park area cannot be used as raw material in the manufacture of commercial products.<sup>2</sup> In a specific example, ginseng collected under a research permit could not then be used to make a product that is sold commercially that contains the ginseng. However, there is no prohibition against the commercial use of synthetic or other non-naturally occurring compounds whose discovery and development resulted from research that initially involved the biological material collected (ginseng in this example) from a national park pursuant to an NPS research permit.

This FEIS addresses the development of servicewide management practices relating to the implementation of existing NPS policy. A National Environmental Policy Act (NEPA) document of this sort has a broad scope, is general in nature, and is termed a “programmatic EIS.” It describes the conditions under which certain activities may be authorized and provides potential general standards for management. This EIS evaluates alternative choices for implementing existing policies while evaluating the possible environmental impacts of activities that may be included in any proposal.

Because the description of the potential program at this level is general, the analysis of environmental impacts is conducted at a general level. Thus, the type and amount of data relating to possible impacts are presented at the general level. If Alternative B (Implement Benefits-Sharing) is selected, then NEPA review (EIS, EA, or CE) of specific benefits-sharing agreements that might be established by individual parks in the future can be tiered from this programmatic EIS. If an individual park proposed site-specific resource management projects using non-monetary or monetary benefits generated by a benefits-sharing program, such projects would receive a separate environmental review for potential project-specific impacts in compliance with NEPA.

## **1.2 Background**

### **1.2.1 Changing Technologies and Their Role in the Programmatic Benefits-Sharing Proposal**

The NPS has determined that it needs to propose servicewide NPS management practices to address the NPS’s interest in the use of the results of research involving NPS research specimens. Although the NPS has concluded that research permit regulations are “adequate to ensure protection of park resources” during the conduct of research activities,<sup>3</sup> and some benefits resulting from research are shared with the NPS,<sup>4</sup> regulations and policies stop short of providing for routine benefits-sharing related to commercially valuable research results.

Currently, an average of more than 200 national parks annually host independent research efforts, authorized under permits generated under current policies and procedures. As discussed below (Section 1.3), the current permit policy focuses on potential impacts of proposed research activities on parks and does not fully address the interests of the NPS in the potential results of such research. Current NPS policy regarding permits controls access to park resources, but the policy does not always take full advantage of opportunities to coordinate research activities between independent scientists and park managers, nor does it guarantee that the NPS will eventually share in the benefits from independently conducted research.

The proposal to implement benefits-sharing (Alternative B) would provide for the efficient and equitable sharing of valuable research results generated by research involving NPS research specimens (*see* Chapter 2, Alternative B). New and changing technologies have made this proposal desirable, as the following recent events illustrate:

(1) New research techniques, particularly in microbiology and molecular biology, have allowed remarkable advances in technologies with industrial, medical, and other marketable

## What is the NPS benefits-sharing proposal?

The management practices proposed in Alternative B (Implement Benefits-Sharing) would apply to research projects involving research specimens collected from units of the National Park System that subsequently resulted in useful discoveries or inventions with some valuable commercial application. A benefits-sharing agreement would provide the terms and conditions for the further development and use of such valuable discoveries, inventions, or other research results. All such researchers would be required to enter into a benefits-sharing agreement with the NPS before using their research results for any commercial purpose. See Chapter 2, Section 2.4 for a description of the “benefits” that could be generated by benefits-sharing agreements. Under the proposal (Alternative B), a benefits-sharing agreement would not regulate or authorize any researcher’s access to NPS resources.

uses. Studies of park resources, including rare bacteria and unique plants and animals, expand beneficial scientific knowledge, and research results occasionally generate substantial commercial profits.<sup>5</sup> This FEIS uses the term “bioprospecting” to describe biological research that could result in a discovery with some commercial application (*see* Glossary and Chapter 3, Section 3.4.3). Bioprospectors (researchers who engage in bioprospecting) are the researchers most likely to be involved in benefits-sharing. Bioprospecting does not require the grand-scale resource consumption of extractive industries that are typically associated with the term “prospecting,” such as timber harvesting and mining. In this case, the “prospecting” is for new knowledge.

(2) In recent years, the value of research results has been enhanced by developments in intellectual property rights laws, evolving trade practices, and advances in specimen collection and product-development research. Some research discoveries, including those derived from study of NPS research specimens, are potentially worth millions of dollars to private firms (*see also* this chapter, Section 1.7.1). Until now, the NPS has had no provisions to allow the NPS to claim any share of these economic benefits, which often don’t materialize until years or even decades after completion of the permitted research.

(3) Yellowstone National Park has taken the lead in clarifying issues and options related to the current NPS policy for the eventual sharing of benefits between private individuals, companies, and the NPS. In September 1995, Yellowstone convened a major multidisciplinary conference on microbiological research in extreme environments such as the park’s hot springs. The conference included discussions with the university and corporate scientific research communities, conservationists, park managers, legal experts, journalists, and others to explore issues and possible options for NPS management of valuable research results.

(4) At the request of the NPS director in 1996, Yellowstone National Park negotiated a landmark draft agreement with the Diversa Corporation of San Diego, California. The agreement (finalized in May 1998 after extensive public comments) provided for the NPS to share in the economic and scientific research benefits from Diversa research involving specimens collected at Yellowstone.<sup>6</sup>

(5) Early in 1998, the Yellowstone–Diversa agreement was challenged in court on several grounds related to the NPS Organic Act and other federal laws. The court upheld the Yellowstone–Diversa agreement and dismissed the plaintiffs’ case with prejudice, but required the NPS to complete a NEPA analysis of the agreement (*see* this chapter, Section 1.7.6).

This FEIS provides a programmatic NEPA analysis for benefits-sharing agreements servicewide. In addition, this FEIS analyzes the potential programmatic impacts of benefits-sharing in an individual park context, including Yellowstone National Park, which will comply with the court’s mandate to evaluate the impacts of the benefits-sharing agreement between Yellowstone National Park and Diversa Corporation: the Yellowstone–Diversa Cooperative Research and Development Agreement (CRADA).

This FEIS examines the potential environmental impacts of three alternatives: implementing benefits-sharing agreements when information derived from research specimens collected from units of the National Park System results in commercial value; continuing the current practice of not requiring benefits-sharing (the “no action” alternative); and barring researchers whose studies might result in commercially viable products from collecting research specimens in the national parks.

## **1.2.2 The National Park System’s Natural Resources Invite Scientific Studies**

Bioprospectors often focus their searches in the world’s unique and pristine ecosystems, and national parks have been popular bioprospecting sites for many years. At nearly 400 park units and 84.4 million total acres, the National Park System constitutes a vast and complex diversity of ecosystems that represent a large majority of the variety of physical and biological features found within the U.S. today.<sup>7</sup> Parks attract independent researchers in part because parks offer opportunities to study preserved and protected natural resources.

The fundamental purpose of the national park system, established by the NPS Organic Act and reaffirmed by the General Authorities Act, as amended, begins with a mandate to conserve park resources and values.<sup>8</sup> This has resulted in a National Park System containing well-preserved examples of North America’s biological diversity.

To a large extent, the biodiversity of the U.S. is exemplified by the National Park System.<sup>9</sup> Scientists recognize a variety of “ecoregion divisions” in the U.S., based upon each division’s unique combination of climate, landforms, vegetation, soil composition, fauna, and other factors.<sup>10</sup> National park units are located within every terrestrial ecoregion division of the U.S., so the NPS conserves and manages examples of nearly all the variety of life found in the United States today (*see* figures 1.2.2-1 and 1.2.2-2 and table 1.2.2).

The natural resources managed by the NPS are attractive to researchers precisely because of the protection they have been afforded within the parks. For example, some organisms that are no longer commonplace in the U.S. can still be found within national parks because they are legally protected land- or waterscapes, and parks are often more pristine than the lands that surround them.

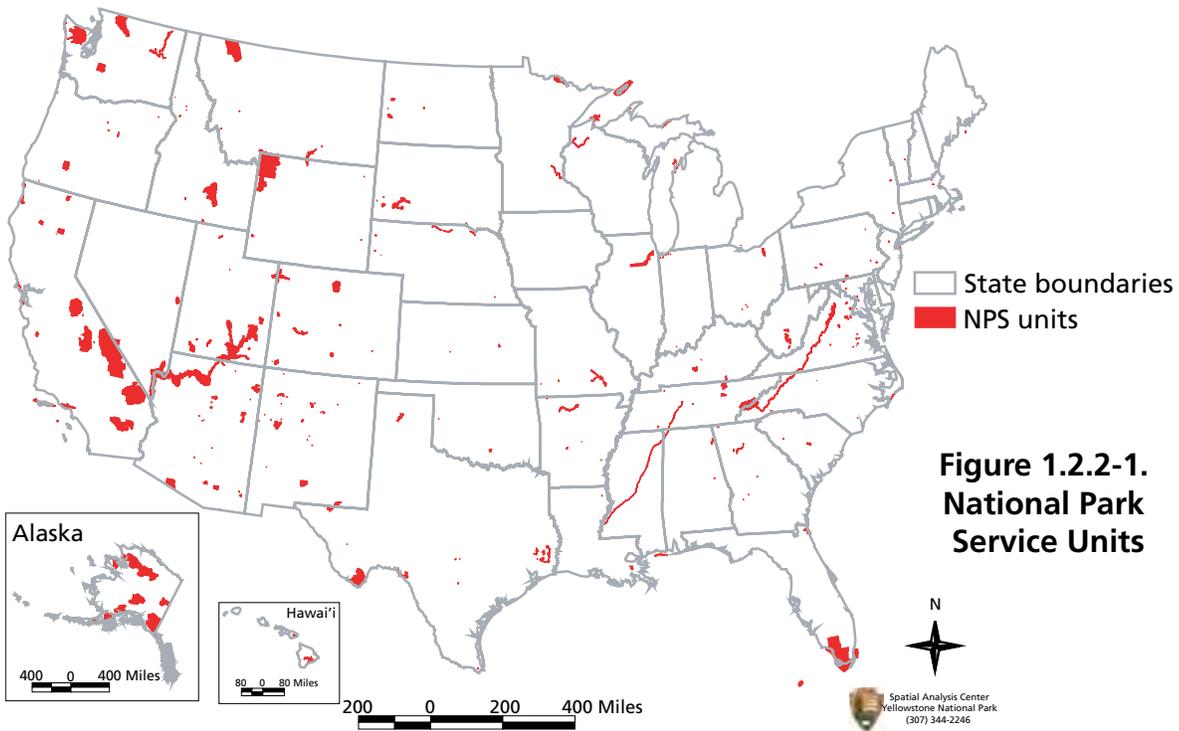


Figure 1.2.2-1. National park units are spread across the United States.

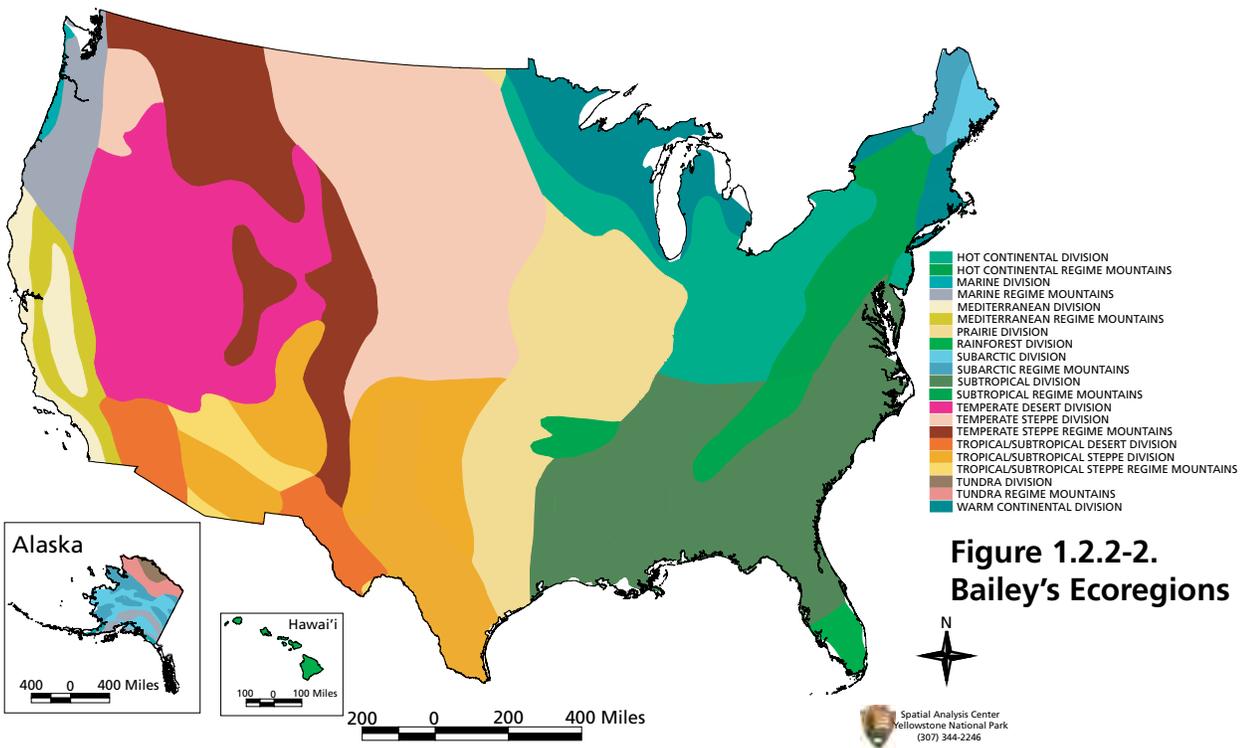


Figure 1.2.2-2. National park units are located within every terrestrial ecoregion of the U.S.

National parks offer unique opportunities to study natural systems and living things. It is increasingly obvious to park managers, scientists, and others that the more that is learned about the organisms existing in parks, the more it is confirmed that national parks are important places of special and complex biological diversity. Because of this special status, the NPS expects that researchers will continue to seek out opportunities to study natural resources in the national parks.

**Table 1.2.2. National Park System acreage in each ecoregion division**

<b>Ecoregion division</b>	<b>Park units</b>	<b>NPS acres</b>
Hot Continental	70	797,240
Hot Continental Regime Mountains	18	792,250
Marine	4	19,940
Marine Regime Mountains	11	10,134,550
Mediterranean	14	650,480
Mediterranean Regime Mountains	11	2,048,900
Prairie	9	58,570
Rainforest Regime Mountains	6	259,110
Savanna	4	2,512,620
Savanna Regime Mountains	5	16,490
Subarctic	4	3,116,240
Subarctic Regime Mountains	4	18,651,840
Subtropical	66	630,730
Subtropical Regime Mountains	1	5,730
Temperate Desert	18	1,659,760
Temperate Desert Regime Mountains	5	351,410
Temperate Steppe	20	440,930
Temperate Steppe Regime Mountains	23	4,356,930
Tropical/Subtropical Desert	20	7,951,130
Tropical/Subtropical Regime Mountains	11	216,920
Tropical/Subtropical Steppe	33	3,066,250
Tundra	7	3,581,970
Tundra Regime Mountains	7	20,631,280
Warm Continental	12	679,560
Warm Continental Regime Mountains	2	780

Table 1.2.2. National parks are represented in every ecoregion division in the United States.

### **1.2.3 Current Research in U.S. National Parks**

The NPS has authorized the collection of research specimens from units of the National Park System for qualified research purposes as an established national park management activity for more than 100 years. This long-standing practice today is administered through Scientific Research and Collecting Permits (“research permits”) issued and administered by the NPS under 36 CFR 1.6 and 2.5. Every research permit application is reviewed for compliance with NEPA requirements and other laws, regulations, and policies.<sup>11</sup> Park superintendents are required to “include in a permit the terms and conditions that the superintendent deems necessary to protect park resources.”<sup>12</sup>

A thorough understanding of natural resources is essential to the effective management and long-term preservation of national parks, and requires a sound scientific basis.<sup>13</sup> The NPS

is increasingly enlisting the skills and talents of research partners to develop the scientific information needed to make effective management decisions, and is striving to make the parks more accessible to scientists (*see also* Chapter 3, Section 3.2).

National parks offer unique opportunities to study natural systems and living things, and the NPS encourages independent researchers to study park resources. Scientific research is encouraged by the NPS, provided that research activities cause no harm to the parks. Research activities may be conducted by any scientist who qualifies for an NPS Scientific Research and Collecting Permit (research permit) without regard to whether that scientist is affiliated with or funded by public or private sources.<sup>14</sup> All researchers who obtain NPS research permits, whether from public or private entities, are subject to the same NPS scientific research and specimen collection laws, regulations, policies, and guidelines. Although researchers may apply for permission to conduct research that may include collecting research specimens in any of the nearly 400 park units of the NPS, the nearly 300 parks that have already hosted independent research are most likely to do so in the future.<sup>15</sup>

Research permit terms require scientists to submit a yearly summary of their park research activities, known as an Investigator's Annual Report (IAR). Copies of field notes and scientific publications may also be required by the park. From 1992 through 2004, the NPS received approximately 30,000 IAR reports about permitted scientific studies in 289 different national park units (*see also* Chapter 3, Section 3.4.1).<sup>16</sup> Significantly more parks received IARs in recent years (2001–2004, when an average of 235 parks received IARs each year), than in the past (1992–1999).<sup>17</sup>

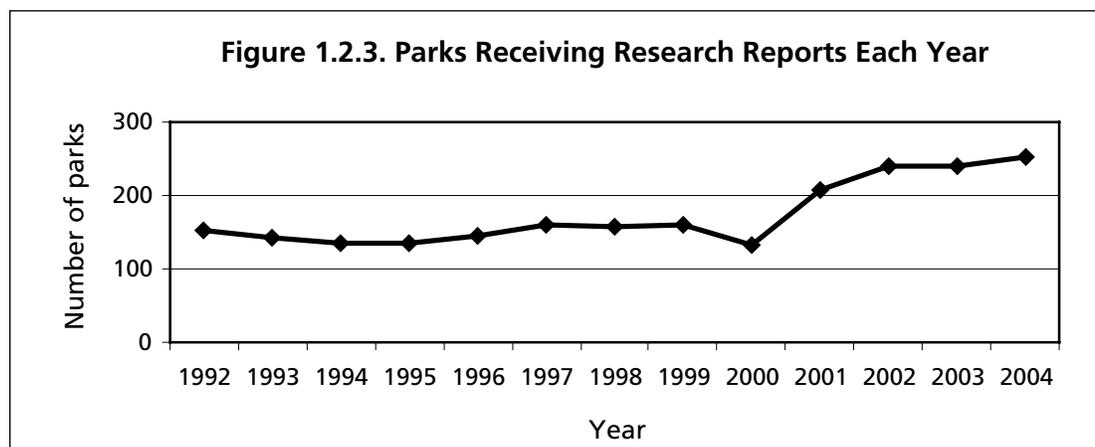


Figure 1.2.3. An average of 235 parks received research reports (IARs) each year during 2001–2004.

In order to make well-informed management decisions, NPS resource managers follow leads found in IARs, and use the results and conclusions presented in research publications. The NPS natural resources bibliography database contains approximately 246,000 entries, including more than 70,000 research articles published in scientific journals and approximately 107,000 formal and informal scientific reports about park natural resources.<sup>18</sup>

## 1.2.4 Commercial Applications of NPS-related Research

Advances in research technologies, intellectual property rights laws, and other fields now make it possible to generate substantial scientific and economic benefits from research activities in ways that were not possible—or even conceived of—in the past. Some research results involving study of specimens collected in U.S. national parks have provided useful and valuable commercial applications. In some cases, such research results have been patented. Research with potential for commercial application continues to occur under the authority of NPS research permits.

### 1.2.4.1 NPS-related research results protected by patents

Between 1978 and 2007, the U.S. Patent Office issued at least 55 patents that involved research results related to the study of biological material originating in U.S. national parks, 53 from Yellowstone National Park and 2 from Yosemite (*see* figure 1.2.4.1). The patents described a wide variety of inventions.

The first reported potential commercial application of research results based on the study of NPS research specimens was brought to the agency's attention in 1980, when it was discovered that the Department of Energy had filed a patent application on a high-temperature fermentation process derived from results of research on a microorganism collected at Yellowstone National Park.

### Media reports about research results involving research specimens collected in national parks

In 1993, it was reported that research projects involving seven different types of thermophilic microorganisms originally collected at Yellowstone National Park had resulted in the following discoveries with actual or potential commercial applications: oxidizing sulfide; turning cornstarch into a road de-icer; making enzymes used in molecular biology; making enzymes used in studying DNA; producing enzymes used to make perfumes and lactic acid; and converting cellulose into ethanol.<sup>19</sup>

In March 1994, it was reported that “[s]ome discoveries with commercial application include microbes that ferment cellulose from corn cobs into ethanol (*Thermoanaerobacter ethanolicus*); turn corn starch into a natural road de-icer (*Clostridium thermoautotrophicum*); produce enzymes used to make perfume and lactic acid (*Thermoanaerobium brockii*); and convert corn starch to sugar (*Acidothermus cellulolyticus*).”<sup>20</sup>

Later in 1994, there were reports that research on several strains of previously unknown types of microorganisms first discovered at Carlsbad Caverns National Park produced substances that could inhibit or kill leukemia cells.<sup>21</sup>

In 1996, it was reported that research carried out at the Department of Energy's Pacific Northwest Laboratory involving samples of *Sulfolobus acidocaldarius* originating at Yellowstone National Park had resulted in the discovery and development of new processes for recycling discarded rubber tires.<sup>22</sup>

Likewise, in 1997, it was reported that a variety of different research projects involving thermophilic microorganisms originating from Yellowstone National Park resulted in the following discoveries with potential commercial applications: improving texture of baked goods; converting milk to cheese; tenderizing meat; improving clarity, flavor, and foam in beer brewing; removing oils and grease from fabrics; breaking down wood components in paper production; replacing chemicals in paper bleaching; improving textiles' ability to absorb dyes; and replacing chemicals in tanning leather.<sup>23</sup>

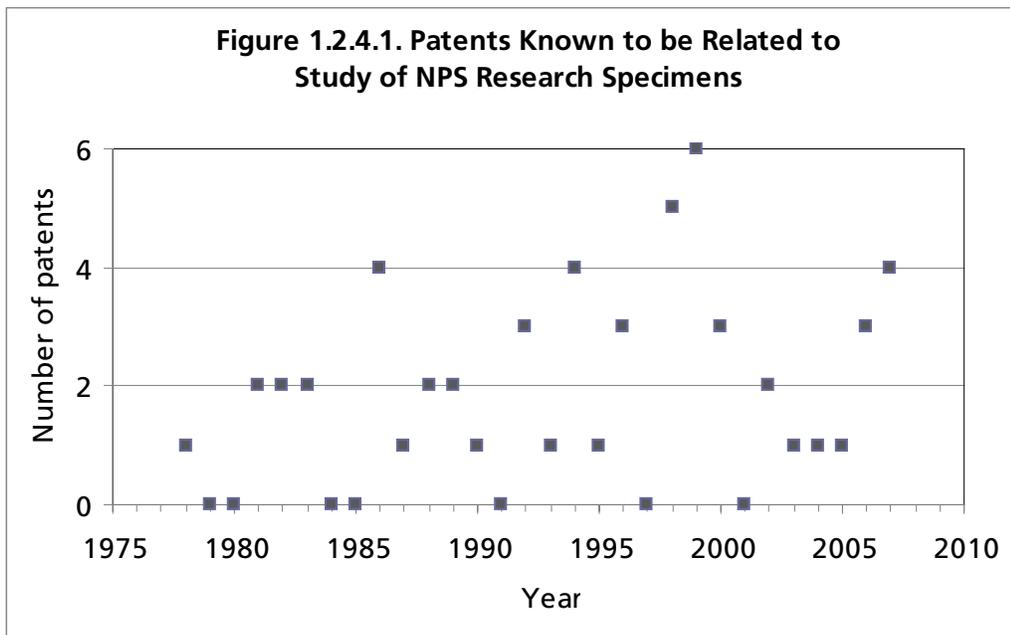


Figure 1.2.4.1. Between 1978 and 2007, The U.S. Patent and Trademark Office granted at least 55 patents based upon research results related to the study of biological material originating in U.S. national parks.

The best-known example of valuable research results involving study of an NPS research specimen was the invention of the Polymerase Chain Reaction (PCR), a process that facilitates widespread uses of DNA analyses and revolutionized the study of biology. PCR generated significant profits for its owners. The PCR patents disclosed that the process used “Taq polymerase,” an enzyme isolated from *Thermus aquaticus* bacteria collected in Yellowstone National Park and then grown in the laboratory for further study. The importance of research involving *T. aquaticus* was summarized in Congressional testimony offered by D. Allan Bromley (then Director of the White House Office of Science and Technology Policy and Science Advisor to President George H. W. Bush) in 1991:

*Thomas Brock, a microbiologist at the University of Wisconsin [sic], discovered a form of bacteria in the thermal vents of Yellowstone that can survive at very high temperature. From these bacteria an enzyme was extracted that is stable at near-boiling temperatures. Nearly two decades later this enzyme proved to be vital in the process known as the polymerase chain reaction, which is used to duplicate specific pieces of DNA. Today, PCR is the basis of a multimillion dollar business with applications ranging from the rapid diagnosis of disease to forensic medicine.<sup>24</sup>*

Other patents related to park-related research results include but are not limited to the following commercial purposes:

- Enzymes that can be utilized in a wide variety of industries including food processing, baking, pharmaceuticals, agriculture, textiles, detergents, and cosmetics;
- Biologically based methods and products used for bioremediation of hazardous waste;

- Methods and products to enhance oil recovery and remove sulfur compounds and metals from crude oil;
- New compounds with anti-tumor and antibiotic activity; and
- A nanotechnology method for building extremely small structures for purposes such as high-speed computers.

The only available information about the commercial value of patents related to the study of NPS specimens concerns the patents related to the development of PCR. The economic value associated only with the acquisition of the patent rights resulting from the invention of PCR has been reported to be in excess of \$300 million. The economic value of the subsequent development and use of those patents has been reported to be as much as \$100 million annually.

Not all patented inventions generate revenue or other income. There are no published statistical reports that document the “value” of individual patents, and the NPS has neither required any reports nor systematically collected information concerning revenue or other income generated by research results involving study of research specimens originating from U.S. national parks.

Patent applications related to the study of NPS specimens continue to be filed. For example, at least four NPS-related patent applications were filed in 2007, and at least four in 2008.

#### ***1.2.4.2 Commercial uses of research results without patenting***

Research results can be used for commercial application without being patented. For example, the Diversa Corporation announced in early 2002 that it was beginning to market a new product identified as Pyrolase 200™, which resulted from research involving thermophilic microorganisms collected at Yellowstone National Park. Pyrolase 200™ is not the subject of a patent.

Researchers can also derive income from the development of a service for hire. For example, a researcher’s major source of income could be derived from performing research for others, under contract, using proprietary methods the researcher developed from study of NPS research specimens.

## **1.3 Purpose and Need for a Proposal to Implement Benefits-Sharing**

### ***(Specific Problems with Existing Procedures)***

The purpose of this EIS is to “examine potential environmental impacts of various methods of implementing the provisions of law that authorize benefits-sharing agreements while ensuring the integrity of resources” (67 Fed. Reg. 18034, 18035 (April 12, 2002)). As previously discussed in Chapter 1, in light of new and changing technologies, a need has emerged to clarify the rights and responsibilities of researchers and the NPS regarding valuable research results, including whether or not the NPS will require benefits-sharing. To be considered a success, actions proposed in the EIS must also strengthen conservation and protection of resources managed by the NPS and strengthen the scientific capacity of NPS

managers. In addition, the alternatives must not influence or affect research permit decision-making. These fundamental elements of the purpose of the EIS are discussed in Section 1.4, which elaborates on the objectives and goals NPS intends to fulfill by taking action.

The National Park Service has determined that it needs servicewide guidance to address the NPS's interest in the financial and other benefits from the results of research involving park research specimens. Alternative B's proposal to implement benefits-sharing responds to the new understanding of the potential for commercial application of research results described in Section 1.2.4 of this chapter.

The preparation of this FEIS will ensure that the basic foundation for decision-making regarding benefits-sharing has been developed in consultation with interested stakeholders and other members of the public, and adopted by park managers and NPS leadership after an adequate analysis of the potential environmental impacts of alternative courses of action. In addition, it will fulfill requirements ordered by the federal district court for the NPS to complete any and all review mandated by NEPA in regard to benefits-sharing in the NPS.

The need to propose new NPS management practices for benefits-sharing is indicated by the difference between the conditions that presently exist and the desired future conditions that could be met by the objectives discussed in Section 1.4 of this chapter. The following unresolved issues and concerns contrast with the objectives outlined below and include elements included in Alternative B's programmatic proposal to implement benefits-sharing.

### **1.3.1 Existing Conditions: Clarity of Rights and Responsibilities Regarding Research Results**

The rights and responsibilities of researchers and NPS managers in connection with the allocation of benefits from valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks are unclear. Section 5935(d) of the National Parks Omnibus Management Act of 1998 (NPOMA) states, "The Secretary [of the Interior] may enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements." Detailed NPS guidance on how to accomplish this does not exist.

NPS research permits require benefits-sharing, but provide no details on how to achieve that sharing. All NPS research permits are issued subject to the condition that research results may not be used for commercial purposes unless the researcher has entered into a benefits-sharing agreement with the NPS.<sup>25</sup> However, the NPS has no standardized, servicewide benefits-sharing agreements in use and provides no guidance to parks regarding the elements necessary to include in a benefits-sharing agreement. The absence of such systematic guidance has resulted in confusion among some members of the public and research community, as well as within some parts of the NPS.

NPS policies do not adequately describe the critical difference between commercial use of research specimens and commercial use of research results.<sup>26</sup> Commercial use of research specimens is prohibited (*see* 36 CFR 2.1). However, the commercial use of knowledge derived from the specimens via research (research results) is not prohibited. Commercial use of research results has, in the past, been left entirely up to researchers, without involvement

from the NPS. The lack of clarity about the meaning of the NPS research permit's reference to "commercial or other revenue-generating purposes" has resulted in confusion among some members of the public and the research community, as well as within some parts of the NPS.

The NPS's standardized research permits state that the unauthorized transfer of research specimens to third parties is prohibited. Through contractual provisions of the research permit, the NPS controls access to collected specimens. NPS also controls transfers of collected specimens, research specimens, any components of collected specimens or research specimens, any products, and research results.<sup>27</sup> Existing servicewide standardized procedures to authorize loans of specimens apply specifically to permanently retained specimens and do not apply to specimens, or components of permanently retained specimens, that are to be destroyed through analysis or discarded after analysis (i.e., nonpermanent specimens) although both permanent and nonpermanent specimens remain Federal property. The absence of systematic guidance about transfers of nonpermanent specimens or components of specimens has resulted in confusion among some members of the public and research community, as well as within some parts of the NPS regarding when nonpermanent specimen transfer authorizations must be requested and how NPS is to act upon such requests.

Specimens permitted for collection and destructive analysis or discard are nonpermanent. The act of destructive analysis destroys the collected specimen and sometimes yields material that is part of the researcher's research results. The absence of systematic guidance about transfers of this material has also resulted in confusion among some members of the public and research community, as well as within some parts of the NPS regarding when authorization must be requested to transfer these materials and how NPS is to act upon such requests.

### **1.3.2 Existing Conditions: Science for Park Management**

The National Parks Omnibus Management Act of 1998 (NPOMA) directs the NPS to take necessary measures "to assure the full and proper utilization of the results of scientific study for park management decisions" while encouraging use of national parks by researchers "for study to the benefit of park management as well as broader scientific value." The NPS has not implemented benefits-sharing although clear legal authority exists to do so. Therefore, the NPS is not using every means at its disposal to assure full utilization of scientific study for park management. The need for more and better scientific information about park plants, animals, ecosystems, and their interrelationships is widely recognized.<sup>28</sup> Some collaboration currently occurs between the NPS and researchers, but it is often sporadic and inconsistent, because the NPS sometimes fails to use existing requirements or incentives for researchers to engage in closer partnerships with parks. In many cases, scientists conducting research involving park resources have more knowledge about those resources than NPS staff (*see* Chapter 3, Section 3.2.1). Park managers often find themselves making unnecessarily difficult decisions because they have not adequately obtained the scientific information that exists.

In order to further resource protection goals, park management strives to inform and educate the public about park resources through interpretation of available scientific knowledge. A fundamental goal of NPS interpretation is to present accurate information in such a way that people will begin to understand and appreciate the significance of the parks and their

resources.<sup>29</sup> The quality of information used for interpretive services is dependent on the quality of the available scientific information about park resources (*see* Chapter 3, Section 3.3.4).

## **1.4 Objectives of the Proposal and Its Alternatives**

The following objectives were identified to help determine the reasonableness of each alternative, and to select the preferred alternative and the environmentally preferred alternative (the ultimate selection of the environmentally preferred alternative is guided by the impact analysis in Chapter 4). These objectives proceed from NPS mandates that include legislation, regulations, executive orders, and governing policies. The objectives were identified based on the existing conditions described in Section 1.3 of this chapter.

The alternatives together examine a range of possible solutions to the problems discussed in the existing conditions while addressing the objectives of this FEIS. Meeting the objectives will advance the NPS from existing conditions toward desired future conditions.

### **1.4.1 Desired Future Condition: Clarity of Rights and Responsibilities Regarding Research Results**

The rights and responsibilities of researchers and NPS managers in connection with research results involving study of NPS research specimens will be clarified by selection of one of the alternatives in this FEIS.

**OBJECTIVE 1:** Identify the role, if any, of the NPS in the event a researcher wishes to commercialize his/her research results involving study of NPS research specimens.

Objective 1.1: Determine whether or not benefits-sharing will be required.

Objective 1.2: Ensure equity and efficiency in connection with any benefits-sharing agreements between the NPS and independent researchers.

Alternative B (Implement Benefits-Sharing) must provide enough information about proposed agreements to allow all parties to anticipate that such agreements would likely be equitable and efficient.

### **1.4.2 Desired Future Condition: Science for Park Management**

The National Parks Omnibus Management Act of 1998 (NPOMA) directs the NPS “to assure that management of units of the National Park System is enhanced by the availability and utilization of a broad program of the highest quality science and information.”<sup>30</sup>

**OBJECTIVE 2:** Strengthen conservation and protection of resources managed by the NPS by deepening understanding of biodiversity and physical and biological processes.

Objective 2.1: Enhance the scope and quality of scientific data reported to the NPS by the research community.

A thorough understanding of resources is essential to the effective management and long-term preservation of national parks, and requires a sound scientific basis.<sup>31</sup> Virtually all parks have challenges to their conservation mandate that only good science—meaning new knowledge—can define with sufficient detail to allow park managers to meet those challenges. Knowledge from researchers who could enter into benefits-sharing agreements could provide park managers with new, high-quality sources of knowledge to manage park resources that would be otherwise unavailable to them.

Objective 2.2: Strengthen the scientific capacity of NPS managers through increased collaboration with independent researchers.

“Scientific capacity” is used here to mean the ability to perform scientific activities such as collecting and analyzing data and applying the results to management decision-making. Although the NPS performs a wide range of mission-oriented science in support of its natural and cultural resource stewardship responsibilities, it employs few research-grade scientists. The cooperative involvement of research experts outside the NPS (federal and non-federal public and private agencies, organizations, individuals, and other entities) regularly assists the NPS with obtaining information essential for effective resource management.<sup>32</sup>

### **1.4.3 Desired Future Condition: Research Permit Issuance Is Not Influenced By Potential Benefits-Sharing**

In the absence of any mitigation measures (*see* EIS sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5), implementation of Alternative B (Implement Benefits-Sharing) could result in inappropriate consideration of separate benefits-sharing issues at the time NPS research permits are issued. For example, some park officials might be inclined to approve a permit based on the applicant’s representation that valuable research results were likely, whereas other park officials might be inclined to disapprove permit applications involving commercial research firms for reasons not related to the merits of the proposed research activity.

In addition, because the thorough understanding of resources essential to effective management of national parks requires a sound scientific basis, no alternative should discourage researchers from conducting park-related research.

**OBJECTIVE 3:** Ensure that the NPS research permitting process is independent, objective, and unaffected by actions proposed in this FEIS.

Objective 3.1: Research involving units of the NPS continues to be permitted in accordance with all laws and is unaffected by alternatives proposed in this FEIS.

No alternative would change the regulations and practices that mitigate against improper issuance of NPS research permits. Every research proposal is reviewed for compliance with NEPA requirements and other laws, regulations, and policies.<sup>33</sup> The NPS permits research activities under 36 CFR 1.6, which prohibits the issuance of permits for activities that would adversely affect environmental values (among other criteria). The NPS permits research specimen collection under 36 CFR 2.5, which also prohibits collections that would damage park resources.

Under Alternative B (Implement Benefits-Sharing), mitigation measures would be applied to protect NPS research permit coordinators from being inappropriately influenced by benefits-sharing considerations. These measures would ensure that parks adhere to the strict standards in place regarding the issuance of NPS research permits. Mitigation efforts would focus on management controls as a means of managing the risk that benefits sharing might inappropriately influence park permitting decisions (*see* Chapter 4, Section 4.4.5.5).<sup>34</sup>

Objective 3.2: Ensure that implementation of the alternatives does not discourage the conduct of research involving units of the NPS.

Development of the NPS benefits-sharing proposal was informed by the management practices of existing and potential benefits-sharing arrangements of other agencies and other countries around the world as well as the experience gained during development of the Yellowstone–Diversa CRADA (*see* Appendix G: Background for Benefits-Sharing and Technology Transfer). Insights gained suggested that benefits-sharing management practices that provide for the efficient and equitable sharing of valuable research results generated by research involving NPS research specimens would be most likely to be accepted by researchers without discouraging them from applying for NPS research permits. This concept was incorporated into Alternative B (Implement Benefits-Sharing).

The extent to which Alternative C (Prohibit Specimen Collection for Any Commercially-Related Research Purposes) could discourage research involving units of the NPS is evaluated in Chapter 4, Section 4.5.4.

## 1.5 Benefits-Sharing by National Parks and Other Organizations

Although this FEIS has been prepared due to the precedent-setting nature of implementing benefits-sharing in the NPS, benefits-sharing has already been implemented by various other organizations in the U.S. and around the world. For purposes of this FEIS, the term “benefits-sharing” refers to the equitable and efficient sharing of benefits—between researchers, their institutions, and a land management agency—that result from research involving research specimens originating from the lands under that agency’s jurisdiction.

Appendix G provides an overview of existing benefits-sharing arrangements. Depending on the facts and circumstances, the research results subject to a benefits-sharing agreement may generate either monetary or non-monetary benefits (or both). Existing benefits-sharing arrangements were examined by the NPS in preparation for proposing implementation of benefits-sharing.

## 1.6 Commercial Use of Research Results Discovered by Federal or Academic Scientists

In general, federal and academic institutions do not themselves commercialize research results. Usually, intermediate research results, as the intellectual property of the researcher and his institution, are offered for sale, lease, license, or other transfer for value to another institution for further research and development and eventual commercialization. The term “technology transfer” is used when such intellectual property is sold, leased, licensed, or otherwise transferred for value. Technology transfer by federal and academic research institutions is reviewed in Appendix G.

## 1.7 Legal Framework

The following sections provide a brief overview of relevant laws (Sections 1.7.1 *and* 1.7.2), regulations (Section 1.7.3), policies (Sections 1.7.4 *and* 1.7.5), and judicial decisions (Section 1.7.6) applicable to this FEIS.

The management of the National Park System and its programs is guided by the U.S. Constitution, public laws (*see* this chapter, Sections 1.7.1 *and* 1.7.2), treaties, proclamations, executive orders (*see* this chapter, Section 1.7.2), regulations (*see* this chapter, Section 1.7.3), and directives of the Secretary of the Interior and the Assistant Secretary for Fish and Wildlife and Parks, as interpreted by the judiciary (*see* this chapter, Section 1.7.6). NPS policy must be consistent with these authorities, and with appropriate delegation of authority.

Servicewide policy is articulated by the director of the NPS. *NPS Management Policies* is the primary servicewide policy document of the NPS, and is the highest of three levels of guidance documents in the NPS Directives System (*see* this chapter, Section 1.7.4). Interim

updates or amendments may be accomplished through Director's Orders (the second level of the NPS Directives System), which also serve as a vehicle to clarify or supplement *NPS Management Policies* to meet the needs of NPS managers (*see* this chapter, Section 1.7.5). The most detailed and comprehensive guidance on implementing servicewide policy is usually in the form of handbooks or reference manuals issued by associate directors (the third level of the NPS Directives System) (*see* this chapter, Section 1.7.5).

### **1.7.1 NPS Mandates: Laws Enacted by Congress Specifically for the NPS**

The most important statutory directive for the NPS is provided by the interrelated provisions of the NPS Organic Act of 1916 and the NPS General Authorities Act of 1970, including amendments to the latter law enacted in 1978.

#### ***National Park Service Organic Act of 1916 and the NPS General Authorities Act of 1970, including amendments enacted in 1978***

The NPS Organic Act establishes the NPS in the Department of the Interior to “promote and regulate the use of the Federal areas known as national parks, monuments, and reservations hereinafter specified.”<sup>35</sup>

The key management-related provision of the Organic Act is: “[The National Park Service] shall promote and regulate the use of the Federal areas known as national parks, monuments, and reservations hereinafter specified . . . by such means and measures as conform to the fundamental purpose of the said parks, monuments, and reservations, which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.”<sup>36</sup>

Congress supplemented and clarified the provisions of the Organic Act through the General Authorities Act. The key part of that act, as amended, is: “Congress declares that the national park system, which began with establishment of Yellowstone National Park in 1872, has since grown to include superlative natural, historic, and recreation areas in every major region of the United States. . . . The authorization of activities shall be construed and the protection, management, and administration of these areas shall be conducted in light of the high public value and integrity of the National Park System and shall not be exercised in derogation of the values and purposes for which these various areas have been established, except as may have been or shall be directly and specifically provided by Congress.”<sup>37</sup>

#### ***The National Parks Omnibus Management Act of 1998 (NPOMA)***

NPOMA directs the NPS to support both “science for parks” and “parks for science” (*see* Chapter 3, Section 3.2). NPOMA specifically incorporates scientific study as a purpose of the National Park System “to encourage others to use the National Park System for study to the benefit of park management as well as broader scientific value, where such study is consistent with the Act of August 25, 1916 (commonly known as the National Park Service Organic Act; 16 USC 1 *et seq.*).”<sup>38</sup> NPOMA directs the secretary of the interior to “assure that management of units of the National Park System is enhanced by the availability and utilization of a broad program of the highest quality science and information.”<sup>39</sup> NPOMA permits the secretary

of the interior to solicit, receive, and consider requests from federal, non-federal, public, or private entities to use any unit of the National Park System for purposes of scientific study.<sup>40</sup> Finally, it specifically authorizes the NPS to “enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements.”<sup>41</sup>

### ***Individual NPS unit enabling legislation***

Each unit of the National Park System is governed by its own enabling legislation or proclamation, which provides specific legal authorities and direction for each park.<sup>42</sup> Parks must review their enabling legislation to determine if it contains explicit guidance that would prevail over servicewide policy.

## **1.7.2 Other Laws**

### ***National Environmental Policy Act of 1969 (NEPA)***

NEPA promotes efforts to prevent or eliminate environmental damage by requiring a “detailed statement on the environmental impact[s]” of “major Federal actions affecting the quality of the human environment.”<sup>43</sup> This FEIS has been prepared as NEPA directs to analyze the potential environmental impacts of benefits-sharing as well as alternatives to benefits-sharing. The FEIS also serves as a vehicle for the NPS to make a diligent effort to involve the interested and affected public before making decisions regarding benefits-sharing.

### ***Federal Technology Transfer Act of 1986 (FTTA)***

The FTTA stipulates that technology and industrial innovation are important to the U.S., and that “[c]ooperation among academia, Federal laboratories, labor, and industry” should be renewed, expanded, and strengthened for the purpose of improving the economic, environmental, and social well-being of the U.S.<sup>44</sup>

The FTTA defines Cooperative Research and Development Agreements (CRADAs) as “any agreement between one or more Federal laboratories and one or more non-Federal parties under which the government, through its laboratories, provides personnel, services, facilities, equipment or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the mission of the laboratory.”<sup>45</sup>

For purposes of the FTTA, a federal “laboratory” is defined as “a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.”<sup>46</sup> The FTTA authorizes the directors of federal laboratories to enter into CRADAs with other federal agencies, state and local governments, industrial organizations, public foundations, private foundations, non-profit organizations, and other persons.<sup>47</sup> Like other federal facilities that carry out research activities, units of the National Park System that satisfy the FTTA definition of a “laboratory” are eligible to enter into CRADAs.<sup>48</sup>

Executive Order 12591 authorizes delegation of authority to federal laboratories to enter into CRADAs with “other Federal laboratories, State and local governments, universities and the private sector.”<sup>49</sup> Alternative B (Implement Benefits-Sharing) proposes to implement this

authority by providing for individual parks that are laboratories under the FTTA to negotiate and implement benefits-sharing agreements (*see* Glossary).

### **1.7.3 NPS Regulations**

Specific NPS regulations that have guided the preparation of this FEIS are reviewed briefly below. These regulations provide for the proper use, management, government, and protection of persons, property, and natural and cultural resources within areas under the jurisdiction of the National Park Service. These regulations implement the statutory purposes of units of the National Park System as established in the NPS Organic Act (*see* above).

#### ***Permits (36 CFR 1.6)***

This regulation authorizes park superintendents to issue permits for activities that are otherwise restricted or denied to the general public and requires superintendents to “include in a permit the terms and conditions that the superintendent deems necessary to protect park resources.” Issuance of a permit is based on a determination by the park superintendent that the following factors “will not be adversely impacted”:

- Public health and safety
- Environment or scenic values
- Natural or cultural resources
- Scientific research
- Implementation of management responsibilities
- Proper allocation and use of facilities
- Avoidance of conflict among visitor use activities

#### ***Research specimens (36 CFR 2.5)***

This regulation authorizes park superintendents to issue research specimen collection permits if the collection is necessary to scientific or resource management goals and only if such collections would not damage park resources.

#### ***Preservation of natural, cultural and archeological resources (36 CFR 2.1)***

This regulation prohibits the sale or commercial use of “natural products.” There is an important distinction between sale or commercial use of natural products collected from national parks and the discovery of intellectual knowledge from research results followed by the development of commercial applications from that intellectual knowledge (*see* this chapter, Section 1.1, *and* Chapter 2, Section 2.4.5).<sup>50</sup>

### **1.7.4 NPS Management Policies**

Specific NPS policies that have guided the preparation of this FEIS are reviewed briefly below.

Once laws are enacted, authority for interpreting and implementing them is delegated to

appropriate levels of government. In carrying out this function, the NPS, like other federal agencies, develops policies that are guided by and consistent with the Constitution, public laws, Executive proclamations and orders, and regulations and directives from higher authorities. Servicewide policy is articulated by the director of the NPS. Policy sets the framework and provides direction for all management decisions, including the decision informed by this FEIS: whether or not to implement benefits-sharing.

### ***Chapter 1: The Foundation***

Chapter 1 of *NPS Management Policies 2006* describes and interprets the provisions of the NPS Organic Act and the NPS General Authorities Act as they relate to the need to avoid impairment of park resources and values. The “impairment” prohibited by these statutes is described as “an impact that, in the professional judgment of the responsible NPS manager, would harm the integrity of park resources or values, including the opportunities that otherwise would be present for the enjoyment of those resources or values.” *NPS Management Policies 2006* also explains that “[w]hether an impact meets this definition depends on the particular resources and values that would be affected; the severity, duration, and timing of the impact; the direct and indirect effects of the impact; and the cumulative effects of the impact in question and other impacts.”

### ***Chapter 4: Natural Resource Management***

Chapter 4 provides that the NPS “will preserve the natural resources, processes, systems, and values of units of the national park system in an unimpaired condition” pursuant to the NPS Organic Act, NPOMA, NEPA, and other laws. It clarifies NPS policies relating to studies and collections, independent studies, and collections associated with development of commercial products.<sup>51</sup> Chapter 4 explains that “[t]he [National Park] Service will encourage appropriately reviewed natural resource studies whenever such studies are consistent with applicable laws and policies. These studies support the NPS mission by providing the Service, the scientific community, and the public with an understanding of park resources, processes, values, and uses that will be cumulative and constantly refined. This approach will provide a scientific and scholarly basis for park planning, development, operations, management, education, and interpretive activities.”<sup>52</sup>

### ***Chapter 5: Cultural Resources Management***

Chapter 5 describes the management of NPS museum collections, including biological specimens and associated documentation.

### ***Chapter 8: Use of the Parks***

Chapter 8 provides that “[s]tudies, research, and collection activities by non-NPS personnel involving natural and cultural resources will be encouraged and facilitated when they otherwise comport with NPS policies,” and that “[s]cientific activities that involve field work or specimen collection . . . require a permit issued by the superintendent that prescribes appropriate conditions for protecting park resources, visitors, and operations.”<sup>53</sup>

## **1.7.5 NPS Director’s Orders, Handbooks, and Other Guidance Documents**

Director’s Orders clarify or supplement the NPS Management Policies to meet the needs of

NPS managers. Subordinate to Director's Orders, handbooks or reference manuals issued by associate directors provide the most detailed and comprehensive guidance on implementing servicewide policy. Handbooks do not impose any new servicewide requirements unless the NPS director has specifically authorized them to do so, but often reiterate or compile requirements (i.e., laws, regulations, policies) that have been imposed by higher authorities. NPS managers find additional guidance in various other documents prepared under the NPS director's authority.

Specific NPS guidance documents that were consulted in the preparation of this FEIS are reviewed briefly below.

### ***Director's Order and Handbook 12: Conservation Planning, Environmental Impact Analysis, and Decision-Making***

This handbook provides instructions for the NEPA process in the NPS. The sections of this handbook derive in whole or in part from Council on Environmental Quality (CEQ) regulations or Department of the Interior NEPA guidelines, giving them the force of law. The processes described in this handbook are binding on all NPS personnel.

This handbook also directs that NPS management decisions be based on "ample technical and scientific studies properly considered and appropriate to decisions made."<sup>54</sup> It prohibits the NPS from undertaking any activity that "would, or is likely to, impair park resources or values."<sup>55</sup>

### ***Director's Order 20: Agreements***

Director's Order 20 encourages NPS park and program managers to "actively seek opportunities to efficiently and economically accomplish the NPS mission by entering into advantageous relationships with Federal and non-Federal entities."

### ***Director's Order 24: NPS Collections Management***

Director's Order 24 and the related NPS Museum Handbook describe the procedures for managing specimens within the museum collections consistent with 36 CFR 2.5 and RPRS. They also describe procedures for lending specimens to repositories and other qualified borrowers.

### ***Administrative Guide for Park Research Coordinators***

This guide describes the procedures a park is to use for determining whether or not to issue an NPS Scientific Research and Collecting Permit (research permit). It explains that an application for a research permit should be evaluated for its scientific validity, researcher and institutional qualifications, its benefit to the park service and the public, and its actual or potential impacts to park resources, visitor experiences, wilderness, or safety. The guide notes that the NPS should encourage "a broad range of research in parks."

### ***NPS Scientific Research and Collecting Permits: General Conditions***

The general conditions provide that permittees shall comply with all applicable laws and regulations of the National Park System and other federal, state, and area laws, and that "[n]o specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting Permit."<sup>56</sup> They prohibit unauthorized third-party transfers of any

specimens collected. They stipulate that research results derived from collected specimens must be used for scientific and educational purposes only, and that research results may not be used commercially unless the permittee has entered into a CRADA or other approved benefits-sharing agreement with the NPS.<sup>57</sup>

Two of the alternatives considered in this FEIS would require further clarification of these conditions through preparation of new or amended Director's Orders. Alternative A would allow the use of research results for commercial purposes without a benefits-sharing requirement (*see* Chapter 2, Section 2.3). Alternative C would not authorize the commercial use of research results (with some exceptions) and would not require benefits-sharing (*see* Chapter 2, Section 2.5). Alternative B would implement the general conditions as written (*see* Chapter 2, Section 2.4).

### ***NPS Natural Resource Challenge***

The NPS Natural Resource Challenge states, “[n]ational parks are preserved so that this generation and future generations can enjoy, benefit, and learn from them.”<sup>58</sup> It notes that the NPS requires more information about plants, animals, ecosystems, and their interrelationships in order to protect them, and must enlist others in the scientific community to help.<sup>59</sup> It states, “Acquiring, applying, and promulgating scientific knowledge gained in parks to ensure protection and enjoyment requires cooperation with public agencies, universities, and non-governmental organizations;” “[P]arks can and should be centers for broad scientific research and inquiry;” and “Research should be facilitated in parks where it can be done without impairing other park values.”<sup>60</sup>

### ***U.S. Department of the Interior GPRA Strategic Plan 2007–2012***<sup>61</sup>

The Department of the Interior (DOI) Strategic Plan updates and replaces the 2001–2005 National Park Service Strategic Plan. The DOI Strategic Plan states that the mission of the NPS is to “preserve unimpaired the natural and cultural resources and values of the national park system for the enjoyment, education, and inspiration of this and future generations. The NPS cooperates with partners to extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world”<sup>62</sup>

## **1.7.6 Judicial Decisions**

### ***Edmonds Institute, et al. v. Babbitt, et al., 93 F. Supp. 2d 63 (DDC 2000)***

The U.S. District Court heard plaintiffs’ claims that the Yellowstone–Diversa CRADA violated the National Park Service (NPS) Organic Act of 1916, the Yellowstone National Park Organic Act, and the FTTA, and then rejected those claims on all counts and dismissed the plaintiffs’ case with prejudice. Specifically, the court ruled that the Yellowstone–Diversa CRADA satisfies the requirements of the NPS and Yellowstone National Park Organic Acts as well as the FTTA,<sup>63</sup> does not authorize an impermissible “consumptive use” of park resources,<sup>64</sup> does not conflict with the conservation mandate of the NPS and Yellowstone Organic Acts,<sup>65</sup> and does not involve the “sale or commercial use” of park resources.<sup>66</sup> (*See* Appendix I.)

### ***Edmonds Institute, et al. v. Babbitt, et al., 42 F. Supp. 2d 1 (DDC 1999)***

The U.S. District Court heard plaintiffs’ claims that the Yellowstone–Diversa CRADA violated the public trust doctrine and that the NPS failed to demonstrate compliance with NEPA,

dismissed the claim regarding the public trust doctrine, and ruled that the NPS had failed to demonstrate compliance with NEPA, and suspended the CRADA pending compliance with the court's order that the NPS meet the requirements mandated by NEPA.<sup>67</sup> (*See* Appendix I.)

***Public Citizen Health Research Group v. National Institutes of Health, et al., CA No. 00-1847 (DDC 2002) (Memorandum Opinion dated March 11, 2002)***

The U.S. District Court ruled that financial information relating to royalty payments arising under certain licensing agreements and CRADAs are exempt from disclosure under the federal Freedom of Information Act.

***Diamond v. Chakrabarty, 447 US 303 (1980)***

The U.S. Supreme Court ruled that a live, human-modified microorganism is patentable subject matter under 35 USC 101.

***JEM Ag Supply dba Farm Advantage v. Pioneer Hi-Bred Int'l, 534 US 124 (2001)***

The U.S. Supreme Court ruled that plant varieties are eligible for protection by utility patents issued pursuant to 35 USC 101, as well as under the Plant Patent Act of 1930 (35 USC 161 *et seq.*), and the Plant Variety Protection Act of 1970 (7 USC 2321 *et seq.*).

## **1.8 Initial Scoping Process and Public Participation**

Scoping is an early and open process for determining the scope of environmental issues and alternatives to be addressed in an EIS. The public plays an integral role in the scoping process. The NPS used the various points of view expressed in scoping comments to frame the issues to be resolved through the NEPA process, as documented in this EIS.

The NPS published a notice of intent to prepare an environmental assessment (EA) in the Federal Register on June 25, 2001 (66 Fed. Reg. 33712, 33713). Initial scoping occurred June–August 2001 and April–May 2002. During the scoping periods, two newsletters were mailed to more than 5,000 people, requesting comments.<sup>68</sup> A web site provided background information and invited people to comment via e-mail. A press release and fact sheet were distributed to national news media. Articles appeared in a variety of newspapers. Notices were posted in the nationwide NPS Morning Report.

In total, 118 comment messages were received on a variety of items. Most of the messages were received from individuals. Twenty-five organizations also submitted comments. Typically, a single message contained multiple, topical comments. The NPS identified 294 separate topical comments within these 118 messages (*see also* Appendix D: Public Involvement—Scoping).

Every comment in every message received during scoping was identified for consideration by the Interdisciplinary Team (IDT), including comments that were outside the scope of this EIS. All comments and concerns were considered, whether they were presented by several people or a single person. Emphasis in this process was on the content of the comment, rather than the number of people who submitted it.

Initially the NPS planned to write an Environmental Assessment (EA) for benefits-sharing. However, scoping comments persuaded the NPS that an EIS would be more appropriate. The NPS published a notice of intent to prepare an EIS in the Federal Register on April 12, 2002 (67 Fed. Reg. 18034, 18035) followed by the second scoping period, April–May 2002. Issues framed by scoping are described in Section 1.9 of this chapter.

Perhaps because information available to the public about the scoping process was presented in a short newsletter that necessarily gave only a brief outline of benefits-sharing, the NPS received several kinds of comments that did not relate to the EIS. For example, some people assumed that without benefits-sharing, scientific research would not occur in NPS units, and they suggested that scientific research projects should be subject to NEPA review, not realizing that every research permit decision is already required to undergo a case-specific NEPA review. In addition, some people assumed incorrectly that the EIS might propose wholesale commercialization of park resources. These concerns were addressed in the EIS by the specific details included in the Alternatives as described in Chapter 2.

Additional information on public participation, including results of the review of the Draft Environmental Impact Statement, is available by reading Chapter 5, Consultation and Coordination.

## **1.9 Issues and Impact Topics from Scoping**

During scoping, the public and the NPS Interdisciplinary Team (IDT) identified and consolidated a variety of concerns about implementation of benefits-sharing. Some of the concerns raised during scoping are analyzed as impact topics in Chapter 4 (*see* this chapter, Section 1.9.1). General approval or opposition to benefits-sharing was addressed by including alternatives that support or reject benefits-sharing. Specifically, Alternative C, “Prohibit Specimen Collection for Any Commercially Related Research Purposes,” was developed in response to comments opposing benefits-sharing. In response to scoping comments, the NPS also considered an alternative that would have prohibited bioprospecting altogether; “Prohibit Any Commercial Use of Research Results Involving Study of Specimens Collected from NPS Units.” For reasons described in Section 2.7, such an alternative was not analyzed further (*see* Chapter 2). Issues, impacts, and concerns that were not within the scope of the decision to be made in the Final EIS, or that will not be significantly impacted by any of the alternatives, were not analyzed further (*see* this chapter, Section 1.9.2).

### **1.9.1 Issues Analyzed as Impact Topics in Chapter 4**

Potential impacts of the alternatives on each of the following issues were analyzed under each of the alternatives.

- (1) NPS Natural Resource Management (*see* Chapter 3, Section 3.2);
- (2) NPS Visitor Experience and Enjoyment (*see* Chapter 3, Section 3.3);
- (3a) Social Resources: The Research Community (*see* Chapter 3, Section 3.4); and
- (3b) Social Resources: NPS Administrative Operations (*see* Chapter 3, Section 3.5.)

### ***(1) NPS Natural Resource Management***

Scoping respondents advised the NPS to ensure that the information discovered during park research would be available to park managers. Comments were received supporting scientific endeavors in parks, and warning against any action that might chill research activities that could improve understanding of park resources.

Under the proposal, Alternative B (Implement Benefits-Sharing), knowledge, training and education, special services, research-related equipment, and monetary benefits generated by a benefits-sharing agreement would be used by natural resource managers to assist with meeting natural resource management goals. Alternative B is therefore predicted to primarily have beneficial impacts on NPS natural resource management. Chapter 3, Section 3.2 describes natural resource management in the NPS. The potential impacts of benefits-sharing on NPS natural resource management are analyzed in Chapter 4 for each alternative.

### ***(2) NPS Visitor Experience and Enjoyment***

The proposal, Alternative B (Implement Benefits-Sharing), is predicted to have primarily beneficial impacts on visitors in two ways: by affecting natural resource management, and by affecting interpretive services. Knowledge, training and education, special services, or research-related equipment generated by a benefits-sharing agreement could be used to prepare or conduct interpretive services. Chapter 3, Section 3.3 describes the aspects of visitor experience and enjoyment in the NPS that could be affected by the alternatives. The potential impacts on visitor experience and enjoyment are analyzed in Chapter 4 for each alternative.

### ***(3a) Social Resources: The Research Community***

The proposal, Alternative B (Implement Benefits-Sharing), is predicted to have a variety of impacts on researchers who hold NPS research permits, such as potential economic gains for researchers, or new requirements placed on research activities or use of research results. In addition, potential impacts of the alternatives on the quantity of independent research activities in parks were analyzed. Chapter 3, Section 3.4 describes the researchers who could be affected by the alternatives. These potential impacts are analyzed in Chapter 4 for each alternative.

### ***(3b) Social Resources: NPS Administrative Operations***

The proposal, Alternative B (Implement Benefits-Sharing), is predicted to have a variety of impacts on NPS administrative operations related to the administrative burden associated with each alternative. Chapter 3, Section 3.5 describes the NPS administrative operations that could be affected by the alternatives, the parks that are most likely to be affected, and the administrative resources available to parks. The predicted impacts on relevant NPS administrative operations are presented in Chapter 4 for each alternative.

## **1.9.2 Issues Not Evaluated Further in this FEIS**

Issues and concerns that are not within the scope of the decision to be made in the Final EIS or that would experience impacts from the alternatives that are minor or less were not analyzed further. Issues not analyzed in detail, and the reasons why they were not subject to detailed analysis in the FEIS, are explained in the following sections. Potential impacts on the

following topics were not evaluated in the FEIS.

### **1.9.2.1. Issues identified during scoping**

#### ***Genetic engineering***

The proposal, Alternative B (Implement Benefits-Sharing), would have no impact on genetic engineering. Issues relating to genetic engineering and the safety of any new medicines, agricultural products, or other discoveries that could result from research involving NPS research specimens are regulated by other agencies, such as the Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.

#### ***Intellectual property rights***

The proposal, Alternative B (Implement Benefits-Sharing), would have no impact on intellectual property rights as recognized in U.S. intellectual property rights laws. No federal action within the scope of this FEIS is proposed to modify any existing U.S. intellectual property rights laws.<sup>69</sup>

#### ***Congressional appropriations***

Overall NPS funding is beyond the scope of the analysis of the potential environmental impacts of benefits-sharing. Existing NPS authority to negotiate equitable, efficient benefits-sharing arrangements with the research community is a congressional authorization, not an appropriation.

#### ***Administration of scientific research activities in the NPS***

Authorization to conduct scientific research in national parks is subject both to well-established NPS regulations and to separate NEPA compliance procedures (*see* this chapter, Section 1.6). Federal actions analyzed in this FEIS would not change the compliance procedures under which research activities could be conducted.

### **1.9.2.2 Other legal compliance disclosures**

CEQ regulations (40 CFR Part 1500) and NPS policy (NPS DO-12) require that the following mandatory topics be addressed in every EIS. The discussion below addresses the topics either by providing the rationale for dismissing the topic from further consideration or directing the reader to the appropriate section of the document where further information on the topic is provided.

#### ***Possible conflicts between the proposed action and local, state, or tribal plans, policies, or controls***

Scoping and public involvement processes conducted for this FEIS have not revealed potential conflicts with plans, policies, or controls of local, state, or tribal governments. In addition, the actions proposed in this document do not recommend any changes to existing local, state, or tribal plans, policies, or controls. Protection of the intellectual property rights of tribes is discussed in Chapter 2, Alternative B, Section 2.4.1. In some instances, the NPS has regulatory or managerial authorities and responsibilities for lands that are under joint jurisdiction or are not federally owned. These authorities and responsibilities may include the issuance of NPS research permits. Ownership of research specimens collected from these areas may vary according to jurisdiction and land status.

### ***Energy requirements and conservation potential***

No alternative in this document will affect or propose a change in energy use in NPS areas. Therefore, this topic was dismissed from further consideration.

### ***Natural or depletable resource requirements and conservation potential***

The range of alternatives, and the purpose and need in this document, are fully within the scope of NPS mandates and policies concerning these topics. Bioharvesting (the extraction of natural resources for commercial use) would continue to be prohibited.<sup>70</sup> Specimen collection would continue to be limited and managed through existing regulation and policy (*see* this chapter, Section 1.2.3), with the exception that Alternative C would provide an additional restriction prohibiting the collection of research specimens for research that was identified or acknowledged by the researcher as being associated with the potential for commercial development. Specimen collection is reviewed and authorized under a process separate and distinct from the benefits-sharing arrangements proposed in this document. As such, a general review of specimen collection activities is outside the scope of this document. While specimen collection is discussed under each alternative, its effects do not vary substantially by alternative, and no changes to the specimen collection regulations or policies are proposed (except in Alternative C as noted above). Therefore, this topic was dismissed from further consideration.

### ***Environmental justice***

Executive Order 12898, “General Actions to Address Environmental Justice in Minority Populations and Low Income Populations,” requires all federal agencies to incorporate environmental justice into their missions by identifying and addressing disproportionately high and adverse human health or environmental effects of their programs and policies on minorities and low-income populations and communities. No element of the alternatives would have health or environmental effects on minorities or low-income populations or communities as defined in the Environmental Protection Agency’s Environmental Justice Guidance. Therefore, environmental justice within the meaning of Executive Order 12898 was not considered as an impact topic in this document.

### ***Wetlands***

Executive Order 11990 (Protection of Wetlands) requires federal agencies such as the NPS to evaluate the impacts its actions are likely to have on wetlands. The executive order requires that short- and long-term adverse impacts associated with occupancy, modification, or destruction of wetlands be avoided whenever possible. No activities are proposed that would alter or modify wetlands. Therefore, wetlands were not considered as an impact topic in this document.

### ***Migratory birds***

Executive Order 11386 (Protection of Migratory Birds) requires federal agencies such as the NPS to ensure that environmental analyses of federal actions required by the NEPA evaluate the effects of actions and agency plans on migratory birds, with emphasis on species of concern. No activities are proposed that would involve migratory birds or alter their habitats. Therefore, migratory birds were not considered as an impact topic in this document.

### ***Floodplain management***

Executive Order 11988 and NPS policy require that impacts to floodplains be considered in NPS undertakings. No proposed activities would occur within or encroach upon floodplains. Therefore, floodplains were not considered as an impact topic in this document.

### ***Prime and unique farmlands***

In August 1980, the CEQ directed that federal agencies must assess the effect of their actions on farmland soils classified by the U.S. Department of Agriculture's Natural Resources Conservation Service as prime or unique. Prime or unique farmland is defined as soil that particularly produces general crops such as common foods, forage, fiber, and oil seed, or unique farmland that produces specialty crops such as fruits, vegetables, and nuts. No soils would be disturbed under this proposal. Therefore, the topic of prime and unique farmlands was not considered as an impact topic in this document.

### ***Threatened and endangered species***

No negative effects on threatened or endangered species have been identified in relation to the actions proposed in this document, and the NPS does not anticipate negative effects on these species. Threatened and endangered species may experience an indirect long-term benefit under some proposed actions, because increased knowledge would allow for better management of these species and their habitat. If benefits-sharing is implemented by the NPS, resulting projects would receive a separate environmental review for potential project-specific impacts to threatened and endangered species and their habitat. This is the case for any project proposed by a park, regardless of its source. Consultation with the U.S. Fish and Wildlife Service (USFWS) concerning threatened and endangered species under 50 CFR part 402, which implements the Endangered Species Act of 1973, was completed. The Benefits-Sharing Draft Environmental Impact Statement was submitted to the U.S. Fish and Wildlife Service in May 2007 for their review as part of the consultation process. Their response can be found in Chapter 5, "Comments from Public Agencies and Tribes."

### ***Archeological and cultural resources, including historic properties listed or eligible for the National Register of Historic Places***

For the most part, cultural, architectural, and historic resources are considered to be outside the scope of analysis, because the alternatives discuss benefits-sharing arrangements in relation to biotic or natural resources. If benefits-sharing is implemented by the NPS, resultant projects would receive a separate environmental review for potential project-specific impacts. No effects on listed eligible National Register properties or other cultural resources have been identified in relation to the actions proposed in this document, and the NPS does not anticipate effects on these resources. Compliance with the National Historic Preservation Act, as amended, occurred through consultation with National Conference of State Historic Preservation Officers (NCSHPO) and the Advisory Council on Historic Preservation (ACHP). Specifically, NPS staff, American Indian tribes, the NCSHPO and the ACHP were consulted concerning identification and evaluation of potential effects on cultural resources. The Benefits-Sharing Draft Environmental Impact Statement was submitted to both the NCSHPO and the ACHP in March 2007 for their review as part of the consultation process. Their responses can be found in Chapter 5, "Comments from Public Agencies and Tribes."

### ***Ecologically critical areas, wild and scenic rivers, or other unique natural resources***

The range of alternatives, and the purpose and need expressed in this document, are fully within the scope of NPS mandates and policies concerning these topics. No action proposed in the alternatives would affect the eligibility or designation of a wild and scenic river or wilderness area. If benefits-sharing is implemented by the NPS, resultant projects would receive a separate environmental review for potential project-specific impacts to wilderness, wild and scenic rivers, or other ecologically critical or unique natural resources. This is the case for any project proposed by a park, regardless of the source of the project.

### ***Public health and safety***

Public health and safety would not be impacted directly by any of the alternatives. There could be indirect beneficial effects on public health, for example, resulting from increased collaboration between park staff and researchers leading to the development of new pharmaceuticals (*see* this chapter, Section 1.2.4). However, because of the uncertainties that characterize the scientific research and development process that are described throughout this FEIS, it would be speculative to attempt to describe any specific impact on public health that could result.

### ***Sacred sites and Indian Trust resources***

Consultation was completed with all Federally recognized Native American tribes including those who may be affected by the alternatives. Responses from tribal groups can be found in Chapter 5, “Comments from Public Agencies and Tribes.” No substantive comments voicing an adverse impact were received. No effects on sacred sites or Indian Trust resources have been identified in relation to actions proposed in this document, and the NPS does not anticipate effects on these resources. Should benefits-sharing agreements be employed by the NPS, resultant projects would receive a separate environmental review for potential project-specific impacts. Potential unforeseen, park-specific issues that may arise in the future would be resolved on a case-by-case basis.

### ***Urban quality and design of the built environment***

No alternative in this document will affect or propose a change to urban quality or the built environments in NPS areas. Therefore, this topic is dismissed from further consideration.

## **Notes**

### **Section 1.1 Introduction**

<sup>1</sup> This FEIS uses the term “national parks” to include any unit of the National Park System.

<sup>2</sup> 36 CFR 2.1.

### **Section 1.2 Background**

<sup>3</sup> *See* 48 Fed. Reg. 30252, 30274 (June 30, 1983).

<sup>4</sup> As part of the research permit terms, scientists are required to submit a yearly summary of their park research activities, known as an Investigator’s Annual Report. In addition, copies of field notes and scientific publications may be required by the park.

<sup>5</sup> *See, e.g.,* B. Marrs and M. Madigan, “Extremophiles,” *Scientific American* (April 1997): 82–87.

<sup>6</sup> *Diversa* remained subject to all of the restrictions designed to protect NPS resources contained in its pre-existing Scientific Research and Collecting Permits and other underlying NPS regulations. *See also*

*Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, at 65–66 (DDC 2000) (“Prior to the CRADA, Diversa or other researchers were free to remove any specimen within the purview of their permit and develop it as they wished. If such development led to commercial uses, the Park Service never saw any proceeds from the derivative products. Thus, recognizing that resources yielding potentially valuable properties were being removed from Yellowstone with no remuneration to Yellowstone or the American people, officials at Interior began to consider a resource management scheme, patterned on the successes of Costa Rica and other nations, which would use bioprospecting to provide funds and incentives for the conservation of biological diversity.”). In June 2007, Diversa and another company merged to form Verenum Corporation. The Yellowstone-Diversa CRADA explicitly provided that successors would be obligated to benefits-share (Article 15.1), even if the CRADA is terminated (Article 12.4). To reduce confusion, the EIS will continue to refer to the company as Diversa.

- <sup>7</sup> These units are variously designated as national parks, monuments, preserves, lakeshores, seashores, wild and scenic rivers, trails, historic sites, military parks, battlefields, historical parks, recreation areas, memorials, and parkways (National Park Service, “Statistical Abstract,” (2001), available online at <[www2.nature.nps.gov/stats/abst2001.pdf](http://www2.nature.nps.gov/stats/abst2001.pdf)>, last accessed February 1, 2006).
- <sup>8</sup> National Park Service, *NPS Management Policies 2006*, 1.4.3. (Washington, D.C.: U.S. Department of the Interior, 2006), hereafter *NPS Management Policies 2006*.
- <sup>9</sup> More detailed descriptions of NPS natural resources, including plants, fish, wildlife and their habitats, have been developed by individual park units (see <[www.nature.nps.gov](http://www.nature.nps.gov)>, last accessed February 1, 2006).
- <sup>10</sup> R. G. Bailey, *Descriptions of the Ecoregions of the United States*, 2d ed. (1st ed. 1980) (Washington, D.C.: USDA Forest Service, 1995).
- <sup>11</sup> National Park Service, “Application Procedures and Requirements for Scientific Research and Collecting Permits (2002), available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008.
- <sup>12</sup> 36 CFR 1.6(e).
- <sup>13</sup> See, e.g., United States, Committee on Improving the Science and Technology Programs of the National Park Service, *Science and the National Parks* (Washington, D.C.: National Academy Press, 1992), and R. W. Sellars, *Preserving Nature in the National Parks: A History* (New Haven: Yale University Press, 1997).
- <sup>14</sup> See also National Parks Omnibus Management Act of 1998, at Section 205(a) (16 USC 5935(a)): “The Secretary may solicit, receive, and consider requests from Federal or non-Federal public or private agencies, organizations, individuals, or other entities for the use of any unit of the National Park System for purposes of scientific study.”
- <sup>15</sup> 36 CFR 2.5. See also this document, “Chapter 3, Section 3.5.3 Park units most likely to be affected by Alternative B (Implement Benefits-Sharing).”
- <sup>16</sup> National Park Service Research Permit Reporting System (RPRS) data, available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008.
- <sup>17</sup> The number of research projects ongoing throughout the NPS between 1992 and 2004 was estimated by reviewing servicewide research reports compiled in the RPRS (see <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008).
- <sup>18</sup> W. Schumacher, NPS Bibliographic Coordinator, pers. comm. to Benefits-Sharing Evaluation Team, August 16, 2005.
- <sup>19</sup> M. Milstein, “Microbes have variety of uses,” *Billings Gazette* (December 5, 1993).
- <sup>20</sup> C. Potera. “Biotech finds Yellowstone National Park a Thermophilic Microbe Hotbed,” *Genetic Engineering News* (March 15, 1994): 35.
- <sup>21</sup> R. Wolf, “Yellowstone discovery: Should U.S. get the profits?” *San Jose Mercury News* (July 25, 1994): 8F.
- <sup>22</sup> *Discover*, “Rubber Reborn” (July 1996): 88.
- <sup>23</sup> T. M. Burton, “Yellowstone’s Geysers Spout Valuable Microorganisms,” *Wall Street Journal* (August 11, 1997): B1.
- <sup>24</sup> Testimony of D. Allan Bromley, Director, Office of Science and Technology Policy, before the Committee on Science, Space, and Technology, U.S. House of Representatives, February 20, 1991. It should be noted that Dr. Brock was affiliated with Indiana University (not Wisconsin) when *T. aquaticus* was first discovered in 1966. See T. Brock, “The Value of Basic Research: Discovery of *Thermus aquaticus* and Other Extreme Thermophiles,” *Genetics* 146: 1207; see also F. Grifo and J. Rosenthal, *Biodiversity and Human Health* (Washington, D.C.: Island Press, 1997), xiii, “The contributions of biodiversity to human health have even more potential today when the sciences are able to make extraordinary contributions at the level of the molecule. . . . Probably no more dramatic example exists than the polymerase chain reaction: an extraordinary magnifying reaction that can multiply tiny amounts of genetic material a billion times over in a very short time. This Nobel Prize winning reaction depends on a heat resistant enzyme from a bacterium isolated from a Yellowstone hot spring. Valuable in a wide array of research, PCR is the fundamental underpinning of the human genome project which will characterize our entire genetic composition and render benefits for human health beyond estimation.”

### Section 1.3 Need for a proposal to implement benefits-sharing (specific problems with existing procedures)

- <sup>25</sup> General Condition 6 of the standardized NPS Scientific Research and Collecting Permit reads, in part, “Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a Cooperative Research And Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS” (National Park Service, “General Conditions for Scientific Research and Collecting Permit,” Section 6, available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008).
- <sup>26</sup> The courts also have upheld the distinction recognized by the NPS between management of “research specimens” and “research results.” See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).
- <sup>27</sup> General Condition 6 of the standardized NPS Scientific Research and Collecting Permit reads, in part, “The sale of collected research specimens or other unauthorized transfers to third parties is prohibited. Furthermore, if the permittee sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without a CRADA or other approved benefit-sharing agreement with NPS, permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled including but not limited to injunctive relief against the permittee.”
- <sup>28</sup> National Park Service, *The Natural Resource Challenge: The National Park Service’s Action Plan for Preserving Natural Resources* (Washington, D.C.: National Park Service, 1999).
- <sup>29</sup> *NPS Management Policies 2006*, Chapter 7.

### Section 1.4 Objectives of the Proposal and Its Alternatives (the Purpose of the EIS)

- <sup>30</sup> National Parks Omnibus Management Act of 1998, Section 5932.
- <sup>31</sup> See, e.g., United States, Committee on Improving the Science and Technology Programs of the National Park Service, *Science and the National Parks* (Washington, D.C.: National Academy Press, 1992), and Sellars, *Preserving Nature in the National Parks*.
- <sup>32</sup> *NPS Management Policies 2006*, 4.2.
- <sup>33</sup> National Park Service, “Application Procedures and Requirements for Scientific Research and Collecting Permits.”
- <sup>34</sup> The U.S. Office of Management and Budget (OMB) instructs all federal agencies regarding methods to ensure that federal programs are managed with integrity and in compliance with applicable law (see OMB Circular No. A-123.) *NPS Management Policies 2006* requires the NPS to comply with these instructions (see *NPS Management Policies 2006*, 1.9). This FEIS follows OMB direction to ensure that those who approve park research permits are not influenced by benefits-sharing considerations.

### Section 1.7 Legal framework

- <sup>35</sup> 16 USC 1.
- <sup>36</sup> *Ibid.*
- <sup>37</sup> 16 USC 1a-1.
- <sup>38</sup> 16 USC 5931.
- <sup>39</sup> 16 USC 5932.
- <sup>40</sup> 16 USC 5935(a).
- <sup>41</sup> 16 USC 5935(d).
- <sup>42</sup> *NPS Management Policies 2006*, Section 1.4.3.1.
- <sup>43</sup> 42 USC 4331–4332.
- <sup>44</sup> 15 USC 3701(1), (3).
- <sup>45</sup> 15 USC 3710a(d)(1).
- <sup>46</sup> 15 USC 3710a(d)(2)(A).
- <sup>47</sup> 15 USC 3710a(a), (a)(1).
- <sup>48</sup> See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).
- <sup>49</sup> 52 Fed. Reg. 13414 (April 22, 1987).
- <sup>50</sup> See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).
- <sup>51</sup> *NPS Management Policies 2001*, “Chapter 4: Natural resource management, Section 4.2 Studies and collections”; “Section 4.2.2 Independent studies”; and “Section 4.2.4 Collection associated with the development of commercial products.”
- <sup>52</sup> *Ibid.*, “Chapter 4: Natural resource management, Section 4.2 Studies and collections.”

- <sup>53</sup> *Ibid.*, “Chapter 8: Use of the parks, Section 8.10 Natural and cultural studies research and collection activities.”
- <sup>54</sup> National Park Service. 2001. *Director’s Order 12: Conservation planning, environmental impact analysis, and decision-making*, Section 4.4.
- <sup>55</sup> *Ibid.*, Section 4.7.
- <sup>56</sup> See National Park Service, “General Conditions for Scientific Research and Collecting Permit,” Section 6.
- <sup>57</sup> See *ibid.*
- <sup>58</sup> NPS *Natural Resource Challenge*, “Section 1, Goals.”
- <sup>59</sup> *Ibid.*, “Introduction.”
- <sup>60</sup> *Ibid.*, “Challenges and strategies: collaboration”; and “Challenges and strategies: parks for science.”
- <sup>61</sup> GPRA refers to the Government Performance and Results Act of 1993.
- <sup>62</sup> Department of the Interior. 2007. GPRA Strategic Plan Fiscal Year 2007–2012, Department of the Interior Bureaus and their missions.
- <sup>63</sup> 93 F. Supp. 2d 63, at 67–71.
- <sup>64</sup> 93 F. Supp. 2d 63, at 70.
- <sup>65</sup> *Ibid.*
- <sup>66</sup> 93 F. Supp. 2d 63, at 71–72.
- <sup>67</sup> 42 F. Supp 2d 1, at 16–17 and 20.

### **Section 1.8 Initial scoping process and public involvement**

- <sup>68</sup> The mailing list of more than 5,000 included research scientists working in national park units servicerwide, biotechnology associations, Native American tribes, organizations with an interest in national parks, NPS personnel, and others who expressed interest.
- <sup>69</sup> The U.S. Supreme Court has ruled on the applicability of various U.S. intellectual property rights laws in connection with inventions arising from the use of biological specimens. See, e.g., *Diamond v. Chakrabarty*, 447 US 303 (1980); and *JEM Ag Supply Inc. dba Farm Advantage Inc. v. Pioneer Hi-Bred International, Inc.*, 534 US 124 (2001).
- <sup>70</sup> In some cases, natural resource extraction activities are specifically mandated by a park’s enabling legislation. Such mandated uses of park resources would not be affected by the alternatives in this FEIS.

# **Chapter 2**

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## **Alternatives**

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## 2.1 Introduction

### ***The Programmatic Proposal to Implement Benefits-Sharing, and Alternatives to the Proposal***

This chapter provides a description of the alternatives analyzed in this final environmental impact statement (FEIS), whose purpose is to “examine potential environmental impacts of various methods of implementing the provisions of law that authorize benefits-sharing agreements while ensuring the integrity of resources.”<sup>1</sup>

Chapter 2 (Section 2.2) begins by discussing National Park Service (NPS) procedures and policies identified by the public as important to be retained. These procedures and policies would remain unchanged by all of the alternatives in this FEIS. Specifically, natural products would not be sold (*see also* Chapter 1, Section 1.7.3); all research permit applications would continue to be evaluated under the National Environmental Policy Act of 1969 (NEPA) and other NPS regulations (*see also* Chapter 1, Section 1.7.2); and researchers’ discoveries would continue to be eligible for protection under all applicable U.S. intellectual property rights laws.

The elements of each Alternative are presented in Sections 2.3, 2.4, and 2.5. The alternatives analyzed are:

**Alternative A:** No Benefits-Sharing/No Action (*see* Section 2.2);

**Alternative B:** Implement Benefits-Sharing (*Environmentally Preferred Alternative*) with the following variations (*see* Section 2.3):

- **Alternative B1:** Always disclose royalty rate and related information;
- **Alternative B2:** Comply with confidentiality laws regarding disclosure of royalty rate or related information (*Preferred Alternative*); and
- **Alternative B3:** Never disclose royalty rate or related information; and

**Alternative C:** Prohibit Research Specimen Collection for Any Commercially Related Research Purposes (*see* Section 2.4).

#### **FEIS objectives**

The FEIS objectives shown below (*see* Chapter 1, Section 1.4) help to guide the selection of the preferred alternative. Accordingly, the FEIS alternatives need to meet the FEIS objectives.

**Objective 1:** Identify the role, if any, of the National Park Service in the event a researcher wishes to commercialize his/her research results involving study of NPS research specimens.

**Objective 2:** Strengthen conservation and protection of resources managed by the NPS by deepening understanding of biodiversity and ecological processes.

**Objective 3:** Ensure that the NPS research permitting process is independent, objective, and unaffected by the benefits-sharing considerations proposed in this FEIS, and that research continues to be permitted in accordance with all laws.

These alternatives were developed based on information provided in comments received from the public and the FEIS's Interdisciplinary Team, as well as from the internal scoping process conducted by the NPS for this FEIS (*see* Chapter 1, Section 1.9 and Appendix D).

Mitigation measures would be applied to Alternative B (Implement Benefits-Sharing) to prevent the research permitting process from being influenced by benefits-sharing considerations. These are described in Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5.

Section 2.7 discusses the selection of Alternative B as the environmentally preferred alternative based on Chapter 4's impact analysis (*see also* Chapter 4, Section 4.4).

## **2.2 NPS Policies and Procedures That Would Remain Unchanged Under Every Alternative**

### **2.2.1 Prohibition of Commercial Use of Natural Products**

The sale or commercial use of natural products obtained from units of the National Park System would continue to be prohibited pursuant to 36 CFR 2.1. No element of any alternative would authorize any consumptive use of any park resources, or otherwise change the existing general prohibition against consumptive harvesting of park resources for any reason.

The NPS recognizes a distinction between the commercial use of research specimens, which is prohibited by regulation, and the commercial use of research results derived from study of those specimens, which is not prohibited by NPS regulations or federal law and has been upheld on judicial review (*see* Chapter 1, Section 1.3.1). The commercial use or sale of research specimens themselves is prohibited by regulation. However, the commercial use of knowledge derived from the specimens via research is not prohibited.

Some scoping respondents also requested that the NPS consider regarding the commercial use of research results as "commercialization," and disallow it. Alternative C does so (*see this* chapter, Section 2.4).

#### **What is the NPS benefits-sharing proposal?**

The management practices proposed in Alternative B (Implement Benefits-Sharing) would apply to research projects involving research specimens collected from units of the National Park System that subsequently resulted in useful discoveries or inventions with some valuable commercial application. A benefits-sharing agreement would provide the terms and conditions for the further development and use of such valuable discoveries, inventions, or other research results. All such researchers would be required to enter into a benefits-sharing agreement with the NPS before using their research results for any commercial purpose. *See* Chapter 4, Section 4.4.1 for a description of the "benefits" that could be generated by benefits-sharing agreements. Under the proposal (Alternative B), a benefits-sharing agreement would not regulate or authorize any researcher's access to NPS resources.

## 2.2.2 NPS Research Permit Procedures

Under all alternatives, all decisions regarding NPS Scientific Research and Collecting Permits (hereafter “research permits”) would continue to be reviewed in accordance with NEPA requirements. Every NPS research permit application would continue to be evaluated on a case-by-case basis in compliance with established NPS regulations, and would be issued based on a finding by the park superintendent that public health and safety, environmental or scenic values, natural or cultural resources, scientific research, implementation of management responsibilities, proper allocation and use of facilities, or the avoidance of conflict among visitor use activities would not be adversely impacted, as required by 36 CFR 1.6(a) (*see* Chapter 1, Sections 1.2.3 and 1.7.3). All qualified researchers would continue to be required to satisfy all permit application terms and conditions in order to receive a research permit. All researchers in units of the National Park System would continue to be required to follow all terms of the application and permit, the permit’s General Conditions, and any park-specific or permit-specific conditions contained in their permits. Third-party transfer of research specimens and material originating as an NPS research specimen, including those intended to be consumed in analysis, would continue to require written authorization from the NPS as specified by the General Conditions. Transfer of permanently retained specimens would continue to be managed by NPS museum specimen loan procedures.

All permitted researchers would also continue to be required to submit “Investigator’s Annual Reports” (IARs), copies of publications, and other materials as agreed, including copies of field notes, databases, maps, photos, and/or other materials (*see* Chapter 1, Section 1.2.3). IARs, in which researchers explain their objectives and findings, would continue to be available over the Internet for access by the public as well as by NPS personnel.<sup>2</sup>

## 2.2.3 Intellectual Property Unaffected

Any discoveries and inventions resulting from research activities involving use of research specimens lawfully collected from national parks would continue to be eligible for protection under all applicable U.S. intellectual property rights laws.

## 2.3 Alternative A: No Benefits-Sharing/ No Action

For analytical purposes, Alternative A is the “No Action” alternative because it would leave unchanged the NPS policies and practices regarding commercial use of research results that existed prior to negotiation of the Yellowstone–Diversa Cooperative Research and Development Agreement (CRADA) in 1997–1998.

Currently, the NPS does not negotiate benefits-sharing agreements. This would continue under Alternative A. Accordingly, the NPS director would issue an order clarifying the provisions of Section 4.2.4 (“Collection Associated with the Development of Commercial Products”) of *NPS Management Policies 2006* to provide that there is no requirement for negotiation of benefits-sharing agreements.

Under Alternative A, the NPS would continue not to implement the “benefits-sharing” term contained in the NPS Scientific Research and Collecting Permit General Conditions. Implementation of Alternative A would require the NPS director to issue an order clarifying the *NPS Management Policies* to provide that there is no requirement for negotiation of benefits-sharing agreements. Researchers could continue to develop any valuable discoveries, inventions, or other results derived from research activities involving NPS research material (their research results) for any lawful purpose without further obligation or responsibility to the NPS.

Research specimens and material originating as an NPS research specimen would continue to be usable for approved research purposes (including research activities that might lead to discoveries that could be commercialized because they were useful in terms of health care, nutrition, agriculture, environmental management, industrial, or other processes with potential commercial or other economic value), whether collected directly by a permitted researcher or obtained from an authorized third-party source such as a culture collection.

Under Alternative A, the NPS would continue to issue research permits for the performance of research, including the collection of research specimens, in units of the National Park System to qualified researchers pursuant to 36 CFR 1.6 and 2.5, as well as in compliance with NEPA (*see also* this chapter, Section 2.2.2 and Chapter 1, Section 1.2.3).<sup>3</sup>

### **2.3.1 Alternative A and the Yellowstone–Diversa CRADA**

Implementation of Alternative A would reflect NPS practice and policy in effect prior to the draft benefits-sharing agreement negotiated between Yellowstone National Park and the Diversa Corporation in August 1997. Implementation of Alternative A would require Yellowstone and Diversa to nullify the CRADA that was finalized in May 1998, including the return of all monetary benefits provided to Yellowstone by Diversa pursuant to the CRADA prior to suspension of the agreement.

## **2.4 Alternative B: Implement Benefits-Sharing**

General management procedures under the proposal to implement benefits-sharing are described in this section.<sup>4</sup> Alternative B is the environmentally preferred alternative.

If Alternative B is selected, one of the following three approaches to the disclosure of agreement royalty rates and related information will also be selected. Alternative B2 is the preferred alternative.

**Alternative B. Implement Benefits-Sharing (*Environmentally Preferred Alternative*) with:**

- Alternative B1.** Always disclose royalty rate and related information
- Alternative B2.** Comply with confidentiality laws regarding disclosure of royalty rate or related information (*Preferred Alternative*)
- Alternative B3.** Never disclose royalty rate or related information

Under Alternative B, all researchers who study material originating as an NPS research specimen would be subject to the management practices proposed in this alternative. Researchers who have not collected park specimens themselves but who have obtained park specimens or their derivatives from permitted researchers or third-party entities such as culture collections are termed “third-party researchers.” Under Alternative B, third-party researchers would have the same rights and responsibilities as the NPS permittee who conducted the original research and collected the original research specimen.

Under Alternative B, parks would use a standardized Material Transfer Agreement (MTA) (see example in Appendix B) to facilitate compliance with the research permit General Condition that third-party transfer of research specimens and material originating as an NPS research specimen requires written authorization from the NPS.<sup>5</sup> The standardized MTA (also referred to as the example MTA in this document) could undergo minor customizations or modifications if necessary once actual use occurs. By agreeing to the terms of the MTA, third-party recipient researchers would specifically acknowledge and agree to the same terms and conditions for use of research material that apply to all permitted researchers who collect research specimens directly from units of the National Park System. This would subject all researchers to the same terms and conditions for use of research material originally acquired from a U.S. national park.

### 2.4.1 Necessity for a Benefits-Sharing Agreement

Under Alternative B, if research activities involving research specimens collected from units of the National Park System resulted in useful discoveries, inventions, or other commercially valuable applications, a benefits-sharing agreement would be required to provide the terms and conditions for sharing with the NPS benefits resulting from their further development and use.<sup>6</sup> Negotiation of such an agreement would implement the requirements of the General Conditions that apply to research permits as well as Section 4.2.4 (“Collection Associated with the Development of Commercial Products”) of *NPS Management Policies 2006*.

**Application**—the act of putting something to a special use or purpose; a specific use to which something is put; the capacity of being usable; relevance (*The American Heritage Dictionary*, 2d College Edition).

Issuance of a research permit would not necessarily entail supplemental negotiation of a benefits-sharing agreement, because many research projects do not result in, or have the potential to result in, commercially valuable discoveries. Research permit issuance would precede and remain separate from negotiation of any benefits-sharing agreement.

Researchers would be required to negotiate a benefits-sharing agreement with the NPS unit that issued their research permit (or MTA) before undertaking commercial development of any research results involving study of NPS research specimens. This requirement would apply regardless of whether a researcher collected the specimen directly from a national park unit or obtained it from a third-party source such as another researcher or a culture collection. Researchers would be responsible for initiating benefits-sharing negotiations with the NPS under the provisions of the research permit or MTA to which the researcher had agreed when accepting the permit or MTA.

Variations in the timing and negotiation of benefits-sharing agreements could occur. In some cases, a benefits-sharing agreement could be negotiated following a commercial discovery. A benefits-sharing agreement could also be established earlier in the process, before or during the discovery stage of research and development when the researcher began collecting material, screening for potentially useful properties, or isolating and purifying new and active biochemicals and compounds. This would allow both parties to clarify their rights and obligations. Negotiations of specific monetary benefits could also be deferred until and if the researcher subsequently decided to pursue commercial development of research results, for example, product development.

#### **2.4.1.1 Parties to an agreement**

Under Alternative B, individual parks would negotiate, implement, and monitor benefits-sharing agreements in much the same way that they currently manage a variety of agreements with other institutional entities. Expertise in park-specific concerns, priorities, resource conservation needs, and research-related available park expertise would be provided by the individual park involved in negotiating a benefits-sharing agreement.<sup>7</sup> Mitigation measures would protect parks from excessive workloads associated with benefits-sharing or associated with a park's unfamiliarity with executing a benefits-sharing agreement, and are described in Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5.

Under Alternative B, NPS units that are federal laboratories within the meaning of the Federal Technology Transfer Act of 1986 (FTTA) could implement benefits-sharing through negotiation of CRADAs (see Section 2.4.2).<sup>8</sup>

In the event that research activities involved the use of traditional knowledge or other valuable proprietary input from a Native American community or other source, it would be the responsibility of the park and the researcher to include such individuals or groups in any benefits-sharing arrangement as appropriate.

### **2.4.2 Procedure**

#### **2.4.2.1 Type of agreement**

Of the various methods of implementing benefits-sharing agreements (such as CRADAs, cooperative agreements, and other contractual arrangements described in the *NPS Agreements Handbook*), the NPS has identified CRADAs, as authorized under the FTTA, as the appropriate agreement type for implementing benefits-sharing under Alternative B. While NPS believes that CRADAs are best suited for benefits-sharing, this does not preclude the potential use of other agreement types that the NPS has the authority to use.<sup>9</sup>

The proposed standardized agreement (example provided in Appendix A), which would be implemented as a CRADA, is consistent with the general terms and conditions used in CRADAs by many other agencies throughout the federal government as well as the general terms and conditions contained in the CRADA initially negotiated by Yellowstone National Park and the Diversa Corporation.<sup>10</sup> The proposed standardized CRADA is also designed to further the fundamental mission of the National Park Service: conservation of park resources. The standardized CRADA (also referred to as the example CRADA in this document) could undergo minor customizations or modifications if necessary once actual use occurs.

### **2.4.2.2 Standardized General Provisions**

The proposed standardized CRADA (*see* Appendix A) provides general terms and conditions (the “General Provisions”) that would specify the rights and responsibilities of researchers and the NPS in connection with any subsequent development of commercially valuable discoveries, inventions, or other results of research activities involving research specimens lawfully collected from units of the National Park System (referred to in this FEIS as “parks”). The General Provisions include but are not limited to standardized terms and conditions relating to record-keeping and reporting, verification, intellectual property rights, successors, and assignment.<sup>11</sup>

No CRADA (or any other type of benefits-sharing agreement) would authorize any research activities in parks that otherwise require a permit. The General Provisions would apply only to development of discoveries, inventions, and other valuable research findings resulting from use of research specimens lawfully collected pursuant to an NPS research permit. In this way, the proposed standardized CRADA would reinforce existing NPS policy against consumptive use of park resources (*see* Section 2.2.1) while also clarifying the rights and responsibilities of researchers and the NPS in connection with any subsequent development of commercially valuable discoveries or inventions resulting from research activities involving NPS research specimens.

The General Provisions provide an approved framework to allow sharing of scientific and monetary benefits resulting from improved cooperation between national parks and the research community. They reinforce protection of park resources included in the underlying research permit, while also optimizing opportunities for improved cooperation between national parks and the research community. CRADAs have been used to strengthen cooperative research activities between federal agencies and private sector researchers since enactment of the FTTA.

### **2.4.2.3 Negotiation of benefits**

Specific terms and conditions describing the various non-monetary and monetary benefits that would be obligated by a benefits-sharing agreement would be negotiated individually for each agreement (*see* Chapter 4, Section 4.4).

Non-monetary benefits, up-front payments, or immediately available performance-based payments could be negotiated immediately upon entering into an agreement. Many potential non-monetary benefits relating to scientific information, technology transfers and training, and institutional capacity-building could be developed at any time during a research project. Non-monetary benefits are described in general below at Section 2.4.2 and more specifically in Chapter 4.

Some monetary benefits, such as royalties, are contingent on actual development of a valuable discovery or invention that may or may not result from a research project. Negotiation of any contingent monetary terms of a benefits-sharing agreement would occur during a second step of the negotiation process subsequent to a researcher’s decision to pursue commercial development of research results. Researchers, including those who had not previously entered into a benefits-sharing agreement, would be required to enter into a benefits-sharing agreement and negotiate—with the park—royalty or other monetary terms that are contingent on actual commercial development of a discovery or invention before using any such discovery or invention for any commercial purpose. In this way, the eventual specific commercial use

of research results could be more clearly anticipated, more information would be available regarding the “fair value” of such research results, and the resulting agreement terms would be more equitable.

#### **2.4.2.4 Managing and reporting on benefits-sharing agreements**

Under Alternative B, individual parks would take the lead to negotiate, implement, and monitor benefits-sharing agreements in much the same way that they currently manage a variety of agreements with other entities. Parks would have the assistance of personnel experienced and knowledgeable in the specialized field of authorizing and controlling the commercial use of research results. Benefits-sharing negotiations would be a team effort including an appropriate mix of NPS staff (*see* the description of technical assistance that would be available to parks in Section 2.4.6.1). By entering into a benefits-sharing agreement, researchers would undertake expanded obligations, including the possible sharing of scientific or monetary benefits resulting from research. The scope of such expanded obligations would be negotiable, but would be required to be “equitable” and “efficient” as stipulated in Section 205(d) of the National Parks Omnibus Management Act of 1998 (NPOMA).<sup>12</sup>

All agreements would be circulated for review and clearance along with a copy of the associated research permit and any supporting documentation (study proposal, environmental review forms, etc.). Agreements would be recommended by the regional director, and reviewed by the Department of Interior Solicitor’s Office and the NPS director before an agreement could be signed by the park superintendent and the researcher. The standardized terms of the General Provisions could not be changed in a specific benefits-sharing agreement without the approval of the Department of the Interior’s Office of the Solicitor.

The NPS would devise and implement an appropriate accounting procedure to ensure that any monetary benefits resulting from implementation of any benefits-sharing agreements would be monitored and accounted for to the high standard called for in existing law, regulation, and policy.<sup>13</sup>

The NPS would submit annual reports to Congress summarizing the amount of royalties or other income received from CRADAs, as provided by the FTTA.<sup>14</sup> In addition, the NPS would report non-monetary benefits generated by CRADAs each year.

### **2.4.3 Disposition of Benefits**

All benefits received by the NPS under any type of benefits-sharing agreement would be dedicated to the conservation of resources protected and managed by the NPS.

Individual park units that are identified as federal laboratories would receive and use the benefits resulting from a benefits-sharing agreement. Any funds received by the NPS from CRADA-related activities would be managed in compliance with the provisions of the FTTA.<sup>15</sup> CRADA benefits must be used for scientific purposes. Therefore, this FEIS focuses on the scientific aspect of resource conservation and management.

### **2.4.4 Variations in Confidentiality: Alternatives B1, B2 and B3**

There are three different ways that the NPS could treat financial information such as royalty rates in benefits-sharing agreements. Under each of these three variations, the NPS would

provide Congress and the public with an annual report summarizing the non-monetary and monetary benefits the NPS received under benefits-sharing agreements. However, the three variations described below (Alternatives B1, B2, and B3) differ in the way additional financial details would be disclosed to the public.

If Alternative B is selected, one of these different approaches to the disclosure of agreement royalty rates and related information will also be selected.

#### ***2.4.4.1 Alternative B1: Implement benefits-sharing agreements and always disclose royalty rate and related information***

During scoping, some members of the public urged the NPS to design a benefits-sharing program that includes full disclosure of all terms and conditions of benefits-sharing agreements, including all financial details. Alternative B1 is responsive to that request.

Under Alternative B1, the full terms and conditions in all benefits-sharing agreements, including royalty rates and other financial information, would be released to the public upon request. Potential parties to benefits-sharing agreements would be so advised.

#### ***2.4.4.2 Alternative B2: Implement benefits-sharing agreements and comply with confidentiality laws regarding disclosure of royalty rate or related information (Preferred Alternative)***

Under Alternative B2, the NPS would honor confidentiality and unfair business practice laws which protect certain business or commercial information potentially received from benefits-sharing partners. All benefits-sharing agreements would be made available to the public in their entirety upon request unless one or more parties to an agreement objected to the release of any specific information for reasons satisfying one or more of the statutory disclosure exemptions provided under the federal Freedom of Information Act (FOIA) or other laws protecting confidential business information. An objecting party would be required to demonstrate that the information was proprietary or that disclosure would harm an interest protected by FOIA.<sup>16</sup> In such cases, a summary of such information, including the total monetary benefits and a description of non-monetary benefits generated by the agreement, would be prepared and released to the public upon request.

#### ***2.4.4.3 Alternative B3: Implement benefits-sharing agreements and never disclose royalty rate or related information***

Under Alternative B3, all benefits-sharing agreements would be made available to the public in their entirety upon request, but no royalty rate or related financial information would be released under any circumstances. However, a summary of such royalty or financial information, including the total monetary benefits generated by the benefits-sharing agreement, would be prepared and included in the agreement for release to the public upon request.

#### **Variations in confidentiality: Alternatives B1, B2 and B3**

**Alternative B1.** Implement benefits-sharing agreements and always disclose royalty rate and related information

**Alternative B2.** Implement benefits-sharing agreements and comply with confidentiality laws regarding disclosure of royalty rate or related information (Preferred Alternative)

**Alternative B3.** Implement benefits-sharing agreements and never disclose royalty rate or related information

## 2.4.5 Assurances

### 2.4.5.1 Resource protection

Agreements would be reviewed for compliance with NEPA on a case-by-case basis consistent with NPS policy.

Implementation of benefits-sharing agreements under Alternative B would not circumvent or supersede any NPS planning process, permitting authority, or other regulatory procedure or policy. For example, benefits-sharing agreements would not authorize any research activities in parks that otherwise require a permit.

Projects, activities, or programs proposed to be conducted in a park as a secondary result of implementation of benefits-sharing would receive separate, site-specific environmental review as appropriate in compliance with NEPA.

Alternative B retains the current regulatory prohibition against the sale or commercial use of natural products, including research specimens.<sup>17</sup> The NPS recognizes a distinction between the commercial use of research specimens, which is prohibited by regulation, and the use of research results derived from those specimens for commercial purposes. The commercial use or sale of research specimens themselves is prohibited by regulation. However, the commercial use of knowledge derived from the specimens via research is not prohibited (*see* Chapter 1, Section 1.1 and 1.2.4).

No action of Alternative B would authorize any consumptive use of any park resources, or otherwise change the existing general prohibition against consumptive harvesting of park resources for any reason. Under Alternative B, the sale or commercial use of natural products obtained from units of the National Park System would continue to be prohibited pursuant to 36 CFR 2.1.

While the term “natural product” appears in the NPS regulations, it is not defined.<sup>18</sup> However, it is clear from the context of regulations that specifically authorize limited personal consumptive use of certain natural products, such as nuts and berries, that the term refers to naturally occurring material found in national parks. The term also embraces naturally occurring research specimens located in or taken from an NPS unit.

For purposes of the NPS benefits-sharing proposal, the term “natural product” means any naturally occurring research specimen located in or taken from a unit of the National Park System pursuant to a permit issued under 36 CFR 1.6 and 2.5. This definition prevents the “sale or commercial use” of research specimens consistent with existing NPS regulations and policy. It also implements the distinction recognized by the NPS, and upheld by the federal judiciary, between “sale or commercial use” of natural products (which remains prohibited), and commercial development of valuable discoveries, inventions, or other research results from research activities involving research specimens lawfully collected from NPS units. Commercial development of research results involving study of NPS specimens is currently not prohibited, but under Alternative B would be subject to the terms of a CRADA.

The important distinction between research specimens (“natural products”) and research results, which are derived from study of those specimens, is intended to prevent the

marketing or other commoditization of NPS resources, while not interfering with the legitimate development of useful and therefore valuable discoveries from the findings of research involving NPS research specimens. For example, NPS regulations and policy provide that specimens collected from a national park area under a research permit cannot be used as raw material in the manufacture of commercial products.<sup>19</sup>

#### **2.4.5.2 Penalties for non-compliance**

As provided in the standardized General Conditions for all research permits and the proposed Material Transfer Agreements, failure to negotiate a benefits-sharing agreement with the NPS before commercial development of any research results involving any components of any collected specimens (including but not limited to natural organisms, enzymes, or other bioactive molecules, genetic materials, or seeds), could subject the researcher to substantial economic and other legal penalties.<sup>20</sup>

### **2.4.6 Mitigation**

To ensure that implementation of Alternative B mitigates against potential adverse impacts to park natural resources, visitor experience and enjoyment, and affected social resources, a consistent set of mitigation measures would be applied to any actions that could result from the implementation of benefits-sharing. These mitigation measures also would be applied to any future actions taken under the oversight of this FEIS. The NPS would comply with appropriate environmental review requirements under NEPA and any other relevant legislation for any future actions. As part of any such review, the NPS would avoid, minimize, and mitigate adverse impacts or would not take the action.

#### **2.4.6.1 Mitigation: Technical assistance to parks**

Mitigation measures would protect parks from excessive workloads associated with benefits-sharing or pitfalls associated with a park's unfamiliarity with executing a benefits-sharing agreement. Parks would have the assistance of personnel experienced and knowledgeable in the specialized field of authorizing and controlling the commercial use of research results. Personnel with benefits-sharing expertise would be available to provide technical assistance to parks with negotiation of benefits-sharing agreements and related issues, consistent with the CRADA guidelines first published by the Department of the Interior in May 1996. The NPS would consider the best way to acquire the services of a strong negotiator experienced with agreements similar to benefits-sharing agreements to assist parks and ensure the NPS secures a fair deal. Technical assistance would be centrally coordinated and include:

- Providing training and assistance for parks regarding interpretation of law, regulation, and policy relating to implementation of benefits-sharing;
- Developing methods and procedures for efficiently implementing benefits-sharing agreements at the park level;
- Coordinating CRADA functions among parks;
- Developing a servicewide institutional record of benefits-sharing agreements to enhance institutional expertise and efficiency;
- Assisting parks in CRADA negotiations and associated record-keeping, including benefits due and received, and improved tracking of all material originating as a park research specimen; and

- Facilitating, and where appropriate, overseeing work performed by universities, non-governmental organizations, or other private sector entities that might be associated with the management of benefits-sharing, including operational functions such as monitoring and evaluating, accounting, auditing, licensing, or negotiating benefits-sharing agreements.

#### **2.4.6.2 Mitigation: Financial support for administration**

A portion of monetary benefits could be used to offset administrative costs of a benefits-sharing agreement in accordance with the FTTA.

#### **2.4.6.3 Mitigation: Benefits-sharing would not change NPS research permitting procedures or policies**

Under Alternative B, the NPS would continue to issue research permits for the collection of research specimens from units of the National Park System to all qualified researchers in compliance with NEPA and pursuant to 36 CFR 1.6 and 2.5.<sup>21</sup> No CRADA would authorize any research activities in parks that otherwise require a permit. The CRADA would apply only to development of discoveries, inventions, and other valuable research findings resulting from use of research specimens lawfully collected pursuant to an NPS research permit.

Research specimens and material originating as an NPS research specimen would continue to be usable for approved research purposes (including research activities that might lead to discoveries that could be commercialized because they were useful in terms of health care, nutrition, agriculture, environmental management, industrial, or other processes with potential commercial or other economic value), whether studied directly by the permitted researcher or studied subsequently by a researcher who obtained them from an authorized third-party source such as a culture collection.

The prohibition by NPS research permits of the sale or other unauthorized transfer of research specimens or material originating as an NPS research specimen to any third party (thereby reinforcing the prohibition against “sale or commercial use” of natural products collected from NPS units) would not be waived in any benefits-sharing agreement.

Research permits would be issued or permit applications denied without regard to whether the permit applicant was or might become a party to a benefits-sharing agreement. Negotiation and establishment of a benefits-sharing agreement would not change or affect the existing procedures relating to the issuance of permits for research activities.

Issuance of a research permit would not be conditioned on negotiation of a benefits-sharing agreement. Under Alternative B, the NPS director would issue an order clarifying the provisions of Section 4.2.4 of *NPS Management Policies 2006* to provide that there is no requirement for negotiation of a benefits-sharing agreement prior to issuance of any permit.

#### **2.4.6.4 Mitigation: Management controls**

Management controls would minimize the risk that benefits-sharing might inappropriately influence research permitting decisions.<sup>22</sup> These controls would include the following:

##### ***Compliance with law***

Continued implementation and enforcement of the NPS’s research permit regulations and

policy directives protect NPS natural resources against impairment or other adverse impacts. Under these regulations and directives, park superintendents review permit decisions in accordance with NEPA requirements and issue research permits only upon finding that issuance of a permit would not have an adverse impact on:

- Public health and safety;
- Environmental or scenic values;
- Natural or cultural resources;
- Scientific research;
- Implementation of NPS management responsibilities;
- Proper allocation and use of NPS facilities; or
- Avoidance of conflict among visitor use activities.

Permits concerning activities that could impact NPS natural resources are issued by park superintendents pursuant to well-established NPS regulations, including appropriate NEPA review.<sup>23</sup> No alternative would allow any activities currently prohibited by such regulations.

### ***Delegation of authority and organization***

To maintain an appropriate separation between the authorization of park research activities and negotiation of benefits-sharing agreements, benefits-sharing agreements would not authorize any research activities in parks or any other activities that require a permit.<sup>24</sup>

CRADAs would be negotiated only with researchers who had already been issued a research permit. Thus, issuance of a research permit would precede negotiation of a benefits-sharing agreement, thereby separating the timing of the decision about access to research specimens (the research permit) from any decision about entering into a benefits-sharing agreement (the CRADA).

Participation in an existing CRADA would not ensure approval of a researcher's application for a new or renewed research permit; all such applications would be reviewed according to the standard research permit review processes, without regard to the existing CRADA or any other possible benefits-sharing considerations.<sup>25</sup>

### ***Personnel assignments***

Although park superintendents would be the ultimate decision-makers in both cases, separate individuals would manage preparation of benefits-sharing arrangements and research permit issuance decisions.<sup>26</sup> If a park could not provide separate individuals to supervise the separate benefits-sharing and research permit reviewing processes, as may be the case in some smaller parks, the superintendent would seek assistance from another park, a regional office, or national headquarters.

After a CRADA was prepared, it would be recommended by the regional director and reviewed by the Department of Interior Solicitor's Office and the NPS director before it was signed by the park superintendent and the researcher.

Parks would be provided with technical assistance from personnel with specialized technical expertise related to benefits-sharing (*see* this chapter, Section 2.4.6.1). Such technical assistance

would lend a servicewide perspective in implementing benefits-sharing, thereby ensuring that benefits-sharing agreements would be consistent, equitable, and efficient throughout the National Park System. As suggested by the Office of Management and Budget, it would also function as a guard against individuals' exceeding or abusing their assigned authorities.<sup>27</sup>

### **2.4.7 Alternative B and the Yellowstone–Diversa CRADA**

The proposed standardized CRADA (*see* Appendix A) is consistent with the general terms and conditions that appeared in the CRADA initially negotiated by Yellowstone National Park with the Diversa Corporation. However, implementation of Alternative B would require Yellowstone and Diversa to negotiate a new or amended CRADA to conform with the standardized General Provisions provided in Appendix A, should Diversa wish to commercialize research results based on study of specimens collected after 1998, when their research permit conditions required negotiation of a benefits-sharing agreement prior to commercial use of research results involving study of NPS specimens.<sup>28</sup>

## **2.5 Alternative C: Prohibit Specimen Collection for Any Commercially Related Research Purposes**

Under Alternative C, the NPS would prohibit research specimen collection for research involving any potential commercial applications in all units of the National Park System. Researchers requesting research permits who were qualified in all respects pursuant to 36 CFR 1.6 and 2.5, but identified or acknowledged their proposed specimen collections as being associated with potential development of research results for commercial purposes, would be denied permits.

During scoping, the public and the NPS Interdisciplinary Team identified issues related to the proposal to implement benefits-sharing servicewide (*see* Chapter 1, Section 1.9). Alternative C is responsive to some public comments urging the NPS to prohibit commercialization of NPS-related research.

Under Alternative C, the NPS would prepare a new subsection amending the NPS's research specimen collection regulation (36 CFR 2.5) to prohibit research specimen collection for research involving any potential commercial applications.

Under Alternative C, the NPS director would issue an order clarifying the provisions of Section 4.2.4 ("Collection Associated with the Development of Commercial Products") of *NPS Management Policies 2006*. The order would provide that the collection of specimens for research that is identified or acknowledged by the researcher to have potential for commercial development is prohibited, which would make negotiation of benefits-sharing agreements moot.

The development of any inadvertent or other discoveries resulting from research involving NPS research specimens that could have some valuable commercial application would not be authorized, and would remain prohibited pursuant to standardized permit terms and

conditions applicable to research permits unless such development was determined in writing by the NPS director to be in the public interest. Accordingly, the Director's Order clarifying Section 4.2.4 of *NPS Management Policies 2006* would provide that in such cases, the director could subsequently authorize commercial development of an inadvertent or otherwise unexpected valuable discovery. Such a determination would be based on a finding by the director that refusal to authorize such development could be harmful to public health or other overriding public interest (such as discovery and development of an important new medicine).

All research permits issued since late January 2001 and signed prior to the time of Alternative C's regulatory change should have contained, as part of the General Conditions, a requirement that negotiation of a benefits-sharing agreement must occur prior to commercial use of any research results when the research involved study of specimens originating in a park. For those permittees, under Alternative C, the NPS would not prohibit the commercial development of research results and would not make such development contingent on any benefits-sharing obligations. However, all such permittees would be prohibited from acquiring any additional NPS research specimens, because their commercial purpose would be foreseeable.

Under Alternative C, the NPS would continue to issue research permits for the collection of research specimens from units of the National Park System to qualified researchers pursuant to 36 CFR 1.6 and 2.5, as well as in compliance with NPOMA and NEPA (*see also* this chapter, Section 2.2.2).<sup>29</sup>

Research specimens and material originating as an NPS research specimen collected from national parks would continue to be usable for approved research purposes. However, these would **not** include research activities that the researcher identified or acknowledged could be expected to lead to discoveries that could be commercialized because they were useful in terms of health care, nutrition, agriculture, environmental management, industrial, or other processes with potential commercial or other economic value, whether conducted directly by a permitted researcher or by a third-party researcher studying research materials obtained from sources such as another researcher or a culture collection.

Unauthorized commercial development or any other prohibited use of any such research results would be subject to the standardized permit term requiring payment to the NPS of twenty percent (20%) of gross revenue resulting from any such unauthorized commercial or other revenue-generating use. In addition to such payment, the NPS also would remain able to seek any other damages or remedies to which the NPS could be entitled, including but not limited to injunctive relief.

Under Alternative C, parks would use a standardized Material Transfer Agreement (MTA) (*see* Appendix B) to facilitate compliance with the research permit General Condition that third-party transfer of research specimens and material originating as an NPS research specimen requires written authorization from the NPS.<sup>30</sup> By agreeing to the terms of the MTA, third-party recipient researchers would specifically acknowledge and agree to the same terms and conditions for use of research material that apply to all permitted researchers who collect research specimens directly from units of the National Park System. This would subject all researchers to the same terms and conditions for use of research material originally acquired from a U.S. national park.

## 2.5.1 Alternative C and the Yellowstone–Diversa CRADA

Implementation of Alternative C would require Yellowstone and Diversa to nullify the Cooperative Research and Development Agreement (CRADA) they finalized in May 1998, including the return to Diversa of all monetary benefits provided to Yellowstone by Diversa pursuant to the CRADA prior to suspension of the agreement. In addition, Diversa would be prohibited from acquiring any additional NPS research specimens, because their commercial purpose would be foreseeable.

## 2.6 Issues Addressed in the Alternatives

During scoping, the public and the NPS Interdisciplinary Team identified and consolidated a variety of concerns about implementation of benefits-sharing. Some concerns, such as general approval or disapproval of benefits-sharing, were addressed by incorporating the concern into one or more alternatives. One alternative implements benefits-sharing, and two alternatives reject it. The alternatives are described in detail in this chapter and in brief in Table 2.9 at the end of this chapter. The alternatives are:

**Alternative A:** No Benefits-Sharing/No Action;

**Alternative B:** Implement Benefits-Sharing; and

**Alternative C:** Prohibit Research Specimen Collection for Any Commercially Related Research Purposes.

Concerns related to the issues that were expressed during public scoping and were addressed in one or more of the alternatives are shown in Table 2.6 and discussed in Sections 2.6.1 and 2.6.2 below.

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**Table 2.6. Issues addressed in the alternatives**

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Category	Issue
2.6.1 NPS Role Regarding Research Results Used for Commercial Purposes	2.6.1.1 Should benefits-sharing be implemented?
	2.6.1.2 Criteria for requiring benefits-sharing
	2.6.1.3 Content of benefits-sharing agreements
	2.6.1.4 Potential confidentiality of benefits-sharing agreements
	2.6.1.5 Sale or commercial use (“commercialization”) of NPS resources
	2.6.1.6 Impacts of benefits-sharing on potential consumptive use (“harvesting”) of NPS resources
	2.6.1.7 Benefits-sharing and Native American rights
2.6.2 Science for Park Management	2.6.2.1 Uses and distribution of potential benefits
	2.6.2.2 Potential impacts of research on natural resources

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Table 2.6. Some issues identified during scoping were included as elements of the alternatives.

## **2.6.1 NPS Role Regarding Research Results Used for Commercial Purposes**

### **2.6.1.1 *Should benefits-sharing be implemented?***

Scoping respondents expressed contradictory views concerning the appropriateness of benefits-sharing for the NPS. Some insisted that benefits-sharing would be good for the NPS, allowing more effective preservation of resources and serving as a source of pride for Americans. Others were equally adamant that benefits-sharing has no place in a national park, or that the NPS should prohibit the commercial use of any discovery related to the study of park resources and should deny “commercial bioprospectors” permission to study park resources.

The three alternatives provide a clear choice among these points of view. Under Alternative A (No Benefits-Sharing/No Action), the NPS would not implement benefits-sharing. The NPS would continue to leave the decision to use research results for commercial purposes entirely up to the researcher without involvement from the NPS. Under Alternative B, the NPS would implement benefits-sharing when research results involving study of NPS specimens were found to have some commercial application. Under Alternative C, the NPS would propose a new regulation that would prohibit research specimen collection for any commercially related research purposes.

### **2.6.1.2 *Criteria for requiring benefits-sharing***

Scoping respondents suggested a number of conflicting criteria that could be used to determine who should be subject to benefits-sharing, and when that determination should be made. For instance, some suggested that the main criterion for requiring a benefits-sharing agreement should be the affiliation (corporate versus academic) of the researcher. Others suggested that the main criterion should be whether or not the research project had a chance of ever producing a valuable application for research results. Others suggested excluding any project expected to recover only a negligible financial return.

Because many university researchers are supported or otherwise affiliated with corporate or other for-profit research institutions, Alternative B, the benefits-sharing alternative, addresses the criteria for implementation of benefits-sharing by requiring negotiation of a benefits-sharing agreement with researchers, regardless of their affiliation, who desire to undertake commercial development of their research results (*see* this chapter, Sections 2.3 and 2.7.2).

### **2.6.1.3 *Content of benefits-sharing agreements***

Terms and conditions of benefits-sharing agreements were a subject of concern for many scoping respondents. There was virtual unanimity that the NPS should receive “fair value,” but little specific guidance regarding how to achieve such a goal, or what “fair value” meant. Some respondents implied that “industry standards” exist to guide the negotiation of benefits, but did not supply any specific information about such standards.

Alternative B, the only alternative that would implement benefits-sharing, answers these concerns by deferring negotiation of any monetary benefits, such as royalties, that are contingent on actual development of a valuable discovery or invention with some potential commercial purpose until specific discoveries or inventions are made, and before they are applied for any commercial purpose. In this way, the eventual specific commercial use of

research results could be more clearly anticipated and more information would be available regarding the “fair value” of such research results.

A number of people suggested that the paperwork burden associated with a benefits-sharing requirement might discourage researchers from submitting or completing research permit applications, thus effectively reducing the quantity of research performed in the National Park System. Alternative B proposes negotiating agreements only with researchers who foresee a potential commercial application for their research results; thus, most researchers would experience no additional paperwork. Alternative B also proposes using a standardized benefits-sharing instrument for most agreements based on the established CRADAs already in use throughout the federal government, thus providing a familiar routine that would reduce the time needed for simple paperwork chores.

#### ***2.6.1.4 Potential confidentiality of benefits-sharing agreements***

Some scoping respondents opined that all terms and conditions of benefits-sharing agreements should be a matter of public record. Under Alternative B, benefits-sharing agreements would be disclosed to the public, with the possible exception of royalty rates and related financial information. A variety of approaches to disclosure or nondisclosure of royalty rates are presented as Alternatives B1, B2, and B3 (*see* this chapter, Sections 2.4.4.1, 2.4.4.2, and 2.4.4.3).

#### ***2.6.1.5 Sale or commercial use (“commercialization”) of NPS resources***

Many comments were received from people who were under the misimpression that this FEIS concerned a proposal to authorize the commercialization of NPS natural resources. They warned against such commercialization and opposed any programmatic authorization of any commercial use of NPS natural resources.

Commercialization or sale of NPS natural resources is already prohibited by law.<sup>31</sup> Every alternative in the FEIS complies with this NPS regulation that prohibits any sale or commercialization of natural products. By contrast, the commercial development of research results proposed in Alternatives A and B is not prohibited by federal law, regulation, or policy.<sup>32</sup> As defined previously in the FEIS, “research results” are the data, discoveries, inventions, or other knowledge resulting from research activities performed under the authority of an NPS Scientific Research and Collecting Permit.

Alternative C (Prohibit Specimen Collection for Any Commercially Related Research Purposes) was developed in response to comments opposing benefits-sharing and opposing commercialization of research discoveries. Alternative C would not implement benefits-sharing and would also prohibit the commercial development of any discoveries resulting from research involving NPS research specimens unless such development was determined in writing by the NPS director to be in the public interest.

#### ***2.6.1.6 Impacts of benefits-sharing on potential consumptive use (“harvesting”) of NPS resources***

A number of scoping respondents were under the misapprehension that benefits-sharing agreements would authorize inappropriate commercial harvests of NPS biological resources; there was also concern that once an NPS resource was understood to be valuable, there might be pressure to harvest or poach that resource.

Every alternative is consistent with the current regulation prohibiting sale or commercial use of natural products.<sup>33</sup> There is an important distinction between the use of research specimens for commercial purposes, which is prohibited by regulation, and the use of research results for commercial purposes, which is not prohibited by NPS regulations. This distinction has been upheld on judicial review (*Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000)).

Research involving NPS specimens could result in discoveries with commercial applications under every alternative, although Alternative C would likely reduce the number of such discoveries.<sup>34</sup> New knowledge about NPS resources will be discovered regardless of which alternative is selected.

### **2.6.1.7 Benefits-sharing and Native American rights**

During scoping, the NPS was advised not to neglect the intellectual property rights of Native American or other traditionally associated peoples. Alternative A maintains the current practice of leaving the decision to use research results for commercial purposes entirely up to the researcher without involvement from the NPS. Accordingly, respecting the rights of Native Americans would, under Alternative A, also be left entirely up to researchers. Alternative B acknowledges the rights of Native American communities who participate or otherwise provide input to a research project that leads to development of valuable research results. Under Alternative C, the commercial development of any discoveries resulting from research involving NPS research would be prohibited (unless such development was determined in writing by the NPS director to be in the public interest), and no benefits-sharing agreements would be implemented.

## **2.6.2 Science for Park Management**

### **2.6.2.1 Uses and distribution of potential benefits**

The public presented many views of how best to use both monetary and non-monetary benefits. Suggestions included support of conservation, restoration, preservation, research, and education projects. Alternative B (Implement Benefits-Sharing) would dedicate all benefits received by the NPS under any type of benefits-sharing agreement to the conservation of resources protected and managed by the NPS.

### **2.6.2.2 Potential impacts of research on natural resources**

Some scientific research activities impact natural resources. Scoping comments cautioned the NPS against proposing any benefits-sharing plan that would allow research permits to be issued or denied based upon their potential for contributing economic benefits to the parks, regardless of their potential for impacting park resources. The potential impacts of proposed research activities are evaluated and either allowed or prohibited through a separate process that would not be affected by the proposed benefits-sharing management practices.

Alternative B (Implement Benefits-Sharing) proposes mitigation measures to separate the research permitting process from benefits-sharing considerations (*see* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5).

## **2.7 Alternatives Considered But Not Analyzed Further**

The following alternatives were considered during preparation of this FEIS, but were not analyzed further for the reasons provided.

### **2.7.1 Prohibit Collection of Research Specimens from NPS Units**

This alternative would have prohibited the collection of all research specimens from all NPS units.

Because specimen collection is an important part of many research projects, its prohibition would restrict research activities in national parks at a level contrary to the objectives of both Title II of NPOMA and of NPS policy that encourages appropriate research (*see* Chapter 1, Section 1.2.3 *and* Chapter 3, Section 3.2.1). Such prohibition would be a radical reversal of long-standing NPS policy. A proposal to completely eliminate authorization of specimen collecting for research would eliminate any need to manage commercially valuable discoveries that may ensue, but would also eliminate many otherwise legitimate research activities authorized by law and policy.

For these reasons, this alternative was considered but not analyzed further.

### **2.7.2 Prohibit Collection of Research Specimens from NPS Units by Non-Academic Researchers**

This alternative would have prohibited non-academic researchers from collecting research specimens in any NPS unit.

Because specimen collection is an important part of many research projects, its prohibition would effectively eliminate the opportunity for many researchers with ties to non-academic institutions to study park resources. To prohibit the collection of research specimens by non-academic researchers would restrict research activities in national parks at a level contrary to the objectives of both Title II of NPOMA and of NPS policy that encourages appropriate research (*see* Chapter 1, Section 1.2.3 *and* Chapter 3, Section 3.2.1).

In addition, many scientific studies conducted by researchers who are affiliated with academic institutions are either sponsored by or related in some way to research conducted by government or other non-academic research firms. Therefore, it would not be feasible to distinguish between academic and non-academic researchers merely on the basis of their employer's organizational structure. This indistinguishability would cause need for increased scrutiny of researcher financial and collegial relationships without a rational basis that is consistent with NPS policy or that would meet Objective 2 for this FEIS (*see* Chapter 1, Section 1.4).<sup>35</sup>

For these reasons, this alternative was considered but not analyzed further.

### 2.7.3 Exempt Academic Researchers from Benefits-Sharing Agreements

This alternative would have exempted academic researchers from having to negotiate benefits-sharing agreements.

Because many university researchers are supported or otherwise affiliated with corporate or other for-profit research institutions, there is no rational basis for an across-the-board benefits-sharing exemption for academic researchers. In addition, many universities have successful technology transfer offices that are accustomed to sharing benefits resulting from their researchers' work through the use of licensing agreements and other compensatory arrangements.

To exempt academic researchers from benefits-sharing agreements would not implement the authorization contained in NPOMA for negotiation of benefits-sharing agreements that are "equitable."<sup>36</sup> To exempt all academic researchers from benefits-sharing agreements could also create unintended loopholes for those supported by or otherwise affiliated with corporate or other for-profit research firms.

For these reasons, this alternative was considered but not analyzed further.

### 2.7.4 Prohibit Any Commercial Use of Research Results Involving Study of Specimens Collected from NPS Units

This alternative would have created a new, absolute prohibition against the development of any commercial use of research results involving specimens collected from units of the NPS. It is important to note that this alternative is distinct from Alternative C, which concerns a possible new prohibition against the *collection* of research specimens from national parks for any research purposes that could have some commercial applications and prohibits the commercial development of any inadvertent discoveries resulting from research involving NPS research specimens unless the NPS director determines such development to be in the public interest.

Any person (including scientists whose research activities involve research specimens lawfully collected from NPS units) is free to protect the valuable results of their research through U.S. patent and other intellectual property rights laws. An absolute prohibition against the development of any commercial use of research results involving specimens collected from NPS units would be contrary to the policies of the United States as expressed through the intellectual property rights and other laws that encourage discovery and technological innovation. The important distinction recognized by the NPS between prohibiting commercial use of research specimens, while permitting development of research results derived from those specimens in ways that may have some valuable commercial application, has been upheld by the federal judiciary.<sup>37</sup>

Finally, in the absence of evidence of any unacceptable impact to NPS resources, to prohibit *any* commercial use of research results that involved specimens collected from NPS units could arbitrarily deprive society of important discoveries and also have a chilling effect on research in units of the National Park System. Such consequences would be contrary to a

wide range of NPS policies as well as NPOMA.

For these reasons, this alternative was considered but not analyzed further.

## 2.8 Determination of the Environmentally Preferred Alternative

The purpose of selecting an environmentally preferred alternative is to identify, for the public and decision-makers, the alternative that “causes the least damage to the biological and physical environment; it also means the alternative which best protects, preserves, and enhances historic, cultural, and natural resources.”<sup>38</sup> The environmentally preferred alternative is selected by applying the criteria found in Section 101 of NEPA. The characteristics that make Alternative B the environmentally preferred alternative are summarized below for each criterion of NEPA Section 101.

1) Fulfill the responsibilities of each generation as trustee of the environment for succeeding generations.

- Only Alternative B (Implement Benefits-Sharing) prepares the NPS to utilize an available legal tool, benefits-sharing, to improve resource conservation through the non-monetary and monetary benefits it could receive from research involving study of NPS resources.
- Alternative A (No Benefits-Sharing) would fail to use an available legal tool, benefits-sharing, to improve park resource conservation. In addition, under Alternative A, study of NPS specimens could lead to economic gains for non-NPS entities only, and therefore could be considered to be inadequate management of environmental assets.
- Alternative C (Prohibit Specimen Collection for Any Commercially Related Purposes) would fail to use an available legal tool, benefits-sharing, to improve park resource conservation.

2) Ensure for all Americans safe, healthful, productive, and aesthetically and culturally pleasing surroundings.

- Alternative B ensures that researchers could develop and commercialize their research results for applications that could improve health, safety, and productivity. Alternative B is also expected to result in beneficial impacts to park natural resource management and visitor experience and enjoyment, thus enhancing the NPS’s ability to meet this criterion.
- Alternative A also ensures that researchers could develop and commercialize their research results for applications that could improve health, safety, and productivity. However, Alternative A’s impact on park natural resource management and visitor experience and enjoyment would be less beneficial than Alternative B. Thus, the NPS’s ability to meet this criterion would be less under Alternative A than under Alternative B.
- Alternative C fails to meet this criterion because research that could be expected to lead to discoveries with commercial applications that could improve health,

safety, and productivity would be prohibited. Researchers would also be prohibited from developing unexpected research results for commercial applications that could improve health, safety, and productivity.

3) Attain the widest range of beneficial uses of the environment without degradation, risk of health or safety, or other undesirable and unintended consequences.

- Under Alternative B, NPS-related research results could be used to develop and commercialize a wide variety of beneficial applications in fields such as health, agriculture, nutrition, and a host of other industries. Alternative B would make no change to the strict resource protection standards in place for NPS research permitting, thus preventing degradation of the environment. No undesirable or unintended consequences of Alternative B have been identified during this NEPA analysis.
- Alternative A would also meet this criterion for the same reasons that Alternative B meets it.
- Alternative C fails to meet this criterion because research that could be expected to lead to discoveries with commercial applications in health care, nutrition, agriculture, environmental management, or industrial fields would be prohibited. Accordingly, Alternative C would not attain the widest range of beneficial uses of the environment.

4) Preserve important historic, cultural, and natural aspects of our national heritage and maintain, wherever possible, an environment that supports diversity and variety of individual choice.

- Alternative B would bolster conservation and protection of the aspects of our national heritage that are managed by the NPS by dedicating all benefits derived from benefits-sharing to National Park System resource conservation. Alternative B would supplement the resource information already received from permitted researchers. Through benefits-sharing, NPS employees could improve their abilities and their tools to perform research to inform resource management decisions. Alternative B would improve resource protection by deepening understanding of biodiversity and ecological processes under NPS management.
- Alternative A would also meet this criterion, but to a lesser degree than Alternative B. Alternative A is likely to provide fewer non-monetary benefits to parks than Alternative B, and no monetary benefits at all.
- Alternative C's prohibition of some research projects could lead to a reduction in the scientific information that would have been generated from research under Alternatives A or B. Thus, effective management and long-term preservation of the natural aspects of our national heritage contained in parks could be more difficult than under Alternatives A or B.

5) Achieve a balance between population and resource use that would permit high standards of living and a wide sharing of life's amenities.

- Achievement of this objective would be unaffected by selection of any alternative in this FEIS, because none of the alternatives propose any use of resources. (Collection and study of resources is governed by a separate research permitting process.)

6) Enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources.

- Achievement of this objective would be unaffected by selection of any alternative in this FEIS, because none of the alternatives propose any use of resources. (Collection and study of resources is governed by a separate research permitting process.)

## 2.9 Summary of Alternatives and Effects

This section presents the alternatives and their environmental impacts in a comparative format. The following two tables list the issues to provide a clear basis of choice for the decision-maker. Table 2.9-1 is a summary of the alternatives and Table 2.9-2 summarizes the effects of the alternatives.

**Table 2.9-1. Comparison of Alternatives**

	A. No Benefits-Sharing/No Action	B. Implement Benefits-Sharing			C. Prohibit Research Specimen Collection for Any Commercially Related Research Purposes
		B1. Always Disclose Royalty Rate and Related Information	B2. Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate and Related Information	B3. Never Disclose Royalty Rate or Related Information	
Would benefits-sharing be implemented?	No	Yes	Yes	Yes	No
Would research still be permitted in national parks?	Yes	Yes	Yes	Yes	Yes
Would research specimen collection still be permitted in national parks?	Yes	Yes	Yes	Yes	Yes (except for any research purposes that could have some commercial application)
Would applications for research permits be evaluated on a site-specific, case-by-case basis?	Yes	Yes	Yes	Yes	Yes
Would there be any change in the way research permit applications are evaluated?	No	No	No	No	Yes (permit applications for research specimen collection for research activities with potential commercial applications would be denied)
Would sale or commercial use of research specimens collected from national parks be authorized?	No	No	No	No	No
Would researchers who were benefits-sharing partners be granted more access to national park resources than other researchers?	n/a	No	No	No	n/a
Would researchers be required to enter into a benefits-sharing agreement before receiving an NPS research permit?	No	No	No	No	No
Would researchers have to report their results to the NPS?	Yes	Yes	Yes	Yes	Yes
Would third-party research specimen transfer require written authorization from the NPS?	Yes	Yes	Yes	Yes	Yes
Would a standardized format be provided to parks to authorize third-party transfers of research specimens that are intended to be consumed in analysis?	No	Yes	Yes	Yes	Yes
Would researchers be able to commercialize their research results?	Yes	Yes	Yes	Yes	No (unless a "public interest" exception was granted by the NPS director)
Would Yellowstone seek to implement the CRADA with Diversa?	No	Yes	Yes	Yes	No
What would "benefits" be used for?	n/a	Resource conservation	Resource conservation	Resource conservation	n/a
Would a benefits-sharing agreement authorize research specimen collection activities in national parks?	No	No	No	No	No
Would the total monetary and other benefits generated by benefits-sharing agreements be reported to the public?	n/a	Yes	Yes	Yes	n/a
Would negotiated royalty rates included in the terms of benefits-sharing agreements be reported to the public?	n/a	Yes	Yes (unless determined to be exempt from disclosure under FOIA)	No	n/a
Would a researcher whose research results could have great benefit to society (such as a cure for a serious disease) be allowed to commercialize those research results?	Yes	Yes	Yes	Yes	No (unless specifically authorized by the NPS director)

**Table 2.9-2. Summary of Effects\***

Natural Resource Management				
Alternative A No Benefits-Sharing/No Action	Alternative B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
<b>All contexts</b> <ul style="list-style-type: none"> <li>Choosing not to implement benefits-sharing would result in no change in the availability of "science for parks."</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>Increased availability of "science for parks" provided by non-monetary and monetary benefits from benefits-sharing agreements would have a beneficial impact. However, B1 could discourage researchers and benefits-sharing partners and compromise NPS's ability to negotiate.</li> </ul>		<b>All contexts</b> <ul style="list-style-type: none"> <li>Increased availability of "science for parks" provided by non-monetary and monetary benefits from benefits-sharing agreements would have a beneficial impact. Impacts in all contexts would be the same as for Alternative B2.</li> </ul>	
<b>Servicewide</b> <ul style="list-style-type: none"> <li>No impact.</li> </ul>	<b>Servicewide and Yellowstone</b> <ul style="list-style-type: none"> <li>Impacts would be somewhat less beneficial than Alternative B2, because there would be fewer benefits-sharing agreements than under Alternative B2 and those agreements could be less favorable to the NPS than those negotiated under Alternative B2.</li> </ul>	<b>Servicewide</b> <ul style="list-style-type: none"> <li>Non-monetary benefits could have negligible-to-major beneficial impacts.</li> <li>Short-term beneficial impacts of monetary benefits could be negligible.</li> <li>Long-term beneficial impacts of monetary benefits could range from negligible to minor.</li> </ul>		<b>Servicewide</b> <ul style="list-style-type: none"> <li>The loss of a few current and potential future research projects would have negligible adverse impacts to the NPS.</li> </ul>
<b>Yellowstone</b> <ul style="list-style-type: none"> <li>The return of all monetary benefits provided to Yellowstone by Diversa would have a negligible adverse impact.</li> </ul>		<b>Yellowstone</b> <ul style="list-style-type: none"> <li>Non-monetary benefits could have minor-to-major beneficial impacts.</li> <li>Monetary benefits could have short-term negligible beneficial impacts.</li> <li>Monetary benefits could have long-term negligible-to-major beneficial impacts.</li> </ul>		<b>Yellowstone</b> <ul style="list-style-type: none"> <li>The potential loss of at least 3% of independent research projects would have negligible adverse impacts.</li> <li>The potential loss of a single scientific study revealing important new information about Yellowstone's natural resources could be negligible-to-major.</li> </ul>
<b>Individual parks</b> <ul style="list-style-type: none"> <li>No impact.</li> </ul>	<b>Individual parks</b> <ul style="list-style-type: none"> <li>Fewer parks would experience the beneficial impacts of Alternative B2.</li> </ul>	<b>Individual parks</b> <ul style="list-style-type: none"> <li>Beneficial impacts to parks that receive non-monetary benefits could be negligible-to-major.</li> <li>Beneficial impacts to parks that receive monetary benefits during the immediate benefits period could be negligible-to-major, with the majority of parks studied experiencing no more than negligible impacts.</li> <li>Beneficial impacts to parks that receive monetary benefits during the deferred benefits period could range from negligible to major.</li> </ul>		<b>Individual parks</b> <ul style="list-style-type: none"> <li>The impacts of a potential loss of knowledge from abandoned or never-begun research could be long-term, adverse, and negligible-to-major.</li> </ul>

**Table 2.9-2. Summary of Effects, continued**

Visitor Experience and Enjoyment				
Alternative A No Benefits-Sharing/No Action	Alternative B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
<b>All contexts</b> • No impact. Choosing not to implement benefits-sharing would result in no change in the availability of “science for parks” (scientific knowledge and assistance), and therefore no change in visitor experience and enjoyment.	<b>All contexts</b> • Increased availability of “science for parks” would have a beneficial impact. However, B1 could discourage researchers and benefits-sharing partners and compromise the NPS’s ability to negotiate.	<b>All contexts</b> • Increased availability of “science for parks” would have a beneficial impact in all contexts.	<b>All contexts</b> • Increased availability of “science for parks” would have a beneficial impact. • Impacts in all contexts would be the same as for Alternative B2.	<b>All contexts</b> • Decreased availability of “science for parks” could have adverse impacts in all contexts.
	<b>Servicewide and Yellowstone</b> • Impacts would be somewhat less beneficial than Alternative B2, because there would be fewer benefits-sharing agreements than under Alternative B2 and those agreements could be less favorable to the NPS than those negotiated under Alternative B2.	<b>Servicewide</b> • At least negligible and possibly minor impacts.		<b>Servicewide</b> • Negligible impact.
		<b>Yellowstone</b> • Negligible-to-minor impacts.		<b>Yellowstone</b> • Negligible-to-minor impacts.
	<b>Individual parks</b> • Fewer parks would experience the beneficial impacts of Alternative B2.	<b>Individual parks</b> • Negligible-to-moderate impacts.		<b>Individual parks</b> • Negligible-to-major impacts.

**Table 2.9-2. Summary of Effects, continued**

<b>Social Resources: The Research Community</b>				
<b>Alternative A No Benefits-Sharing/No Action</b>	<b>Alternative B. Implement Benefits-Sharing</b>			<b>Alternative C Prohibit Specimen Collection for Commercially Related Research</b>
	<b>Alternative B1 Always Disclose Royalty Rate and Related Information</b>	<b>Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information</b>	<b>Alternative B3 Never Disclose Royalty Rate or Related Information</b>	
	<p><b>Declared bioprospectors</b></p> <ul style="list-style-type: none"> <li>The obligation to share benefits would have a long-term negligible adverse impact.</li> <li>Because there would be potential economic and competitive impacts to researchers whose proprietary financial information was disclosed, and some researchers may abandon or never begin studies involving NPS-related research specimens to avoid potential disclosure, impacts would be more adverse than Alternative B2.</li> </ul>	<p><b>Declared bioprospectors</b></p> <ul style="list-style-type: none"> <li>The obligation to share benefits would have a long-term negligible adverse impact.</li> </ul>	<p><b>All contexts</b></p> <ul style="list-style-type: none"> <li>Impacts in all contexts would be the same as for Alternative B2.</li> </ul>	<p><b>Declared bioprospectors</b></p> <ul style="list-style-type: none"> <li>Denial of permission to collect research specimens would have a minor-to-moderate adverse impact.</li> </ul>
				<p><b>Inadvertent and undeclared bioprospectors</b></p> <ul style="list-style-type: none"> <li>Denial of authorization to use research results for commercial purposes could prevent potential beneficial impacts.</li> <li>Those who abandon or never begin park-related research would have negligible-to-major adverse impacts.</li> </ul>
<p><b>Third-party researchers</b></p> <ul style="list-style-type: none"> <li>Third-party researchers and any researchers who wish to supply third-party researchers with research specimens would have long-term negligible adverse impacts, because Alternative A would not provide a servicewide standardized Material Transfer Agreement.</li> </ul>		<p><b>Third-party researchers</b></p> <ul style="list-style-type: none"> <li>The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.</li> </ul>		<p><b>Third-party researchers</b></p> <ul style="list-style-type: none"> <li>The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.</li> <li>If third-party researcher is a bioprospector, see declared, and inadvertent and undeclared bioprospectors above.</li> </ul>
<p><b>All other contexts</b></p> <ul style="list-style-type: none"> <li>Researchers who make valuable discoveries from research involving NPS specimens would have long-term, negligible beneficial impacts.</li> </ul>	<p><b>All other contexts</b></p> <ul style="list-style-type: none"> <li>Impacts to all other researchers would be the same as for Alternative B2.</li> </ul>	<p><b>All other contexts</b></p> <ul style="list-style-type: none"> <li>99% of researchers would experience no adverse impacts.</li> </ul>		<p><b>Other researchers</b></p> <ul style="list-style-type: none"> <li>99% of researchers would experience no adverse impacts.</li> </ul>

**Table 2.9-2. Summary of Effects, continued**

<b>Social Resources: NPS Administrative Operations</b>				
<b>Alternative A No Benefits-Sharing/No Action</b>	<b>Alternative B. Implement Benefits-Sharing</b>			<b>Alternative C Prohibit Specimen Collection for Commercially-Related Research</b>
	<b>Alternative B1 Always Disclose Royalty Rate and Related Information</b>	<b>Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information</b>	<b>Alternative B3 Never Disclose Royalty Rate or Related Information</b>	
<b>Servicewide and individual parks</b> <ul style="list-style-type: none"> <li>• Not having any benefits-sharing agreements to administer would result in no impact.</li> <li>• Not providing a standardized Material Transfer Agreement would result in adverse, negligible impacts.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>• Fewer benefits-sharing agreements would result in less adverse impacts than Alternative B2.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>• The institution of Material Transfer Agreements would have a beneficial impact.</li> <li>• The need to administer benefits-sharing agreements would have an adverse impact.</li> <li>• Impacts would be negligible in all contexts.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>• Impacts would be the same as Alternative B2.</li> </ul>	<b>All contexts</b> <ul style="list-style-type: none"> <li>• A reduction in the number of submitted research proposals and the institution of Material Transfer Agreements would have negligible beneficial impacts in all contexts.</li> </ul>
<b>Yellowstone</b> <ul style="list-style-type: none"> <li>• Not having any benefits-sharing agreements to administer would result in no impact.</li> <li>• Not providing a standardized Material Transfer Agreement would result in no impact.</li> </ul>				

\*Table 2.9-2 summarizes the key impacts that could result from each of the alternatives, including the No Action Alternative. Detailed descriptions of these impacts are provided in Chapter 4. Summary statements are abbreviated and taken out of context to provide a quick comparison by element. The reader is encouraged to review the supporting analysis in Chapter 4. All impacts are estimated in the long term, over the 20-year period following implementation of the alternative, unless otherwise noted. Short-term impacts, when addressed, are estimated for the five-year period after the EIS decision is reached.

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# Notes

## Section 2.1 Introduction

<sup>1</sup> 67 Fed. Reg. 18034, 18035 (April 12, 2002).

## Section 2.2 NPS Policies and Procedures That Would Remain Unchanged Under Every Alternative

<sup>2</sup> Investigator's Annual Reports are available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008.

## Section 2.3 Alternative A: No Benefits-Sharing/No Action

<sup>3</sup> National Park Service directives on the standardized procedures used for the evaluation of scientific research applications and issuance of NPS Scientific Research and Collecting Permits (research permits) specifically provide for NEPA review in connection with each permit. *See* National Park Service, "Application Procedures and Requirements for Scientific Research and Collecting Permits, Review of Proposals," available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008.

## Section 2.4 Alternative B: Implement Benefits-Sharing

<sup>4</sup> This FEIS is a programmatic document, meaning that it is general and comprehensive in scope.

<sup>5</sup> A copy of the draft standardized Material Transfer Agreement developed by the NPS is provided in Appendix B. The NPS developed the draft MTA based on the Uniform Biological Material Transfer Agreement developed and published by the National Institutes of Health/Public Health Service in March 1995. *See* 60 Fed. Reg. 12771 (March 8, 1995).

<sup>6</sup> During the research process, the originally collected specimen may be consumed in analysis, but research results with commercial applications would not have occurred without study of that originally collected specimen. The CRADA and MTA provided in Appendices A and B of this document define the relationship of commercially applicable developments to the originally collected specimen.

<sup>7</sup> The legislative history relating to the Federal Technology Transfer Act of 1986 indicates a Congressional preference for CRADA development and management at the local laboratory level. *See* S. Rep. 99–283 (2d Sess.), Federal Technology Transfer Act of 1986, at page 4 ("To improve technology transfer, the Federal laboratories need clear authority to do cooperative research, and they need to be able to exercise that authority at the laboratory level. Agencies need to delegate to their laboratory directors the authority to manage and promote the results of their research. A requirement to go to agency headquarters for approval of industry collaborative arrangements and patent licensing agreements can effectively prevent them. Lengthy headquarters approval delays can cause businesses to lose interest in developing new technologies"). *See also* Executive Order 12591, 52 Fed. Reg. 13414 (Apr. 22, 1987), requiring federal agency heads to delegate authority to federal laboratories to enter into CRADAs with other federal laboratories, state and local governments, universities, and the private sector.

<sup>8</sup> The FTTA defines the term "laboratory" to mean "a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government" (15 USC 3710a(e)). The statute also gives federal agencies broad discretion relating to laboratory determinations (15 USC 3710a). The legislative history explains that "[t]his is a broad definition which is intended to include the widest possible range of research institutions operated by the Federal Government" (S.Rep. No. 283, 99th Cong., 2d Sess. (1986), at page 11). National parks that satisfy this statutory definition are eligible to enter into CRADAs. At least one federal court has concluded that national park units hosting significant scientific research activities (such as Yellowstone) satisfy this statutory definition. *See Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).

<sup>9</sup> NPS units are currently authorized to enter into Cooperative Agreements, General Agreements, and other types of contractual arrangements with federal, state, educational, tribal, non-profit, and private sector entities to pursue activities that help accomplish the NPS mission. *Director's Order 20* provides guidance on development and administration of agreements negotiated between the NPS and other federal, state, non-profit, and for-profit organizations to further the NPS mission.

<sup>10</sup> *See* Chapter 1, Section 1.8.1.1 of this document, for a description of federal court review of the Yellowstone–Diversa CRADA.

<sup>11</sup> The proposed standardized benefits-sharing CRADA also incorporates important definitions relating to progeny, unmodified derivatives, and modifications that appear in the Uniform Biological Material Transfer Agreement developed with input from the research community and published by the Public

Health Service (National Institutes of Health) in 1995. *See* 60 Fed. Reg. 12771 (March 8, 1995). These definitions clarify important rights and obligations of researchers as well as the NPS in connection with certain foreseeable outputs resulting from biological research activities, and are intended to reinforce the NPS's existing regulatory authority over the wildlife that it protects and manages (which includes "offspring" (*see* 36 CFR 1.4 (NPS regulatory definition of "wildlife"))).

<sup>12</sup> 16 USC 5935(d).

<sup>13</sup> *See, e.g.*, 31 USC 3512 (Executive agency accounting and other financial management reports and plans), 5 CFR 2635 (Title 5—Administrative Personnel, Chapter XVI—Office of Government Ethics, Part 2635—Standards of Ethical Conduct for Employees of the Executive Branch), Department of Interior Departmental Manual, 2001. Parts 331 Cash Accountability, 338 Certifying Officers, and 344 Debt Collection, U.S. Treasury Financial Manual, Vol. I, Part 5 Deposit Regulations, GAO Standards for Internal Control in the Federal Government, and OMB Circular No. A-123. 1995. Management Accountability and Control. Federal Register vol. 60, No. 125, 3879–3872.

<sup>14</sup> *See* 15 USC 3710c(c).

<sup>15</sup> *See* 15 USC 3710a(d)(1) and 3710c.

<sup>16</sup> For example, FOIA exempts "trade secrets and commercial or financial information obtained from a person and privileged or confidential" from disclosure (5 USC 552(b)(4)).

<sup>17</sup> 36 CFR 2.1.

<sup>18</sup> *See, e.g.*, 36 CFR 2.1(c).

<sup>19</sup> 36 CFR 2.1.

<sup>20</sup> The same condition and requirement would apply to researchers who acquired NPS research material subject to the terms of the NPS's draft Material Transfer Agreement (MTA).

<sup>21</sup> NPS directives on the standardized procedures used for the evaluation of scientific research applications and issuance of research permits specifically provide for NEPA review in connection with each permit. *See* National Park Service, *Administrative Guide for Park Research Coordinators and Application Procedures and Requirements for Scientific Research and Collecting Permits*.

<sup>22</sup> *See* OMB Circular A-123, Management Accountability and Control (1995).

<sup>23</sup> *See* 36 CFR 1.6 and 2.5.

<sup>24</sup> *See* this chapter, Section 2.3.2. *see also* *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, at 70 (DDC 2000); *see Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp.2d 63, at 70 (DDC 2000) ("More fundamentally, however, the CRADA does not conflict with the conservation mandate of the organic statutes because it does not grant Diversa the right to collect any research specimens at all. Indeed, contrary to the plaintiffs' assertion, neither the CRADA nor its Scope of Work authorizes Diversa to take any natural materials from Yellowstone. . . . By contrast, to conduct its research activities at Yellowstone, Diversa—like all other researchers in the Park—must apply for and obtain a research permit, which prescribes the terms and conditions of on-site research activities.").

<sup>25</sup> *See* 36 CFR 1.6 and 2.5

<sup>26</sup> Pursuant to OMB Circular No. A-123, Management Accountability and Control.

<sup>27</sup> *See* OMB Circular A-123.

<sup>28</sup> *See Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).

## Section 2.5 Alternative C: Prohibit Specimen Collection for Any Commercially Related Research Purposes

<sup>29</sup> NPS directives on the standardized procedures used for the evaluation of scientific research applications and issuance of research permits specifically provide for NEPA review in connection with each permit. *See* National Park Service, *Administrative Guide for Park Research Coordinators and Application Procedures and Requirements for Scientific Research and Collecting Permits*.

<sup>30</sup> A copy of the draft standardized MTA developed by NPS is provided in Appendix B. The NPS developed the draft MTA based on the Uniform Biological Material Transfer Agreement developed and published by the National Institutes of Health/Public Health Service in March 1995. *See* 60 Fed. Reg. 12771 (March 8, 1995).

## Section 2.6 Issues Addressed in the Alternatives

<sup>31</sup> 36 CFR 2.1.

<sup>32</sup> This distinction has been reviewed and upheld on judicial review. *See Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).

<sup>33</sup> 36 CFR 2.1.

<sup>34</sup> Under Alternative A (No Benefits-Sharing/No Action), the NPS would not implement benefits-sharing. However, this would not affect the probability that research results related to study of NPS specimens would continue to produce commercial applications. Alternative B would implement benefits-sharing for such research results. Accordingly, under both Alternatives A and B, NPS research specimens could

be studied for commercially related purposes. Alternative C proposes a new regulation prohibiting the collection of research specimens if researchers identify or acknowledge their proposed specimen collections as being associated with research that has potential for development of commercial applications. However, inadvertent discoveries of commercial applications for research results would still be inevitable.

## **Section 2.7 Alternatives Considered But Not Analyzed Further**

<sup>35</sup> Objective 2, introduced in Chapter 1, Section 1.4 of this document, is: “Assure that the NPS research permitting process is independent, objective, and unaffected by any benefits-sharing considerations, and research continues to be permitted in accordance with all laws.”

<sup>36</sup> 16 USC 5395(d).

<sup>37</sup> See *Edmonds Institute, et al., v. Babbitt, et al.*, 93 F. Supp. 2d 63, at 72 (DDC 2000).

## **Section 2.8 Determination of the Environmentally Preferred Alternative**

<sup>38</sup> 46 Fed. Reg. 18026 (1981).

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# **Chapter 3**

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## **Affected Environment**

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## 3.1 Introduction

Chapter 3 presents the existing conditions of resources that the three alternatives (described in Chapter 2) could affect (either adversely or beneficially). The resources discussed below are referred to as “impact topics” because they are resources that the National Park Service (NPS) has identified as potentially receiving impacts from the alternatives analyzed in this FEIS (*see* Chapter 1, Section 1.9).

The impact topics are:

- (1) NPS Natural Resource Management (*see* Section 3.2);
- (2) NPS Visitor Experience and Enjoyment (*see* Section 3.3);
- (3a) Social Resources: The Research Community (*see* Section 3.4); and
- (3b) Social Resources: NPS Administrative Operations (*see* Section 3.5.)

Chapter 3 does not describe possible impacts or effects on the impact topics. Instead, Chapter 4 discusses the potential impacts or effects.

The impact topics discussed in this chapter came both from public comments (during scoping, as summarized in Chapter 1, Section 1.8 and Appendix D) and from internal NPS comments and questions. Selection of major impact topics also took into account federal laws, executive orders, regulations, and NPS policies (as described in Section 1.2.4).

The impact topics discussed in this chapter do not include many of the more traditional impact topics frequently seen in EISs or EAs, for instance, soils, water quality, wildlife, cultural resources, or economic benefits to communities. The NPS judged that such traditional impact topics were not appropriate because this FEIS is a programmatic document and is therefore not site-specific in its resource discussions. Instead, the alternatives (as described in Chapter 2) include broad, servicewide management actions. Such actions do not have site-specific impacts, so Chapter 3 does not include a profile of site-specific park resources.

If Alternative B (Implement Benefits-Sharing) is selected, then NEPA review (EIS, EA, or CE) of specific benefits-sharing agreements that might be established by individual parks in the future can be tiered from this programmatic EIS. If an individual park proposed site-specific resource management projects using non-monetary or monetary benefits generated by a benefits-sharing program, such projects would receive a separate environmental review for potential project-specific impacts in compliance with NEPA.

## 3.2 NPS Natural Resource Management

Sound management of park resources is the central NPS mission. This section describes current NPS natural resource management, which might experience different impacts from the three alternatives analyzed in this FEIS.

A thorough understanding of natural resources is essential to the effective management and long-term preservation of national parks, and requires a sound scientific basis.<sup>1</sup> Therefore,

scientific research is a vital part of resource stewardship.<sup>2</sup> The nexus between natural resource management and science is described below. This section describes park-related scientific research in qualitative terms.<sup>3</sup>

This section also describes two financial metrics used in Chapter 4 to evaluate potential impacts of monetary benefits that could be generated under Alternative B (Implement Benefits-Sharing). These metrics are the funding needed for natural resource management operations as described in NPS Business Plans (*see* this chapter, section 3.2.2.1) and the FY2007 Congressional appropriation (funding) for the NPS Natural Resource Challenge. Chapter 4 analyzes the potential impacts of the alternatives by comparing these quantitative metrics to available information about the income derived by academic and federal research institutions from licensing intermediate research results to other institutions for further research, development, and eventual commercialization.

### **3.2.1 Natural Resource Management and Science**

The importance of scientific research to natural resource management has been emphasized by Congress in the National Parks Omnibus Management Act of 1998, by the Council on Environmental Quality, and by the NPS's own *Management Policies 2006*. The NPS encourages both "science for parks" and "parks for science," consistent with NPOMA's declaration that scientific study is an authorized use of parks.

Years ago, park managers could protect park resources primarily by foiling poachers and vandals. Modern resource protection is not as simple. For example, air pollution from densely populated Asia reportedly reaches the U.S. Rocky Mountains in just 17 days.<sup>4</sup> In addition, many scientists believe that the introduction and establishment of exotic invasive species from other continents is the single greatest threat to park preservation. Clearly, park protection in the twenty-first century is far more complex than it was with the establishment of the first park in 1872.

#### ***The National Parks Omnibus Management Act of 1998***

In 1998, Congress enacted the National Parks Omnibus Management Act (NPOMA; 16 USC 5901 et seq.), which directed the NPS to manage park resources through the application of science and scientific principles. NPOMA requires the NPS to "conduct scientific study in the National Park System and to use the information gathered for management purposes" (i.e., "science for parks," described in more detail in Section 3.2.1.1), and to "encourage others to use the National Park System for study to the benefit of park management as well as broader scientific value" (i.e., "parks for science," described in more detail in Section 3.2.1.2) (NPOMA 16 USC Sec 5931 (2) and (4)).

#### ***The Council on Environmental Quality (CEQ)***

In managing parks, the NPS responds to recommendations the CEQ made in 1993 for improving consideration of the reasonably foreseeable environmental effects of proposed federal actions, including addressing the importance of scientific research and information sharing (particularly in connection with management of biological resources). They include:

- Actively seek relevant scientific information from sources both within and outside government agencies;

- Encourage and participate in efforts to improve communication, cooperation, and collaboration between and among governmental and non-governmental entities;
- Improve the availability of information on the status and distribution of biodiversity, and on techniques for managing and restoring it; and
- Expand the information base on which biodiversity analyses and management decisions are based.<sup>5</sup>

These recommendations emphasize the importance of improving access to relevant scientific information, and improving incorporation of related research activities and results in biological resource management activities.

### ***NPS Management Policies 2006***

*NPS Management Policies 2006* states that NPS natural resources will be managed to preserve fundamental physical and biological processes, as well as individual species, features, and plant and animal communities. The policies provide general principles for managing biological resources as follows:<sup>6</sup>

- Preserving and restoring the natural abundances, diversities, dynamics, distributions, habitats, and behaviors of native plant and animal populations and the communities and ecosystems in which they occur;
- Restoring native plant and animal populations in parks when they have been extirpated by past human-caused actions; and
- Minimizing human impacts on native plants, animals, populations, communities, and ecosystems, and the processes that sustain them.

Examples of NPS natural resource management policies that are particularly reliant on science include the following:

#### **Planning for Natural Resource Management**

- Planning for park operations, development, and management activities that might affect natural resources will be guided by high-quality, scientifically acceptable information, data, and impact assessment.

#### **Evaluating Impacts on Natural Resources**

- This evaluation must include the application of scholarly, scientific, and technical information in the planning, evaluation, and decision-making processes.

#### **Plant and Animal Population Management**

- Data will be developed, through monitoring, for use in plant and animal management programs.
- Information about species life cycles, ranges, and population dynamics will be presented in park interpretive programs for use in increasing public awareness of management needs for all species, both resident and migrant, that occur in parks.
- The results of managing plant and animal populations will be assessed by conducting follow-up monitoring or other studies to determine the impacts of the management methods on non-targeted, as well as targeted, components of the ecosystem.
- Scientifically valid resource information obtained through consultation with

technical experts, literature review, inventory, monitoring, or research will be used to evaluate the identified need for population management.

Specific natural resource management activities that occur in individual parks are described in greater detail in management plans specific to each park.<sup>7</sup> The impact of the alternatives on the ability of parks to adhere to these management principles is analyzed in Chapter 4.

### **3.2.1.1 Science for parks**

To undertake the first of the responsibilities identified by NPOMA—“science for parks”—more directly, the NPS conducts cooperative research with federal and non-federal public and private agencies, organizations, individuals, and other entities to increase scientific understanding of NPS natural resources.

Virtually all parks have challenges to their conservation mandate that only good science—new knowledge relevant to NPS resource management needs—can define with sufficient detail to allow park managers to meet those challenges. The NPS conducts cooperative research with federal and non-federal public and private agencies, organizations, individuals, and other entities to increase scientific understanding of NPS natural resources. Examples of NPS science projects and partnerships that are designed to meet natural resource management needs include the following:

- The NPS has implemented an Inventory and Monitoring program at 270 parks organized into 32 networks based on the biogeographical similarities of their parks (pursuant to NPOMA § 5934).
- The NPS Alaska Region is focusing on improving the scientific understanding of parks through partnerships with universities and research institutions, as well as state and federal agencies.<sup>8</sup>
- The Northeast Coastal and Barrier Network has created a Technical Steering Committee of highly qualified scientists and park staff charged with assisting and advising the network with the planning and implementation of their long-term monitoring program.<sup>9</sup>
- When monitoring of Channel Islands NP’s fox population indicated the foxes were in grave danger of becoming extinct, this information was made available in time for park managers to initiate a captive-breeding program to stabilize the population. Without the data, the island fox population on at least one of the islands might have been completely lost before the severity of the decline was apparent.<sup>10</sup>
- In 2001, the NPS inaugurated a new network of Research Learning Centers, where scientists, park managers, and the public come together to advance learning about park natural resources. Seventeen of the 32 Learning Centers planned for the NPS were funded by 2008.
- Additional partnerships between the U.S. Geological Survey (USGS) and the NPS, for example the NPS/USGS water quality partnerships in 56 parks, provide information that meets specific park management needs.
- Other NPS/USGS partnerships, such as the volcano observatories in Yellowstone and Hawaii Volcanoes national parks, perform long-term monitoring of park hazards as scientists seek to understand the underlying geologic processes that

fundamentally affect the ecosystems of those parks.

Actions taken under the alternatives could affect the availability of knowledge and tools used to perform these program activities.

Sound science can come from many sources. While the NPS has a modest internal scientific function, and regularly draws on that source, the NPS cannot afford to fund all of the research required for the problem-solving needs of the National Park System (*see* Section 3.2.2).

Successful park resource stewardship requires knowledge about the presence and locations of life forms. The NPS has statutory direction to inventory park biodiversity, and over the long term the contribution of personal services toward this effort by non-NPS scientists and experts has been significant. Much of the project funding has come from non-NPS sources, as well. Although these scientists generally provide the largest single input of new knowledge parks receive, their research objectives are often not based primarily on NPS natural resource management goals, and so park management may be left with gaps in needed information.

In a specific example of the contribution that independent researchers make to the NPS, the majority of new species currently being added to park biodiversity rosters are microbes, but the NPS does not employ permanent, full-time microbiologists to conduct microbial research and funds little research on microbes. The NPS has largely depended upon independent researchers working within the parks for this type of information, and not all researchers systematically share such knowledge with the NPS; nor are all parks positioned to take advantage of such information.

In short, the NPS needs independent research to help develop the scientific information needed to meet its mission to protect the parks. Section 3.4.1 describes the reports made by independent researchers to park units about the knowledge gained during their research.

### **3.2.1.2 Parks for science**

The NPS encourages a broad range of non-NPS research projects addressing the second scientific responsibility established by NPOMA: “parks for science.”<sup>11</sup> Universities, government laboratories and agencies, industry, and consulting firms make up the bulk of scientific expertise found in the U.S., and most research in parks is undertaken by non-NPS scientists (*see* this chapter, Section 3.4).

These non-NPS scientists conduct a substantial amount of research in parks that contributes to the body of scientific knowledge, but does not necessarily present information relevant to recognized resource management concerns, or solutions to resource management problems. Nevertheless, the study topics and results strengthen and broaden knowledge about park resources and ecosystems, building a cumulative knowledge base essential to park resource managers. That knowledge may also contribute information to a future management problem or contribute to a park’s interpretive or educational mission.

NPS guidelines that standardize the management of research specimen collection and related scientific activities throughout the National Park System were updated in January 2001, after the NPS requested and evaluated public comments and review (*see also* Chapter 1, Section 1.2.3).

### 3.2.2 Quantitative Measurements Used for Comparison of the Alternatives

This section describes two financial metrics used in Chapter 4 to evaluate potential impacts of monetary benefits that could be generated under Alternative B (Implement Benefits-Sharing). The two financial metrics are (1) funding available for natural resource management operations as described in park Business Plans and (2) the FY2007 Congressional appropriation (funding) for the NPS Natural Resource Challenge. Chapter 4 analyzes the potential impacts of the alternatives by comparing these quantitative metrics to available information about the benefits derived by academic and federal research institutions from licensing intermediate research results to other institutions for further research, development, and eventual commercialization.

#### 3.2.2.1 NPS Business Plans

The NPS Business Plan Initiative (BPI) is a public-private partnership between the National Park Service, the National Parks Conservation Association, and a consortium of philanthropic organizations that measures the operational needs of national parks in business terms.<sup>12</sup> All parks developing Business Plans applied a common methodology developed by BPI staff and graduate students from the nation’s top business and public policy schools.<sup>13</sup> The BPI has worked with park units of all types from all NPS regions. These units vary in total budget size, visitation, and acreage.

NPS Business Plans provide a detailed picture of funding for park operations. By July 2003, 48 parks had completed Business Plans. Each plan included a summary of current funding for park natural resource management operations. Within this group, 44 parks had a history of hosting independent research projects. Those 44 parks encompass 50% of servicewide acreage, and serve, in this FEIS, to illustrate the state of natural resource management servicewide. Their funding levels are used in Chapter 4’s impact analysis as a metric to

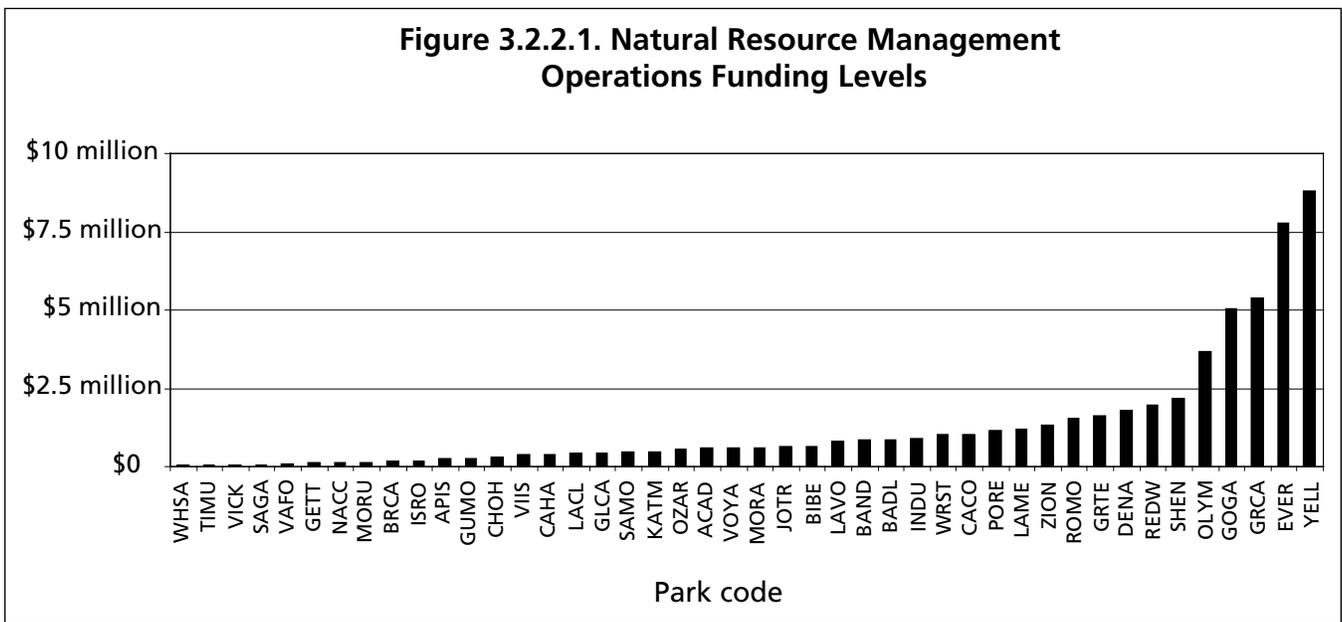


Figure 3.2.2.1. The NPS Business Plan Initiative identified funding levels for natural resource management operations.

evaluate the potential impacts of monetary benefits that could be generated under the preferred alternative.

### **3.2.2.2 The Natural Resource Challenge**

In 1999, the NPS introduced the Natural Resource Challenge (NRC) as its “action plan for preserving natural resources,” with the goal of utilizing high-quality science to improve management of park natural resources.<sup>14</sup> This multi-year action plan is a large and complex conglomeration of programs and activities, organized around three central themes or categories:

- Complete inventories and monitor resources (science for parks),<sup>15</sup>
- Eliminate the most critical resource problems, and
- Attract scientists and good science (parks for science).

In 2007, the NRC program reported total funding of approximately \$78 million for programs supported by the NRC.<sup>16</sup>

## **3.3 NPS Visitor Experience and Enjoyment**

Visitors are a primary consideration for park managers and employees. As such, visitors’ current and future experiences and enjoyment are important topics as the NPS analyzes the impacts from the three alternatives in this FEIS.

The alternatives in this FEIS could affect visitor experience and enjoyment in two ways. First, visitors could be affected by changes to natural resources through the alternatives’ impact on natural resource management as described and analyzed in Chapter 4, Sections 4.3.1, 4.4.2, and 4.5.2. Second, visitors could be affected by changes to interpretive services designed to specifically meet natural resource management goals or changes in interpretation through potential impacts on the scientific information and assistance available for use in NPS interpretive services as analyzed in Chapter 4, Sections 4.3.2, 4.4.3, and 4.5.3.

The availability of “science for parks” can affect the quality of interpretation and therefore visitor experience and enjoyment of parks. This section describes interpretation’s use of scientific research. Chapter 4 analyzes potential impacts of the alternatives by describing how the alternatives might affect the science used specifically for interpretive services.

### **3.3.1 Visitors and Natural Resources**

Natural resources are essential to the quality of many visitors’ experience and enjoyment of the parks. An understanding of natural resources enhances visitor experience, and is valued by visitors. Interpretation can affect visitor behavior in ways that improve a park’s ability to reach natural resource management goals. Accurate information is essential to natural resource interpretation and is dependent on the available scientific information about natural resources in national parks.

In 2001, the National Park Service Comprehensive Survey of the American Public found that 59% of respondents who had visited a national park stated that the main reason they visited national parks was for activities related to the condition of park natural resources, such as

sightseeing, day hiking, wildlife viewing, nature photography, and other activities that allow them to experience and enjoy natural resources. Eighty-four percent of respondents who had visited a national park reported that they went sightseeing while visiting parks, and nearly half (47%) reported that they went day-hiking. These figures suggest that the condition of park natural resources is integral to visitor enjoyment.

### 3.3.2 NPS Interpretive Services

Visitor experience is heightened when it progresses from enjoyment to an understanding of the reasons for a park’s existence, and the significance of its resources. Interpretive materials and programs describe the significance of a park’s resources and help people make connections to these resources. Interpretation facilitates a connection between the interests of the visitor and the meanings found in natural resources.

To enhance and supplement visitor experience, the NPS provides information and interpretive experiences in many different formats (*see* figure 3.3.2). These include written materials such as newspapers and books; indoor and outdoor exhibits; and opportunities to spend time with ranger interpreters. Thirty-three percent of all visitors who enter the parks experience at least the exhibits contained in visitor centers, and many more experience other exhibits. In 2004, park interpreters provided both structured and informal programs such as walks, talks, campfire programs, living history performances, and school programs, contacting visitors more than 148 million times.<sup>17</sup> The NPS’s official web site was accessed more than 124 million times in 2002.<sup>18</sup>

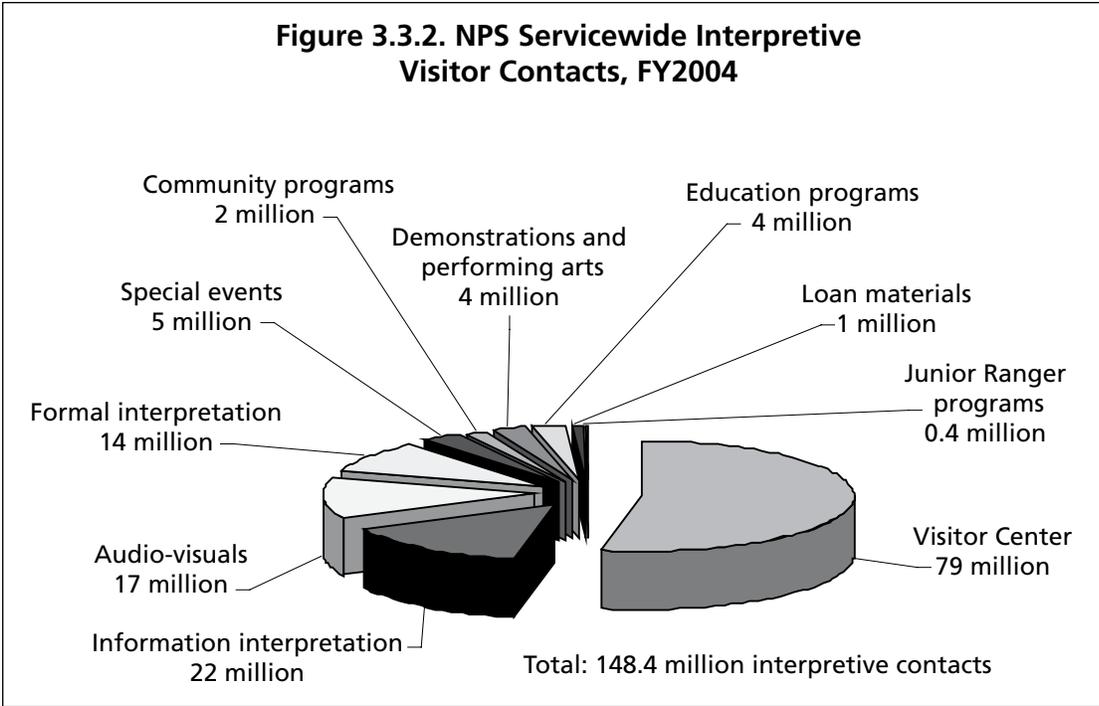


Figure 3.3.2. Millions of park visitors experienced NPS interpretive services in 2004.

### 3.3.3 Interpretation for Natural Resource Management

In parks where visitor behavior can impact natural resources, visitor education programs are a major way to cultivate positive visitor behavior.<sup>19</sup> This type of targeted resource protection interpretation requires scientifically accurate information about the resources of concern and the way people can affect those resources.

Studies have found that visitor respect for—and willingness to comply with—NPS policies and regulations designed to protect natural resources increases when information that explains the connection between the policy and its purpose is clearly developed and disseminated. In this way, interpretation and visitor education play important roles in minimizing potential conflicts and other adverse impacts on NPS natural resources and values that can result from visitor behavior while in the parks.<sup>20</sup>

Park interpretation fills a primary resource preservation role by facilitating public participation in the stewardship of park resources. Interpreters convey principal resource messages to the public and help the public understand its relationship to and impact on resources, thus encouraging them to develop personalized, proactive stewardship ethics.<sup>21</sup>

For example, visitor education at parks like Yellowstone and Yosemite is a component of bear management efforts. Public information dissemination helps reduce conflicts between people and bears by raising visitor awareness of how to store and dispose of food properly, how to camp in bear country, and why park bears should never be fed by visitors. In another example at Petrified Forest National Park, interpretive services have been credited for a 50% decrease in petrified wood theft.<sup>22</sup>

### 3.3.4 Science in Interpretation

One of the fundamental goals of NPS interpretation is to present accurate information in such a way that people will begin to understand and appreciate the significance of the parks and their resources.<sup>23</sup> Good interpretation depends on in-depth resource knowledge as well as knowledge of the audience. The quality of information used for interpretive services depends on the quality of the available scientific information about park resources.

Interpreters must use accurate information when developing interpretive material. They must be knowledgeable about the condition of the park and its resources. Accurate information about resources is essential so that interpretation can strive to provide visitors with the “meaning behind the message” when presenting programs, facilities, exhibits, and publications.

NPS interpretive staff inform and educate visitors about a widening range of natural resource conservation and management issues, requiring a clear and accurate understanding of complex ecosystem relationships discovered through scientific research (*see also* Section 3.3.3).

As individual parks evaluate their interpretive services and plan for the future, they may find that their interpretive services could be made more effective with improved accuracy. For example, Mount Rainier National Park recently reported that much of its interpretive media information was outdated. Some was even inaccurate, in light of newer scientific research.<sup>24</sup>

## 3.4 Social Resources: The Research Community

The social resources described below include (1) members of the scientific research community who have and will continue to desire access to park specimens and (2) park managers who administer research in parks as well as those who would administer any benefits-sharing.

There are two major categories of individuals and supporting institutions within the research community who conduct scientific research involving research specimens originally acquired through an NPS research permit. They are:

- (1) Researchers to whom NPS Scientific Research and Collecting Permits (hereafter “research permits”) have been issued directly, and
- (2) Researchers, termed “third party researchers,” who have obtained specimens or material originating as an NPS research specimen from permitted researchers, non-permitted researchers, or other third-party entities such as culture collections.

Although any researcher might unexpectedly make a discovery with potential for commercial development, all known past, present, and proposed commercial uses of research results involving the study of NPS specimens involved biological specimens (*see* Chapter 1, Section 1.2.4). Accordingly, the researchers who discover or seek to discover useful scientific information from study of biological research specimens would be those most likely to be affected by the alternatives in this FEIS. These researchers are sometimes called “bioprospectors,” and are described in detail later in this chapter (*see* Section 3.4.3).

### 3.4.1 Researchers with NPS Research Permits

Thousands of researchers work on park-related studies every year under the authority of an NPS research permit. An NPS review of research permits issued in 2001 describing the number and variety of researchers determined that most researchers are independent of the NPS and that most research is biological, usually including study of research specimens.

In 2001, the NPS authorized at least 4,632 scientists, from all 50 states and 12 foreign countries, to conduct more than 2,150 studies in national parks.<sup>25</sup> Fifty-two percent of all national parks issued research permits in 2001. The average paperwork burden to each researcher for participation in the NPS Research Permit and Reporting System is approximately 1.6 hours.<sup>26</sup> Authorized research projects were funded by many sources, including institutions such as the National Science Foundation as well as joint corporate and/or university-sponsored consortia. Researchers receiving NPS research permits in 2001 came from both private and public scientific entities such as academic institutions, government institutions, and corporations (non-profit and for-profit), including 635 different institutions, of which 3% appeared to be an incorporated entity other than an educational institution or museum. Seventy-six percent of all 2001 NPS Investigator’s Annual Reports (IARs) concerned studies in the biological sciences, and 60% of all 2001 NPS research permits authorized the collection of biological material as research specimens.

Any qualified researcher is eligible to obtain a Scientific Research and Collecting Permit in

accordance with NPS regulations and guidelines (*see* Chapter 1, Section 1.2.3).<sup>27</sup> All permitted researchers are subject to the same standards of the NPS research permitting system. Currently, researchers can qualify for NPS research permits regardless of whether or not the research might lead to commercially valuable discoveries.<sup>28</sup> The NPS has not historically prohibited researchers from developing any valuable inventions or other scientific discoveries for any lawful purpose.<sup>29</sup>

### **Rules for research**

Scientific research and specimen collection activities in national parks are governed by NPS regulations, and all research permit applications are evaluated under NEPA (*see* Chapter 1, Section 1.2.3). All researchers who obtain research permits to perform research in the NPS—whether from private or public research entities—are subject to the same laws, regulations, policies, and guidelines.

#### **3.4.1.1 Research reporting**

While a research permit is in effect, researchers are required to submit IARs to the NPS; these are available to the public, as well as to NPS personnel.<sup>30</sup> IARs include summary descriptions and explanations of researchers' scientific objectives and findings. The findings presented in IARs average fewer than 200 words in length and serve to prompt interested park managers, park interpreters, other researchers, and members of the public to contact the author for more details.<sup>31</sup> In addition, as part of determining whether or not to issue a permit, park research coordinators analyze study proposals to determine whether copies of field notes, databases, maps, photos, and/or other materials should also be required or requested as a condition of the NPS research permit.<sup>32</sup> After research has concluded, researchers are requested to provide the park with copies of all published material resulting from their park-related research activities.<sup>33</sup> These published works are the most common form of scientific information that parks gain from research results.

#### **3.4.2 Third-Party Researchers**

Third-party researchers are those who have obtained research specimens or material originating as an NPS research specimen from permitted researchers, non-permitted researchers, or other third-party entities such as culture collections. For example, third-party recipients of microbial research specimens (including descendants or derivatives of those specimens) are commonly either culture collections (where living descendants of the original research specimens are commonly stored, propagated, and made available to other researchers) or colleagues of the original NPS permittee who obtain their transfers directly from the permittee. In turn, these recipients commonly transfer the research material (including descendants or derivatives of the originally collected specimens) to additional researchers.

Before 2001, NPS research permit conditions stated that “The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another.” In 2001, a provision was added to the General Conditions of NPS research permits prohibiting third-party transfer of research specimens without prior authorization obtained from the NPS.<sup>34</sup> However,

no systematic way has been established to conduct, manage, or report on all of these authorizations, so there is no centralized, accessible record of the occurrence of all third-party transfers.<sup>35</sup>

### 3.4.3 Research That Could Result in Commercial Application

#### 3.4.3.1 Bioprospecting

Every research project identified by the NPS that involved study of NPS research specimens and has or could have commercial applications for research results has been in the field of biology (*see* Chapter 1, Section 1.2.4). The search for potentially useful discoveries from biological resources existing in nature is not new, but in the early 1990s, this type of research activity was popularly described by a new term: “biodiversity prospecting,” or sometimes simply “bioprospecting.”<sup>36</sup> However, the terms “biodiversity prospecting” and “bioprospecting” have no legal significance or single, universally-accepted definition (*see* box, Definitions for “Bioprospecting”).

This FEIS uses the term “bioprospecting” to describe biological research that could result in a discovery with some commercial application. Bioprospecting research can be targeted at some specific goal or can be a matter of unexpected serendipity. The main difference between bioprospecting and other types of biological research is its objective to search for still-undiscovered attributes of biological specimens that could have some potentially useful and, therefore, valuable applications.

#### Definitions for “bioprospecting”

The terms “biodiversity prospecting” or “bioprospecting” have no legal significance or single, universally-accepted definition. For example, in 1993, the World Resources Institute defined “bioprospecting” to mean “the exploration of biodiversity for commercially valuable genetic and biochemical resources.”<sup>37</sup> In 1997, one of the directors of Costa Rica’s National Biodiversity Institute defined the term to mean “the systematic search for, and development of, new sources of chemical compounds, genes, micro- and macro-organisms, and other valuable natural products for their potential use in agricultural and pharmaceutical industries.”<sup>38</sup> The government of New Zealand recently defined the term to mean “the examination of biological resources (e.g., plants, animals, and microorganisms) for features that may be of value for commercial development.”<sup>39</sup> The term is not defined by, and does not appear in the United Nations Convention on Biological Diversity.

In some places where the term “prospecting” has negative connotations associated with extractive consumptive industries such as mining, the term has been revised. In Australia, the term “biodiscovery” has been used to describe essentially the same types of biological research activities described elsewhere as “bioprospecting.”<sup>40</sup>

While also not appearing in any statute or regulation governing NPS management of national parks, the terms “bioprospecting” and “biodiscovery” do describe many of the types of biological research activities that have occurred involving the study of NPS biological research specimens. For example, studies of chemical compounds, genes, enzymes, and other proteins isolated from NPS research specimens have already resulted in the discovery and development of several applications with potential commercial value (*see* Chapter 1, Section 1.2.4).

The impact analysis in Chapter 4 is informed by common stages in the research and development of a bioprospecting discovery as described below. The stage of research during which an NPS specimen might be collected and studied is the discovery, or first stage of research. The most “valuable” period in bioprospecting research in terms both of usefulness of the discovery to society and potential profitability of the discovery for the developer occurs long after the discovery stage of bioprospecting research.

Bioprospecting research is sometimes, but not always, targeted for a specific use; researchers sometimes have a specific end in mind that involves the search for biological material likely to lead to a particular category of discovery. This type of research has been described as a process that combines “logic with serendipity.”<sup>41</sup>

Following the initial discovery of a potentially useful research result, this process also sometimes includes additional “downstream” research, evaluation, and development activities involving the following steps:

- *Discovery*—collecting material, screening for potentially useful properties, isolating and purifying new and active biochemicals and compounds, and/or describing new chemical, molecular, genetic, or other elements;
- *Protection of intellectual property*—securing legal protection of new structures and/or specific types of bioactivity or new methods that utilize bioactivity that qualify under applicable intellectual property rights laws;
- *Product development*—modifying biochemical structures to improve their efficacy, and/or conducting clinical and/or field trials to demonstrate and compare the effectiveness and safety of the product with others currently on the market;
- *Manufacturing*—developing techniques for larger-scale industrial production of biochemicals (e.g., by total laboratory techniques or purification from cultivated biological material); and
- *Marketing*—introducing/distributing a final product in the market.<sup>42</sup>

The greatest benefit from the initial discovery is developed at the subsequent stages of the research process.<sup>43</sup> However, income or other benefits are not realized from every bioprospecting research project. For example, pharmaceutical research and development has been described as “a series of lotteries that require substantial expenditures and yield uncertain returns a decade or more in the future.”<sup>44</sup> In general, while some can be expected to generate very high returns, most investments in bioprospecting research will not return as much as other “investments.”<sup>45</sup>

### **3.4.3.2 Bioprospectors**

Researchers who perform bioprospecting research have been divided into three categories for impact analysis:

- Researchers who have identified an imminent commercial application for their research results and have informed the NPS about such use are termed “**declared bioprospectors.**”
- Researchers who unexpectedly discover some potential commercial application for their research results are termed “**inadvertent bioprospectors.**” When inadvertent

bioprospectors recognize a commercial use for their research results and inform the NPS, they are reclassified as declared bioprospectors.

- Researchers in fields known to be particularly likely for commercial application but who consider their research to be strictly “basic research,” having no clear route for developing their research into commercial products unless and until they actually discover some valuable research result, are termed “undeclared bioprospectors.” When undeclared bioprospectors recognize a commercial use for their research results and inform the NPS, they are reclassified as declared bioprospectors.

This section discusses each category of bioprospector used for impact analysis: declared bioprospectors, inadvertent bioprospectors, and undeclared bioprospectors.

***Declared bioprospectors***

Some scientists have informed or acknowledged to the NPS that their research results could be used for some commercial purpose. This information was typically supplied incidentally to filing a research permit application or an Investigator’s Annual Report.<sup>46</sup> These scientists (all biologists) can be described as “declared bioprospectors.”

In 2001, 12 research projects involving 23 researchers (0.5% of all researchers named in NPS research permits servicewide) provided the NPS with information that indicated that their research results could possibly have commercial uses.<sup>47</sup> In addition, one researcher described a serendipitous bioprospecting discovery made that year, but requested that it be kept confidential while the researcher decided whether to pursue development of the discovery.

**Table 3.4.3.2. Bioprospectors in NPS units, 2001**

Total researchers named in NPS Scientific Research and Collecting Permits	4,568
Declared bioprospectors	23
Inadvertent bioprospector described a discovery, requested confidentiality, and is now also considered to be a declared bioprospector	1
Total number of bioprospectors known to the NPS	24
Percentage of independent researchers who were declared bioprospectors	0.53%
Number of research projects conducted by declared bioprospectors	12
Number of parks involved	8

Table 3.4.3.2. Less than 1% of researchers holding active NPS research permits were declared bioprospectors in 2001.

The small number of declared bioprospectors in the NPS is also illustrated by information collected by Yellowstone National Park. Because 53 of the 55 patents known to be related to study of NPS research specimens involved specimens first collected at Yellowstone, declared bioprospectors at Yellowstone could be expected to represent most of the declared bioprospectors in the NPS (see Chapter 1, Section 1.2.4). In 1998, Yellowstone National Park asked 245 researchers who had held Yellowstone research permits during the previous

several years to clarify whether their research results might have some possible commercial application. Of 169 respondents, only six reported that they expected a commercial application in the foreseeable future.

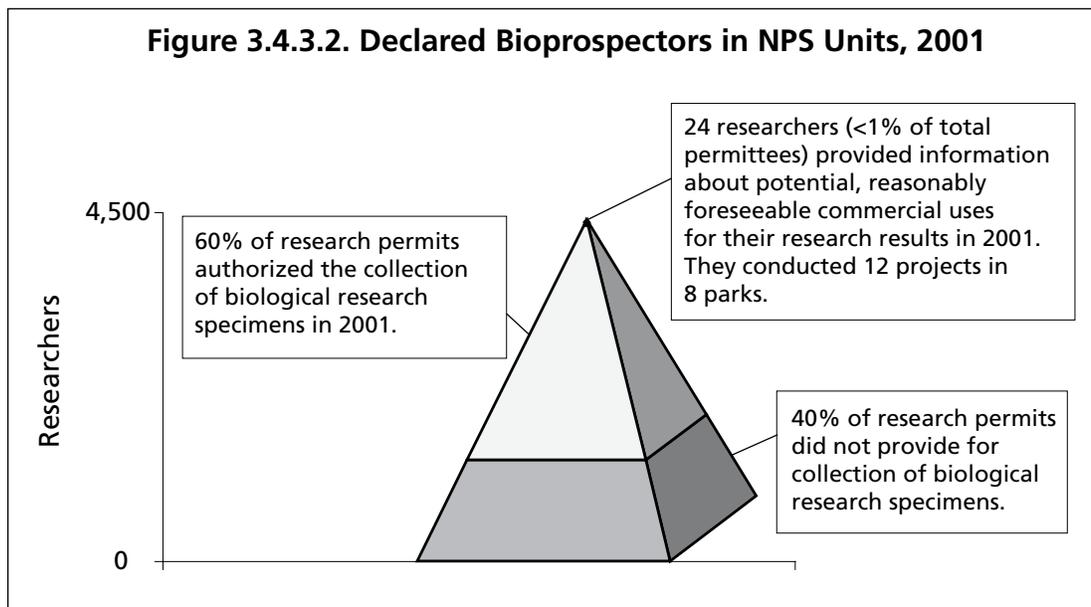


Figure 3.4.3.2. Less than 1% of all independent researchers performing research in NPS units were declared bioprospectors in 2001.

There are several reasons why the number of declared bioprospectors studying national park specimens and material originating as an NPS research specimen is so small. First, because the term “bioprospector” lacks any universally agreed-upon definition, researchers do not necessarily think of themselves as “bioprospectors,” even when their research activities are sufficiently directed toward the discovery of some new, useful application as to be fairly described as “bioprospecting.” Second, the term “commercial use” also has not been defined by the NPS, and therefore may be interpreted differently by different researchers (resulting in different understandings about what it means to be a “bioprospector”). Third, the NPS has not had any voluntary or mandatory way for scientists to systematically identify themselves as researchers who could be using biological material originally sourced from a U.S. national park for research purposes with potential commercially valuable applications. Fourth, premature disclosure of research-related information can disqualify a researcher from applying for and obtaining certain types of intellectual property protection. Finally, many researchers who have developed patentable inventions based on discoveries resulting from research involving NPS biological material obtained the research material from third parties (such as culture collections), rather than directly from a national park. The most prominent example of this is *Thermus aquaticus*, collected from Yellowstone and acquired from a culture collection by the Cetus Corporation, which

#### **Example: declared bioprospector**

Researchers from the Diversa Corporation have consistently informed the NPS that their research activities involving microorganisms collected at Yellowstone could lead to new discoveries with some possible commercial applications.

developed the polymerase chain reaction (PCR) process using Taq polymerase isolated from the microorganism.

### ***Inadvertent bioprospectors***

Some researchers unexpectedly discover some potential commercial application for their research results. In other words, they begin their research activities involving study of NPS biological material for one purpose, but discover something different than what was initially anticipated during the research project. Because of the accidental nature of this type of discovery, virtually any biological researcher could become an “inadvertent bioprospector.” When inadvertent bioprospectors recognize a commercial use for their research results and inform the NPS, they are then considered to be declared bioprospectors. In 2001, for example, one researcher made an inadvertent discovery of a potential commercial application for research results and is now considered a declared bioprospector.

Inadvertent discoveries, albeit accidental, can be reasonably expected to result from research activities involving the study of biological material. While such discoveries appear to have occurred most often during the study of newly discovered microorganisms, accidental discoveries that could have some potential commercial value (such as development of a new anti-cancer drug) can occur in any field of biological study.

As with declared bioprospectors, the NPS has been unable to systematically identify researchers who make accidental, potentially valuable discoveries during research activities involving NPS research specimens. Because such a discovery could occur well beyond the one-year time-frame when the researcher is obligated to submit an Investigator’s Annual Report, it is not known how many inadvertent bioprospectors have made unexpected discoveries with potential commercially valuable applications.

#### **Example: inadvertent bioprospector**

In 1994, an Investigator’s Annual Report revealed that research activities originally focused on the ecology of cave-dwelling microorganisms also yielded unexpected discoveries about certain anti-cancer activity isolated from the microorganisms. Thereafter, the researcher shifted the focus of his research emphasis from how the microbes of interest survived in a cave environment to discovery and development of potential new cancer-fighting compounds.<sup>48</sup>

### ***Undeclared bioprospectors***

Undeclared bioprospectors can be distinguished from inadvertent bioprospectors by the fact that undeclared bioprospectors focus their efforts in fields of research where the likelihood of discovering a novel bioactive compound with some potential commercial utility is not entirely speculative or serendipitous. In this way, they differ from inadvertent bioprospectors, whose discoveries are of a completely unexpected or accidental nature. Undeclared bioprospectors differ from declared bioprospectors in that undeclared bioprospectors consider their research activities to be strictly “basic research” without any potential for commercial development until there has been an actual discovery with some demonstrated commercial application.<sup>49</sup> When undeclared bioprospectors recognize a commercial use for their research

### **Example: undeclared bioprospector**

A researcher who studies the biochemical strategies used by microbes to survive in toxic environments could be reasonably expected to have a chance of discovering new techniques for bioremediation of toxic industrial waste. The study of biological research specimens that thrive in many different types of extreme environments (“extremophiles”) sometimes found in national parks has been a particularly rich field for discoveries with potential commercial applications.<sup>50</sup>

results and inform the NPS, they are reclassified as declared bioprospectors.

Studies involving some types of research specimens found in national parks may be more likely to generate research results with some potential or real commercial value than research involving other types of specimens. For example, all but one of the known patents awarded on inventions that resulted at least in part from research involving NPS specimens involved microorganisms, and most were discovered in extreme environments (mainly in thermal areas at Yellowstone National Park).

Approximately 80 researchers with NPS research permits have been identified by park staff as undeclared bioprospectors since about 1990, regardless of whether the researchers themselves would have agreed. Approximately 10 additional undeclared bioprospectors had some amount of contact with park personnel, but either did not apply for or were discouraged from applying for an NPS research permit (*see* Chapter 1, Section 1.2.4). No reliable predictions can be made about which, if any, undeclared bioprospectors might actually make a discovery with potential commercial application.<sup>51</sup>

### **Types of bioprospectors**

***Declared bioprospectors***—Researchers who provide information to the NPS that their research results could have potential, reasonably foreseeable commercial uses.

***Inadvertent bioprospectors***—Researchers who accidentally make discoveries having some valuable commercial application. When inadvertent bioprospectors recognize a commercial use for their research results and inform the NPS, they are reclassified as declared bioprospectors.

***Undeclared bioprospectors***—Researchers who study specific topics with recognized bioprospecting potential but who have not provided information to the NPS about potential, reasonably foreseeable commercial uses for their research results, or who have not identified a commercial use for their research results. When undeclared bioprospectors recognize a commercial use for their research results and inform the NPS, they are reclassified as declared bioprospectors.

## 3.5 Social Resources: NPS Administrative Operations

Section 3.5 reviews NPS administration of agreements and research permits, both of which could be affected by the alternatives. Although any park could be affected by the alternatives, parks that are most likely to be affected are Yellowstone National Park and other parks currently administering research permits. Chapter 4 analyzes the impact of the alternatives by comparing the administrative effort required to implement the alternatives with the administrative resources currently available in parks.

### 3.5.1 Administration of NPS Agreements

The National Park Service is authorized to enter into different types of agreements with other agencies, organizations, and individuals, including but not limited to the use of cooperative agreements to conduct multi-disciplinary research.<sup>52</sup> These agreements establish formal relationships that allow the NPS to accomplish its mission more efficiently and economically.

The NPS uses agreements to manage activities and relationships with other federal agencies, state and local governments, non-profit and for-profit organizations, corporations, partnerships, and individuals.<sup>53</sup> The director of the NPS has instructed parks to actively seek opportunities to efficiently and economically accomplish the NPS mission by entering into advantageous relationships with federal and non-federal entities.<sup>54</sup>

The procedures for entering into, reviewing, and terminating agreements are well established.<sup>55</sup> Laws and regulations prescribe the manner or conditions under which agreements may be implemented. NPS managers also have substantial latitude in negotiating and entering into different types of agreements.<sup>56</sup>

The NPS regularly enters into agreements for collaborative research projects that advance knowledge about park resources. By law, management of NPS units must be enhanced by the availability and utilization of a broad program of the highest quality science and information.<sup>57</sup>

As the National Park System Advisory Board reported in *Rethinking the National Parks for the 21<sup>st</sup> Century*, “A sophisticated knowledge of resources and their condition is essential. The Service must gain this knowledge through extensive collaboration with other agencies and academia, and its findings must be communicated to the public.” To effectively undertake the

#### **Programs that bring NPS personnel and scientists together**

In 2001, the NPS inaugurated a network of Research Learning Centers where scientists, park managers, and the public come together to advance and share learning about park natural resources.<sup>59</sup> As of July 2007, there were 13 federal agencies, 176 universities and colleges, and 40 other partners involved in interagency Cooperative Ecosystem Studies Units.<sup>60</sup> In addition, the NPS has a strong relationship with the U.S. Geological Survey on subjects from water quality partnerships to volcano observatories.

dual responsibilities of “parks for science” and “science for parks,” NPS personnel conduct cooperative research with federal and non-federal public and private agencies, organizations, individuals, and other entities for the purpose of increasing scientific understanding of NPS natural resources.<sup>58</sup>

### **3.5.2 Administration of NPS Scientific Research and Collecting Permits**

NPS research permits are administered by individual parks through the servicewide NPS Research Permit and Reporting System. The NPS estimates that reviewing and processing application materials and annual reports; conducting environmental reviews and field inspections as needed; and performing necessary typing, photocopying, recordkeeping, mailing, and other standard office activities regarding applications for research permits requires an average of 8.5 person-days per permit.<sup>61</sup>

Alternatives A and B propose no changes to this system. However, during scoping, some comments indicated that the public is concerned that if a potential benefits package were considered as part of a research proposal, parks might be inclined to issue or deny permits based on a new, and to many people, unacceptable criterion. In response, Alternative B includes mitigating measures to ensure that evaluation of research permit applications is not influenced by any benefits-sharing considerations (*see* Chapter 2, Section 2.6).

Alternative C adds a new criterion for approval of a research permit application: the prohibition of research specimen collection for any commercially related purpose. Chapter 4 analyzes the impact of adding this new prohibition.

Since 1992, more than two-thirds of all park units have issued research permits. However, not all parks receive research permit applications or authorize research projects every year (*see* Chapter 1, Section 1.2.3).

The General Conditions of NPS research permits prohibit third-party transfer of research specimens or material originating as an NPS research specimen without prior authorization from the NPS.<sup>62</sup> However, no systematic way has been established to conduct, manage, or report on all of these authorizations. Chapter 4 analyzes the impact of standardizing the procedure for transferring research material that is ultimately consumed in analysis, which would be an addition to the current system designed to track specimens suitable for permanent museum retention.

### **3.5.3 Park Units Most Likely to be Affected by Alternative B (Implement Benefits-Sharing)**

Agreements and research permits are usually administered by individual park units. Because research could be permitted at any unit in the National Park System, any park unit could be involved in benefits-sharing. The NPS cannot know precisely which research projects would be most likely to result in valuable commercial applications, nor in which parks those projects might occur. Based on past history, some park units are more likely to participate in Alternative B’s benefits-sharing program than others.

Because the majority (96%) of the known patents granted for research results involving study of NPS research specimens originally collected from NPS units involve biological specimens originating in Yellowstone, Yellowstone National Park would likely be the first park to participate in a benefits-sharing program if Alternative B were implemented. Additionally, the Yellowstone–Diversa CRADA would be amended to conform to the standardized CRADA in Alternative B (*see* Appendix A). In 2001, six additional researchers provided Yellowstone with information that indicated that their research results could possibly have commercial uses. Accordingly, Yellowstone could expect to enter into additional benefits-sharing agreements if Alternative B were implemented.

Other parks have identified researchers whose research activities could reasonably be expected to result in some valuable discoveries with potential commercial applications. In 2001, seven additional parks, or 1.8% of all park units, received reports about potential commercial uses for research results from projects undertaken through NPS research permits. Since 1990, at least 30 parks have either issued a research permit, received a research permit application, or fielded an inquiry about a possible research proposal from researchers considered to be bioprospectors. As 270 NPS units have issued research permits, and at least 30 have evidence of bioprospecting interest, the number of parks that could be affected by Alternative B could be between 30 and 270.

Finally, all park units are authorized to issue research permits allowing the collection of research specimens for scientific purposes. If the study of those specimens resulted in discoveries or inventions that could have a commercial application, then any park could participate in benefits-sharing under Alternative B. Any park that receives a research permit application would be affected by Alternative C’s new criterion for permit issuance (the prohibition of research specimen collection for any commercially related purpose).

In short, Alternatives B and C would affect NPS administrative operations at Yellowstone National Park as well as other parks, especially those that are already aware of current or potential bioprospectors (30 parks) and those that have already hosted independent research activities (270 parks).

### **3.5.4 Existing Administrative Resources**

Thirty-two of the 44 park Business Plans previously described include information about existing administrative resources.<sup>63</sup> This information is presented in terms of available “full-time equivalents” (FTE); each FTE is the equivalent of one full-time employee and, in this FEIS, represents the amount of work that can be performed by one full-time employee in one year. The Business Plans identify the amount of administrative work that can be accomplished by existing employees as FTE, regardless of how many employees may perform such work on a full- or part-time basis. The number of available administrative FTE in those 32 parks ranges from five to 109. The subset of these FTE that responds to research permit applications similarly varies greatly from a low of less than 0.2 FTE to a high of 2.0 FTE.

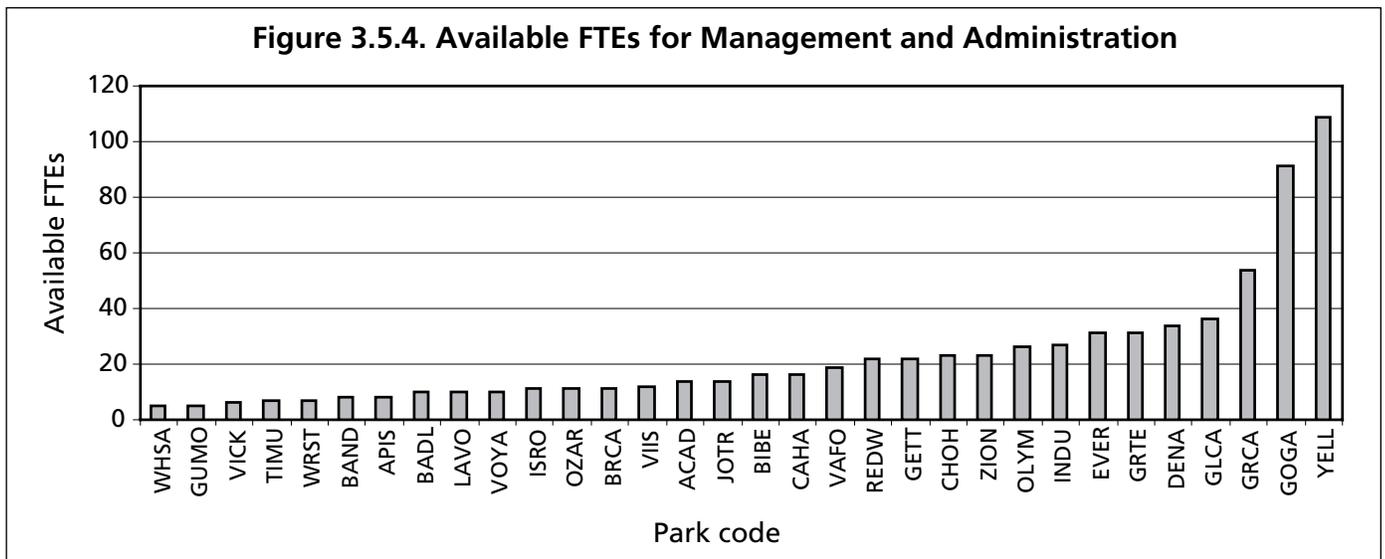


Figure 3.5.4. The number of available administrative FTEs per park varies considerably.

## Notes

### Section 3.2 Natural Resource Management

<sup>1</sup> See, e.g., United States, Committee on Improving the Science and Technology Programs of the National Park Service, *Science and the National Parks* (Washington, D.C.: National Academy Press, 1992), and R. W. Sellars, *Preserving Nature in the National Parks: A History* (New Haven: Yale University Press, 1997).

<sup>2</sup> National Park Service, *National Leadership Council Journal* (April 2001).

<sup>3</sup> Chapter 4 analyzes the potential impacts of the alternatives by describing how the alternatives might affect the quality of park research as it relates to park resource management.

<sup>4</sup> Other examples include much of the bird life that nests and rears young in the parks, which is subject to varying environmental stresses in Central and South America.

<sup>5</sup> Council on Environmental Quality (CEQ), *Incorporating Biodiversity Considerations into Environmental Impact Analysis Under the National Environmental Policy Act* (Washington, D.C.: CEQ, 1993).

<sup>6</sup> National Park Service, *National Park Service Management Policies 2006*, Chapter Four: “Natural Resource Management,” Sections 4.1 and 4.4 (Washington, D.C.: U.S. Department of the Interior, 2006).

<sup>7</sup> *Ibid.*, Section 4.0.

<sup>8</sup> National Park Service, *Natural Resource Challenge in Alaska* (March 2002).

<sup>9</sup> National Park Service, *Northeast Region Natural Resource Challenge Annual Report, 2002*.

<sup>10</sup> National Park Service, *Funding the Natural Resource Challenge: A Report to Congress, FY 2001*, available online at <<http://www.nature.nps.gov/challenge/congress/congressreport2001.pdf>>, last accessed March 20, 2006.

<sup>11</sup> National Park Service, *Management Policies 2006*, Section 4.2 “Studies and Collections.”

<sup>12</sup> The consortium is led by the Kendall Foundation and includes the Vira I. Heinz Foundation, the Walter and Elise Haas Fund, the Compton Foundation, Inc., the Roy A. Hunt Foundation, the National Park Foundation, the David and Lucile Packard Foundation, and the William and Flora Hewlett Foundation.

<sup>13</sup> In 1999, PricewaterhouseCoopers, a private consulting firm, performed an independent analysis of the BPI process, program, and products. Their results provided clear support for the process, indicating that the project could establish a template for business planning in government agencies.

<sup>14</sup> National Park Service, *Natural Resource Challenge: the National Park Service’s Action Plan for Preserving Natural Resources* (Washington, D.C.: National Park Service, 1999), and National Park Service, *Funding the Natural Resource Challenge*.

<sup>15</sup> The Inventory and Monitoring initiative is a program designed to gather information about park resources and develop techniques for monitoring the ecological communities in the National Park System. See National Park Service, *Natural Resource Challenge: the National Park Service’s Action Plan for Preserving Natural Resources*, and G. Williams, *Inventory and Prototype Monitoring of Natural Resources in Selected National Park System Units 1999–2000*, available online at <<http://www.nature.nps.gov/>>

publications/TR2001-1/TitlePage.htm>, last accessed March 14, 2006.

- <sup>16</sup> Although Chapter 4 compares potential monetary benefits to Natural Resource Challenge funding, all such benefits might not be usable by the same programs funded by the NRC.

### Section 3.3 Visitor Experience and Enjoyment

- <sup>17</sup> National Park Service, *NPS Servicewide Interpretive Report FY2004*, “Visitor Contacts,” on file at the Interpretation/Education Division, Office of Partnerships, Interpretation and Education, Volunteers, and Outdoor Recreation, NPS Washington Area Service Office.
- <sup>18</sup> The most recent NPS website data is for FY2002. C. Mayo, NPS Program Director, Interpretation and Education, personal communication to A. Deutch, October 19, 2005.
- <sup>19</sup> M. Gillett, “The Role of Interpretation in Park Operations,” in *Interpretive Skills Lesson Plans*, Module 101: Fulfilling the NPS Mission: The Process of Interpretation of the NPS Interpretive Development Program (1992) (see <<http://www.nps.gov/idp/interp>>, last accessed March 14, 2006).
- <sup>20</sup> K. McCurdy, “Yosemite Wild Bear Project Update,” in *American Park Network Guide to Yosemite National Park* (New York: APN Media, LLC, 2001); S. C. Thompson and K. McCurdy, “Black bear Management in Yosemite National Park: More a People Management Problem, pages 105–114 in J. Auger and H. L. Black, eds., *Proceedings of the Fifth Western Black Bear Workshop: Human–Black Bear Interactions* (Provo: Brigham Young University Press, 1995); and C. J. Widner, “Reducing Theft of Petrified Wood at Petrified Forest National Park,” *Journal of Interpretation Research* 5(1):1–18.
- <sup>21</sup> National Park Service, *Interpretive Development Program*, available online at <<http://www.nps.gov/idp/interp>>, last accessed March 14, 2006.
- <sup>22</sup> Widner, “Reducing Theft of Petrified Wood at Petrified Forest National Park.”
- <sup>23</sup> National Park Service, *Management Policies 2006*, Chapter 7.
- <sup>24</sup> Mount Rainier National Park, *Long-range Interpretive Plan* (Longmire, Wash.: Mount Rainier National Park, 2000).

### Section 3.4 Social Resources: The Research Community

- <sup>25</sup> Unless otherwise attributed, figures provided in this paragraph derive from the analysis of 2001 Research Permit Reporting System (RPRS) data on file at Yellowstone National Park. See also <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008. Note that co-investigators and research assistants may also be named in a permit at the Principal Investigator’s and the park’s discretion. Therefore, in the analysis of the number of scientists permitted to research within NPS, it follows that in a number of instances the named investigators supervised additional field assistants, graduate students, or other students, but no data exists regarding these additional members of the research teams.
- <sup>26</sup> 69 *Federal Register* 31402-31403.
- <sup>27</sup> The RPRS application procedures and requirements for Scientific Research and Collecting Permits state: “Any individual may apply if he/she has qualifications and experience to conduct scientific studies or represents a reputable scientific or educational institution or a federal, tribal, or state agency” (available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008).
- <sup>28</sup> The RPRS application procedures and requirements for Scientific Research and Collecting Permits state: “Separate agreements between the investigator and NPS are required when proposed studies or collected specimens are intended to support commercial research activities” (available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008). This is not currently enforced (Department of the Interior, Office of the Solicitor, “Memo to DOI Chief of Staff, Assistant Secretaries, and Heads of Bureaus and Offices: Research Activities on Lands Managed by the Department that Have Potential Bioprospecting Implications,” September 10, 1998. On file at Yellowstone National Park, Wyoming).
- <sup>29</sup> This distinction and regulatory approach have been upheld on judicial review. See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000), “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the “sale or commercial use” of park resources within the meaning of [36 CFR 2.1]. . . . [T]he Park Service determined that there was a critical distinction between researchers profiting from the sale of the actual specimens themselves, which is prohibited by [36 CFR 2.1], and profiting from a future development based on scientific discoveries resulting from research on those resources, which is permitted. . . . The CRADA, in turn, accords with the regulations because any ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.”
- <sup>30</sup> National Park Service, “NPS Scientific Research and Collecting Permit General Conditions,” available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008.
- <sup>31</sup> Analysis of 2001 RPRS data, on file at Yellowstone National Park.
- <sup>32</sup> “RPRS Application Procedures and Requirements for Scientific Research and Collecting Permits,” available online at <<http://rprs.nps.gov/research>>, last accessed October 24, 2008.
- <sup>33</sup> *Ibid.*

- <sup>34</sup> The standardized General Conditions of NPS research permits read, in part, “The sale of collected research specimens or other unauthorized transfers to third parties is prohibited” (available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008).
- <sup>35</sup> Transfer of permanently retained specimens is managed by NPS museum specimen loan procedures. However, such procedures apply only to permanently retained specimens and do not apply to transfers of specimens or material originating as an NPS research specimen that are intended to be consumed in analysis.
- <sup>36</sup> See U.S. Office of Technology, “Technologies to Maintain Biological Diversity,” *U.S. Office of Technology Assessment* (March 1987), 4, reporting that crop genetic resources account for approximately 50% of productivity increases and for annual contribution of approximately US\$1 billion to U.S. agriculture, and that approximately 25% of the number of prescription drugs in the U.S. are derived from research activities involving plants. One of the first uses of the term was by Dr. Thomas Eisner, Professor of Biology at Cornell University (see T. Eisner, “Prospecting for Nature’s Chemical Riches,” *Issues in Science and Technology* 6(20): 31–34; T. Eisner, “Chemical Prospecting: A Proposal for Action, pages 196–202 in F. H. Bormann and S. R. Kellert, eds., *Ecology, Economics, and Ethics: The Broken Circle* (New Haven: Yale University Press, 1992). The term became much more widely used after publication of the book, *Biodiversity Prospecting* (W. Reid et al., *Biodiversity Prospecting* (Washington D.C.: World Resources Institute, 1993).
- <sup>37</sup> W. Reid et al., *Biodiversity Prospecting*, 1.
- <sup>38</sup> A. Sittenfeld and A. Lovejoy, “Biodiversity Prospecting,” in *Our Planet* (Nairobi: U.N. Environment Programme, 1997), 20.
- <sup>39</sup> Resources and Networks Branch, Ministry of Economic Development, Government of New Zealand, *Bioprospecting in New Zealand* (2002), 5.
- <sup>40</sup> According to the Government of Queensland, Australia, “Biodiscovery means collecting biological resources to identify valuable molecular or genetic information about those biological resources and to utilise that information in the development of bio-products” (Government of Queensland, Australia, “Queensland Biodiscovery Policy Discussion Paper” (May 2002), 31).
- <sup>41</sup> Harvard Business School, Case Study No. N1-593-015 (October 23, 1992), 5.
- <sup>42</sup> Government of New Zealand, *Bioprospecting in New Zealand*, 5, para. 1.6. See also Harvard Business School, Case Study No. N1-593-015, 5 and Exhibit 5 (describing the drug discovery and development process in the U.S.).
- <sup>43</sup> See, e.g., K. ten Kate, and S. A. Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (London: Earthscan Publications, Ltd., 2000), 9–10, reporting that the rates of return in pharmaceutical research where companies have developed drugs from raw materials provided by outside parties are lowest at the early research stages (1–6%), higher when preclinical data is available and involved (5–10%), and higher still when efficacy data has been developed that can be used to identify a potential product (10–15%). See also Government of New Zealand, *Bioprospecting in New Zealand*, 5, para. 1.1.
- <sup>44</sup> A. Artuso, *Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing* (Binghamton, New York: The Haworth Press, 1997), 21.
- <sup>45</sup> *Ibid.*, 51 and 64 (“... the models and analytical techniques presented [by Artuso] can easily be applied to evaluate other natural product R&D programs. . .”).
- <sup>46</sup> In occasional cases, researchers acknowledge the use of biological research specimens used in connection with a valuable commercial application in other contexts (such as in patent documents).
- <sup>47</sup> Deutch, A., “Analysis of the NPS Research Permit Database for Calendar Year 2001,” (2002), on file at Yellowstone National Park.
- <sup>48</sup> L. Mallory, “Isolation of Cancer Chemotherapeutic Natural Products from Cave Microorganisms” (NPS Investigator’s Annual Report, 1994), available online at <<http://rprs.nps.gov/research/ac/iars/search/iarView?reportId=2698>>, last accessed October 24, 2008. This researcher has explained that the application of his initial research results to cancer research occurred only after his initial discovery that the microorganisms under study exuded compounds that interfered with the growth of competing microorganisms.
- <sup>49</sup> The results of a survey undertaken in 1998 by Yellowstone illustrated the difficulty of identifying “undeclared bioprospectors.” In that survey, some researchers who the park considered to be “bioprospectors” disavowed any intention of making commercially useful discoveries. On file at Yellowstone National Park.
- <sup>50</sup> See, e.g., Madigan and Marrs, “Extremophiles,” *Scientific American* (April 1997): 82–87.
- <sup>51</sup> See, e.g., Artuso, *Drugs of Natural Origin*, 120. It is noted that interpretation of available data on screening programs relating to drug discovery is complicated by no standard definition of such terms as “hit rate,” “active compounds,” or “drug leads” (*Ibid.*, 34). Additional variation could be expected when applied to other non-pharmaceutical industries. See also W. H. Lesser and A. F. Krattiger, “The Complexities of Negotiating Terms for Germplasm Collection,” *Diversity* 10(3), 6.

### Section 3.5 Social Resources: NPS Administrative Operations

<sup>52</sup> 16 USC 5933.

<sup>53</sup> National Park Service, *Agreements Handbook*, Chapter 7. (Washington, D.C.: Government Printing Office, 2003).

<sup>54</sup> National Park Service, *NPS Director's Order 20: Agreements* (2003), available online at <<http://www.nps.gov/policy/DOrders/DOrder20.html>>, last accessed March 15, 2006.

<sup>55</sup> *National Park Service Agreements Handbook*, available online at <<http://www.nps.gov/hfc/acquisition/agreements.htm>>, last accessed March 15, 2006.

<sup>56</sup> National Park Service, *NPS Director's Order 20: Agreements*.

<sup>57</sup> 16 USC 5932.

<sup>58</sup> See, e.g., National Park Service, *National Leadership Council Journal*, April 2001 and November 2002.

<sup>59</sup> See <<http://www.nature.nps.gov/learningcenters/centers.cfm>>, last accessed October 15, 2008.

<sup>60</sup> Cooperative Ecosystem Studies Unit matrix of current CESU units and partners, updated July, 2007, available online at <[http://www.cesu.psu.edu/materials/CESU\\_MATRIX\\_July2007.pdf](http://www.cesu.psu.edu/materials/CESU_MATRIX_July2007.pdf)>, last accessed October 15, 2008.

<sup>61</sup> National Park Service, Paperwork Reduction Act submission.

<sup>62</sup> The standardized General Conditions of NPS research permits read, in part, "The sale of collected research specimens or other unauthorized transfers to third parties is prohibited" (available online at <<http://rprs.nps.gov/research/ac/ResearchIndex>>, last accessed October 24, 2008).

<sup>63</sup> Most Business Plans prepared in 1999 (the first year of the Initiative) did not include FTE information.

# **Chapter 4**

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## **Environmental Consequences**

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## 4.1 Introduction

Chapter 4 examines the potential environmental consequences of the alternatives.

The analysis of Alternative A describes future conditions if the National Park Service (NPS) does not implement benefits-sharing. In this way, the potential for Alternatives B or C (whose potential impacts are described here) to improve or degrade these conditions can be examined. Accordingly, this FEIS informs NPS decisionmakers and the public about the effects of adopting each of the alternatives as compared to Alternative A (No Benefits-Sharing/No Action).

Council on Environmental Quality (CEQ) regulations for the National Environmental Policy Act (NEPA) require that agencies determine the environmental issues related to a proposed action that are “deserving of study” (40 CFR §1500.4, §1501.7), and discuss them in proportion to their significance (40 CFR §1502.2 (b)). This determination, and consequent level of discussion for each impact topic, is reflected in the Affected Environment chapter and is a necessary prelude to analysis.

Given its programmatic/planning nature, this FEIS describes the conditions under which certain activities may be conducted and provides potential general standards for management. As a result, the impact topics analyzed here do not represent traditional NEPA topics, such as wildlife or air quality (*see* Chapter 1, Section 1.1.1).

The NPS has proposed to implement benefits-sharing (Alternative B) as a way to improve two existing conditions: (1) the lack of legal clarity with respect to commercial use of NPS specimen-related research results (*see* Chapter 1, Section 1.3.1) and (2) the opportunity to further the current NPS goal of improving the availability of science for park management (“science for parks”; *see* Chapter 1, Section 1.3.2 *and* Chapter 3, Section 3.2.1).

The NPS benefits-sharing proposal (Alternative B) dedicates all benefits to resource conservation, the fundamental purpose of the national park system.<sup>1</sup> The NPS anticipates that benefits-sharing would be conducted through the use of Cooperative Research and Development Agreements (CRADAs), with any benefits generated under such CRADAs to be dedicated to the conservation of resources protected and managed by the NPS. CRADA benefits must be used for scientific purposes.<sup>2</sup> Therefore, this FEIS focuses on the scientific aspect of resource conservation and management.

### What is a CRADA?

A CRADA is defined by the Federal Technology Transfer Act of 1986 (FTTA) (15 USC 3710a et seq.) as “any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the mission of the laboratory. . . .” (15 USC 3710a(d)).

CRADAs offer a framework specifically authorized by statute under which private companies and other research collaborators can provide financial resources and expertise to a federal laboratory facility to augment its own research in exchange for rights in any resulting useful or valuable discovery arising from the research (15 USC 3710a).

## 4.2 Methodologies for Evaluating Impacts

This FEIS uses the approach outlined in the National Park Service (NPS) Handbook, *Conservation Planning, Environmental Impact Analysis, and Decision Making* to identify the intensity (or magnitude) and duration of impacts.

According to the Council on Environmental Quality regulations for implementing the procedural provisions of NEPA (40 CFR 1502.22), if certain information is essential to a reasoned choice among alternatives and the cost of gathering it is not excessive, it must be included or addressed in an EIS. Most of this information is described in Chapters 3 and 4. Additional information and analysis of potential monetary benefits to the NPS under Alternative B (Implement Benefits-Sharing) is presented in Appendix C. Every effort was made to gather all the necessary data needed for analyses in this EIS. Where data were unavailable or incomplete, a discussion of the data's relevance to an analysis and the use of best available data (if applicable) is included in the EIS. While additional information may add precision to estimates or better specify relationships, new or additional information is unlikely to significantly change the understanding of the relationships that form the basis of the effects analysis presented.

Mitigating measures described in Chapters 2 and 4 would be taken during implementation of the alternatives. All impacts have been assessed assuming that mitigating measures already have been implemented. Methodologies used to evaluate potential impacts for each impact topic are described below.

This analysis includes a description of whether impacts are beneficial or adverse, and short-term or long-term. The magnitude of the impact also is described in terms ranging from negligible to major. Impacts disclosed may be direct or indirect. The definition of the magnitude, or intensity, of the impact varies among impact topics, so individual definitions are provided for each. The following definitions apply in general to the impacts analysis.

**Table 4.2. Types and duration of impacts**

<b>Impact category</b>	<b>Definition</b>
<b>Beneficial impact</b>	A positive change in the condition or nature of the resource, usually with respect to a standard or objective. A change that moves a resource toward its desired condition or prevents a foreseeable decline in a resource already existing in its desired condition.
<b>Adverse impact</b>	A negative change in the condition or nature of the resource, usually with respect to a standard or objective. A change that moves a resource away from its desired condition.
<b>Direct impact</b>	An impact that is caused by an action and occurs at the same time and place.
<b>Indirect impact</b>	An impact that is caused by an action but is later in time or farther removed in distance, but is still reasonably foreseeable.
<b>Qualitative impact</b>	An impact that can only be measured by subjective comparison to objectives.
<b>Quantitative impact</b>	An impact that can be measured objectively, usually in numerical terms.
<b>Short-term impact</b>	An impact that in a short time after an action is taken will no longer be detectable. This FEIS considers any change that is evident for 5 years or less to be short-term.
<b>Long-term impact</b>	A change in a resource or its condition that remains evident for more than 20 years.

## 4.2.1 Natural Resource Management

Potential impacts to natural resource management are assessed by determining the extent to which each alternative changes conservation and protection of resources managed by the NPS by weakening or strengthening understanding of biodiversity and ecological processes (*see* Objective 2, Chapter 1, Section 1.4.2). Because the availability of scientific knowledge can impact natural resource management programs, the potential for each alternative to provide scientific knowledge to the NPS is the mechanism for assessing impacts to natural resource management (*see* Chapter 3, Section 3.2).

Qualitative analyses are based on foreseeing whether any changes in the availability of scientific knowledge pertinent to natural resource management goals (“science for parks”) would become available under Alternatives B or C. Alternative A (No Benefits-Sharing/No-Action) serves as a baseline against which to compare the effects of Alternatives B or C.

Qualitative aspects of “science for parks” can be provided by any of the non-monetary benefits described in Section 4.4.1.1.

Quantitative analysis of Alternative B (Implement Benefits-Sharing) compares potential monetary payments to park natural resource management funding levels as well as to servicewide funding attributed to the Natural Resource Challenge in fiscal year (FY) 2007. These comparisons are indicative of the level of intensity of potential impacts (*see* Chapter 3, Section 3.2.2).

Quantitative analysis of Alternative C (Prohibit Research Specimen Collection for Any Commercially Related Research Purposes) examines the proportion of independent researchers who could be expected to be excluded from park research or who could choose not to perform park research because of the prohibition on doing research intended to produce commercially applicable results.

### 4.2.1.1 *Impact intensity thresholds*

#### *Qualitative impact thresholds*

Qualitative impacts are analyzed in terms of the potential for Alternatives B or C to improve or degrade the availability of scientific knowledge to parks for natural resource management purposes.

**No impact:** The action results in no change in new scientific knowledge.

**Negligible:** The action results in a slight change in the availability of new scientific knowledge about park resources.

**Minor:** The action results in a change in the availability of new scientific knowledge about park resources that is directly related to a natural resource management priority.

**Moderate:** The action results in a change in the availability of new scientific knowledge about park resources that is directly related to several natural resource management priorities.

**Major:** The action results in a change in the availability of new scientific knowledge about park resources that is directly related to several natural resource management priorities and substantially affects the management of those resources.

### ***Quantitative impact thresholds***

Quantitative analysis of Alternative B (Implement Benefits-Sharing) compares potential monetary payments to individual park natural resource management funding levels as well as to servicewide FY2007 Natural Resource Challenge funding (*see* Chapter 3, Section 3.2.2).

Quantitative analysis of Alternative C (Prohibit Research Specimen Collection for Any Commercially Related Research Purposes) examines the proportion of independent researchers who could be expected to be excluded from park research.

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**Table 4.2.1. Intensity of quantitative impacts to natural resource management**

<b>Impact intensity</b>	<b>Equivalent to X% of individual park annual natural resource management funding levels</b>	<b>Equivalent to X% of servicewide FY2007 Natural Resource Challenge funding</b>
No impact	No payments	No payments
Negligible	Less than 10%	Less than 5%
Minor	10%	5%
Moderate	20%	10%
Major	35%	15%

**No impact:** The action results in no monetary payments to a park or to the National Park Service.

**Negligible:** The action results in monetary payments equivalent to less than 10% of a park's natural resource management funding level; or servicewide, to less than 5% of servicewide FY2007 Natural Resource Challenge funding.

**Minor:** The action results in monetary payments equivalent to 10–19% of a park's identified natural resource management funding level; or servicewide, to 5–9% of servicewide FY2007 Natural Resource Challenge funding.

**Moderate:** The action results in monetary payments equivalent to 20–34% of a park's identified natural resource management funding level; or servicewide, to 10–14% of servicewide FY2007 Natural Resource Challenge funding.

**Major:** The action results in monetary payments equivalent to more than 35% of a park's identified natural resource management funding level; or servicewide, to more than 15% of servicewide FY2007 Natural Resource Challenge funding.

#### **4.2.1.2 Contexts**

Potential impacts to natural resource management programs are analyzed in three contexts as listed below:

- 1) Servicewide effects;
- 2) Effects to Yellowstone National Park; and
- 3) Effects to other individual parks (Chapter 3, Section 3.5.3, describes the park units most likely to be affected by Alternative B).

Yellowstone National Park was selected for a park-specific analysis following review of the historical patent record. Between 1978 and 2007, the U.S. Patent Office issued at least 55 patents that involved research results related to the study of biological material originating in U.S. national parks, 53 from Yellowstone National Park and 2 from Yosemite. This record suggests that the majority of NPS benefits-sharing agreements could occur between researchers and Yellowstone.

## 4.2.2 Visitor Experience and Enjoyment

The availability of “science for parks” can affect the quality of interpretation as well as the quality of natural resource management, both of which affect visitor experience and enjoyment of parks (*see* Chapter 3, Section 3.3). The impact analysis in this section focuses qualitatively on the impacts to visitor experience and enjoyment from changes in the availability of scientific knowledge and assistance to interpreters.

Under Alternative B, specific interpretive services designed to enhance visitors’ understanding and acceptance of natural resource management goals would benefit from interpretively focused scientific education and training assistance or research. Research for interpretation could include, for example, site-specific research conducted to determine the effectiveness of various interpretive techniques in obtaining visitor compliance with park rules intended to protect natural resources.<sup>3</sup>

### 4.2.2.1 *Impact intensity thresholds*

Impacts are analyzed in terms of the potential for Alternatives B or C to improve or degrade the current availability of scientific knowledge and assistance that could be useful for interpretation related to natural resource protection.

**No impact:** The action results in no more or less new scientific knowledge or assistance to interpretive projects.

**Negligible:** The action results in a slight change in the availability of new scientific knowledge about park resources or scientific assistance to interpretation.

**Minor:** The action results in a noticeable change in the availability of new scientific knowledge about park resources or scientific assistance to interpretation.

**Moderate:** The action results in a readily apparent change in availability of new scientific knowledge about park resources or scientific assistance to interpretation.

**Major:** The action, if beneficial, results in an exceptional change in the availability of new scientific knowledge about park resources or scientific assistance to interpretation. If adverse, the action results in severely less scientific assistance for interpretation.

#### **4.2.2.2 Contexts**

Potential impacts to visitor experience and enjoyment are analyzed in three contexts as listed below:

- 1) Servicewide effects;
- 2) Effects to Yellowstone National Park (to learn why Yellowstone was selected for a park-specific analysis, *see* Section 4.2.1.2); and
- 3) Effects to other individual parks (Chapter 3, Section 3.5.3 describes the park units most likely to be affected by Alternative B).

### **4.2.3 Social Resources: The Research Community**

Several thousand scientists conduct studies each year involving national park research specimens. Some of these researchers could be affected by the alternatives described in this FEIS. Information about them was compiled from servicewide NPS Research Permit and Reporting System (RPRS) records.

#### **4.2.3.1 Impact intensity thresholds**

Impacts to the research community are characterized in terms of potential changes in the conditions researchers may encounter when performing NPS-related research. To assess these changes, three parameters are analyzed to determine impacts: change in administrative burden; change in the potential for researchers to realize economic gains related to commercialization of their research results; and change in how research specimen collections are authorized. Beneficial impacts are those that make a positive change in those conditions (less work, more economic gains, or more lenient specimen collection criteria). Adverse impacts would make a negative change (more work, fewer economic gains, or stricter specimen collection criteria). The intensity of impacts to a researcher's potential to realize economic gains from research results is indicated by the analysis of potential monetary benefits but not characterized as negligible-to-major because of the unpredictable and wide variety of potential commercial applications for research results (*see* Chapter 1, Section 1.2.4).<sup>4</sup>

**No impact:** The action results in researchers experiencing no change in administrative burden, potential economic gains, or research specimen collection authorization for researchers.

**Negligible:** The action results in researchers experiencing a slight but nearly undetectable change in administrative burden or a change in research specimen collection authorization that does not alter researchers' ability to conduct research.

**Minor:** The action results in researchers experiencing a slight but detectable change in administrative burden or a change in research specimen collection authorization; however, researchers may conduct similar research with specimens readily acquired elsewhere.

**Moderate:** The action results in researchers experiencing a readily apparent change in administrative burden for researchers or a change in research specimen collection authorization. Researchers may conduct similar research with specimens acquired with difficulty elsewhere.

**Major:** The action results in researchers experiencing an exceptional (beneficial) or severe (adverse) change in administrative burden for researchers or a change in research specimen collection authorization. Researchers cannot conduct similar research with specimens acquired elsewhere.

#### **4.2.3.2 Contexts**

Potential impacts to the research community are analyzed in five contexts as listed below:

- 1) Declared bioprospectors;
- 2) Inadvertent bioprospectors;
- 3) Undeclared bioprospectors;
- 4) Researchers who transfer NPS research specimens or other material originating as an NPS research specimen to third parties or who receive such transfers; and
- 5) All other researchers (*see* Chapter 3, Section 3.4).

#### **4.2.4 Social Resources: NPS Administrative Operations**

Potential impacts to NPS administrative operations are related to the administrative burden to the NPS anticipated to result from implementation of each alternative. Information about the administrative burden pertinent to each alternative is derived from available NPS Business Plans and the administrative effort associated with the commercial use of research results in academic institutions. Administrative effort is measured in terms of FTE, used in this FEIS to indicate the amount of work that can be performed in one year by one full-time employee. A beneficial impact would result if parks needed fewer FTE to perform administrative functions. An adverse impact would result if more FTE were required.

##### **4.2.4.1 Impact intensity thresholds**

Impacts are analyzed in terms of any changes in FTE required for administrative functions.

**No impact:** The action results in no changes in FTE required for administrative functions.

**Negligible:** The action results in a change equivalent to less than 10% of a park's available administrative FTE, or a very small number of FTE servicewide.

**Minor:** The action results in a change equivalent to at least 10%, but less than 20% of a park's available administrative FTE.

**Moderate:** The action results in a change equivalent to at least 20%, but less than 35% of a park's available administrative FTE.

**Major:** The action results in a change equivalent to at least 35% or more of a park's available administrative FTE.

##### **4.2.4.2 Contexts**

Potential impacts to NPS administrative operations were analyzed in three contexts as listed below:

- 1) Servicewide effects;

- 2) Effects to Yellowstone National Park (to learn why Yellowstone was selected for a park-specific analysis, *see* Section 4.2.1.2); and
- 3) Effects to other individual parks.

### 4.2.5 Impairment

In addition to determining the environmental consequences of the preferred and other alternatives, NPS policy requires analysis of potential effects to determine whether or not actions would impair park resources.<sup>5</sup>

The fundamental purpose of the National Park System, established by the National Park Service Organic Act and reaffirmed by the General Authorities Act, as amended, begins with a mandate to conserve park resources and values. NPS managers must always seek ways to avoid, or to minimize to the greatest degree practicable, adverse impacts on park resources and values. However, the laws do give the NPS the management discretion to allow impacts to park resources and values when necessary and appropriate to fulfill the purposes of a park, as long as the impact does not constitute impairment of the affected resources and values. Although Congress has given the NPS the management discretion to allow certain impacts within parks, that discretion is limited by the statutory requirement that the NPS must leave park resources and values unimpaired, unless a particular law directly and specifically provides otherwise. Prohibited impairment is an impact that, in the professional judgment of the responsible NPS manager, would harm the integrity of park resources or values, including the opportunities that otherwise would be present for the enjoyment of those resources or values. An impact to any park resource or value may constitute an impairment. An impact would be more likely to constitute an impairment to the extent that it affected a resource or value whose conservation is:

- Necessary to fulfill specific purposes identified in the establishing legislation or proclamation of the park;
- Key to the natural or cultural integrity of the park or to opportunities for enjoyment of the park; or
- Identified as a goal in the park's general management plan or other relevant NPS planning documents.

Impairment may result from NPS activities in managing the park, visitor activities, or activities undertaken by concessioners, contractors, and others operating in the park.

This FEIS analyzes the possible environmental impacts of choosing whether or not to implement a certain type of contract; hence, its affected environment and impact topics relate primarily to administrative functions of the NPS. Impairment analyses only apply to natural and cultural resource topics, and do not apply to topics involving visitor use, social resources, or park operations. Therefore, because this document does not carry forward natural or cultural resource topics, impairment will not be analyzed further in this FEIS.

### 4.2.6 Cumulative Impacts

The CEQ defines “cumulative impacts” as the impacts to the environment that result from the incremental impact of each action when added to other past, present, and reasonably foreseeable future actions, regardless of what agency (federal or non-federal) or person

undertakes such actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.<sup>6</sup> A cumulative scenario is a description of other past, present, and reasonably foreseeable future actions. The cumulative scenario for each impact topic is described in the impact analyses for Alternative A.

## **4.3 Alternative A: No Benefits-Sharing/No Action**

Alternative A (No Benefits-Sharing/No Action) represents the current NPS approach to benefits-sharing when commercial use of new discoveries, inventions, and other valuable developments results from scientific research involving NPS resources. Under current practice, the NPS does not implement any benefits-sharing arrangements with the research community.

This alternative serves as a baseline against which to compare the other alternatives. The following sections examine the impacts of choosing not to implement benefits-sharing. Long-term impacts are analyzed over the 20-year period following implementation of the decision following this environmental analysis. This FEIS considers any change that is evident for five years or less to be short-term.

### **4.3.1 Impacts to Natural Resource Management**

Sound management of park resources is the central NPS mission. Scientific research is a vital part of resource stewardship. The scientific contribution to natural resource management is described in Chapter 3, Section 3.2.

#### **4.3.1.1 Servicewide impacts**

Choosing not to implement benefits-sharing under Alternative A (No Benefits-Sharing/No Action) would have neither adverse nor beneficial impacts on NPS natural resource management.

NPS programs and initiatives unrelated to benefits-sharing that impact natural resource management are reviewed in the cumulative scenario (Section 4.3.1.6). In the long term, these programs are expected to improve servicewide natural resource management, but Alternative A's choice to not implement benefits-sharing will have no impact on natural resource management at the servicewide level since no change would occur to the availability of scientific knowledge pertinent to natural resource management goals and no additional funding would be made available for natural resource management.

#### **4.3.1.2 Yellowstone-specific impacts**

Choosing not to implement benefits-sharing under Alternative A (No Benefits-Sharing/No Action) would have adverse impacts on Yellowstone National Park's natural resource management program.

Under Alternative A, the CRADA between Yellowstone National Park and Diversa Corporation, currently suspended, would be nullified. Non-monetary benefits would have been the primary benefit resulting from this CRADA. For example, under the terms of that

CRADA, Diversa used its proprietary techniques and databases to perform two genetic analyses needed for Yellowstone natural resource management at no cost to the park (*see* Appendix F). Additional non-monetary benefits that would have accrued to Yellowstone during the remainder of the Yellowstone–Diversa CRADA’s term would not occur under Alternative A. It is not known what these non-monetary benefits would have been.

All monetary benefits provided to Yellowstone by Diversa pursuant to the CRADA during the brief period of less than a year when the CRADA was active prior to suspension of the agreement would be returned to Diversa. The CRADA’s provision for an up-front payment of \$20,000 per year for five years would have been equivalent in total to 1.14% of the FY2002 operational funding for natural resource management identified in Yellowstone’s Business Plan (*see* Chapter 3, Section 3.2.2). Accordingly, the loss of this payment alone represents a quantitative short-term, adverse, negligible impact on Yellowstone’s natural resource management program.

In addition, Diversa also would not make any performance-based payments to the park whether resulting from development of Pyrolase 200™ or from any other product Diversa has developed from its research activities involving material originally collected in Yellowstone (*see* Section 4.4.2.4 and Chapter 1, Section 1.2.4.2). The amount of these payments cannot be determined because Diversa’s financial reporting obligations under the CRADA are also currently suspended, as are its invention disclosure and related reporting obligations to the NPS. As a result, it is not known whether Diversa has developed any additional products from its research activities involving material originally collected in Yellowstone that might generate additional payment obligations.<sup>7</sup> Therefore, the intensity of the long-term adverse impact of Alternative A to Yellowstone natural resource management over the next 20 years cannot be determined.

#### **4.3.1.3 Individual park impacts**

Choosing not to implement benefits-sharing under Alternative A (No Benefits-Sharing/ No Action) would have neither adverse nor beneficial impacts on individual park natural resource management programs.

NPS programs and initiatives unrelated to benefits-sharing that impact natural resource management are reviewed in Section 4.3.1.6 (the cumulative scenario). In the long term, these programs are expected to improve natural resource management in the approximately 270 individual parks with significant natural resources, but Alternative A’s choice to not implement benefits-sharing will have no impact on natural resource management in any of these parks<sup>8</sup> since no change would occur to the availability of scientific knowledge pertinent to natural resource management goals and no additional funding would be made available for natural resource management.

#### **4.3.1.4 Mitigation measures**

The NPS has not identified any additional mitigation measures (mitigation measures are described *in* EIS Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5).

#### **4.3.1.5 Conclusion**

Under Alternative A, the NPS would choose not to implement benefits-sharing. The NPS would continue to manage its natural resources with the scientific tools and knowledge made

available to it through projects and programs unrelated to benefits-sharing. The wide variety of NPS programs that encourage production and use of scientific knowledge for natural resource management purposes would continue. Resource-management-based cooperative research projects with independent researchers would continue to be conducted.

Alternative A would have a negligible, short-term, adverse impact and a long-term adverse impact of unknown intensity to Yellowstone natural resource management, and no impacts to natural resource management servicewide or to other individual parks.

#### **4.3.1.6 Cumulative impact scenario**

Many actions unrelated to benefits-sharing also affect management of natural resources in the NPS by influencing the availability of useful scientific knowledge. The programs described below each serve to improve natural resource management by enhancing the availability of scientific knowledge necessary for effective park resource management decisions.

The most significant of these actions was the passage, in 1998, of the National Parks Omnibus Management Act (NPOMA). NPOMA specifically declares that scientific study is an authorized use of parks and directs the NPS to seek scientific knowledge for resource management purposes and also to allow study of park resources to the benefit of broader scientific goals. NPOMA directs the National Park Service to implement several of the programs that were subsequently incorporated into the NPS Natural Resource Challenge.

Initiated in 1999, the NPS Natural Resource Challenge requires active, informed management based on sound science. It enlists the skills and talents of research partners to develop the scientific information needed to make effective management decisions. In FY2007, the total annual funding for the Natural Resource Challenge was approximately \$78 million.

The linchpin of the NPS Natural Resource Challenge is the Inventory and Monitoring (I&M) Program, specifically required by NPOMA. The I&M Program provides the information needed to understand and measure performance regarding the condition of resources in parks, including the condition of watersheds, landscapes, marine resources, and biological communities. This information guides park management actions to improve and sustain the health of park resources. By the end of FY2007, all 270 parks with significant natural resources (100%) had identified their vital signs, 197 (73%) had completed the design of their state-of-the-art monitoring plans and implemented vital signs monitoring, and 157 (58%) had completed at least one year of field data collection. In FY2006, \$43 million was allocated for this program.

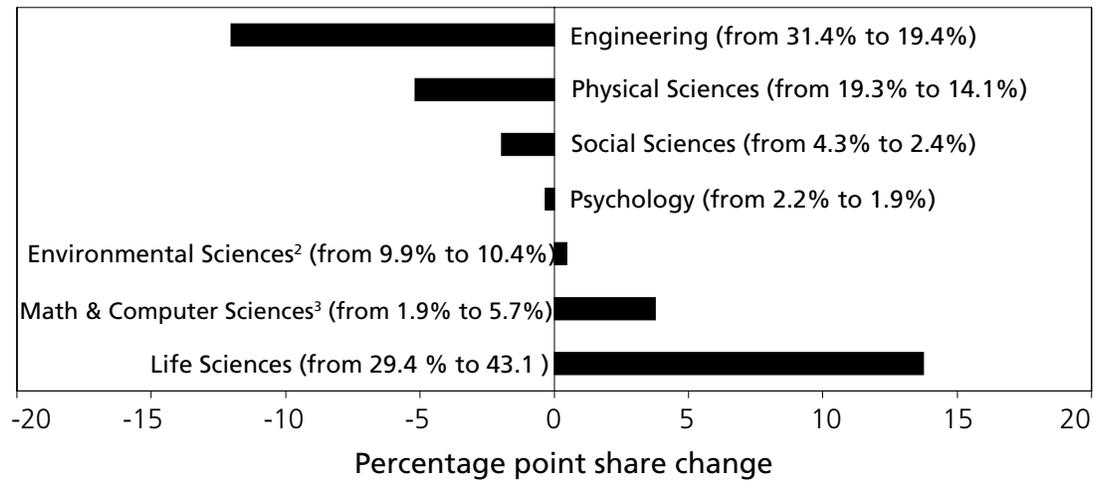
The NPS participates in 17 Cooperative Ecosystem Studies Units (CESUs) to conduct cooperative multi-disciplinary research about NPS resources. CESUs are another program supported by the Natural Resource Challenge and required by NPOMA which provides research, educational opportunities, and technical assistance in the biological, physical, social, and cultural sciences necessary to manage NPS natural and cultural resources.<sup>9</sup> As of July 2007, there were 13 federal agencies, 176 universities, and 40 other partners involved in CESUs.

Other actions that continue to have a significant influence on management of NPS natural resources include partnerships with scientists and other agencies to improve the scientific

knowledge necessary for natural resource management decision-making. For example, in 56 parks, the NPS and USGS have water quality partnerships that provide information related to specific natural resource management needs for parks. Other partnerships, such as the USGS volcano observatories at several national parks and the national visibility monitoring network funded and operated by the U.S. Environmental Protection Agency, the NPS, individual U.S. states, and other land management agencies perform long-term monitoring of park conditions.

In all contexts (servicewide, Yellowstone National Park and other individual parks), NPS programs and initiatives to acquire new scientific knowledge for the management of natural resources, especially those related to NPOMA and the Natural Resource Challenge will continue to have beneficial impacts on management of natural resources.

**Figure 4.3.1.6. Changes in Field Shares of Total Federal Research Funding, 1970–1997<sup>1</sup>**



Note: Other sciences not classified within one of the broad fields listed above are excluded.  
 Source: National Science Foundation, Division of Science Resources Studies, Survey of Federal Funds for Research and Development.

<sup>1</sup>This analysis deals with federal funds that support basic and applied research, but not development.  
<sup>2</sup>In a number of surveys and reports, the designation earth, atmospheric, and oceanographic sciences is used in lieu of environmental sciences.  
<sup>3</sup>These two fields were reported together through 1975.

Figure 4.3.1.6. In addition to a general increase in funding for research, the balance of all federal research funding shifted over the last three decades. In 2003, life sciences research was estimated to account for 54% of federal research funding.<sup>10</sup>

In addition, actions entirely outside the control of the NPS also influence the availability of scientific knowledge for the management of natural resources. Because most of the research involving NPS resources is not funded by the NPS, decisions made by other funding entities affect the availability of scientific knowledge about parks resources. Many researchers who study park research specimens rely on grants from federal agencies to fund their work.<sup>11</sup> Federal obligations for research have grown at different rates for different disciplines, reflecting changes in perceived public needs in those fields, changes in available resources (e.g., scientists, equipment, and facilities), as well as differences in scientific opportunities across disciplines. For example, as shown in Figure 4.3.1.6, federal funding priorities shifted

to the life sciences in the 1990s. More funding was available to researchers studying life sciences in parks. Since 78% of NPS research projects reported in 2001 were in the life sciences, this shift in federal funding emphasis may have had an impact on the scientific knowledge available for management of NPS natural resources.

#### **4.3.1.7 Cumulative impacts**

The NPS programs and initiatives described in the cumulative scenario are expected to have a beneficial long-term cumulative impact on NPS natural resource management in all contexts by providing additional scientific knowledge for park management decisions. The negligible adverse impact Yellowstone might experience in the short-term over the return of monetary benefits to Diversa would not demonstrably alter the cumulative impact to Yellowstone's management of natural resources. Although the intensity of the long-term adverse impact of Alternative A to Yellowstone natural resource management cannot be determined, this impact would contribute to any other potential cumulative decreases. In all contexts, the impacts that result from not implementing benefits-sharing under Alternative A would not demonstrably add to the cumulative impact of actions outlined in the cumulative scenario.

### **4.3.2 Impacts to Visitor Experience and Enjoyment**

Visitor experience and enjoyment can be affected by the quality and quantity of natural resource information provided to interpreters for use in developing interpretive services for visitors. NPS interpreters must rely on accurate and detailed information about park natural resources to become knowledgeable about the condition of their respective parks and their resources and for developing interpretive material for the public including effective programs, exhibits, and publications that optimize visitor experience and enjoyment. Under Alternative A, the NPS would continue to provide interpretive services to visitors using the available information from scientific research.

#### **4.3.2.1 Servicewide impacts**

Choosing not to implement benefits-sharing under Alternative A (No Benefits-Sharing/No Action) would have neither adverse nor beneficial impacts on NPS visitor experience and enjoyment.

In the long term, the programs described in Section 4.3.2.6 are expected to provide additional natural resource knowledge for development of interpretive services, but Alternative A's choice to not implement benefits-sharing will have no impact on visitor experience and enjoyment.

#### **4.3.2.2 Yellowstone-specific impacts**

The potential for Yellowstone-specific impacts is the same as described for the servicewide analysis in Section 4.3.2.1. Alternative A would result in no impacts.

#### **4.3.2.3 Individual park impacts**

The potential for individual park impacts is the same as described for the servicewide analysis in Section 4.3.2.1. Alternative A would result in no impacts.

#### **4.3.2.4 Mitigation measures**

The NPS has not identified any additional mitigation measures (mitigation measures are described in EIS Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5).

#### **4.3.2.5 Conclusion**

Under Alternative A, the NPS would choose not to implement benefits-sharing. The NPS would continue to plan and conduct interpretive services using the available scientific tools and knowledge. There would be no impacts to visitor experience and enjoyment as a result of implementing Alternative A.

#### **4.3.2.6 Cumulative impact scenario**

The cumulative scenario discussed in this section focuses on past, present and reasonably foreseeable actions that could affect visitor experience and enjoyment through potential impacts to NPS interpretive services at the servicewide, Yellowstone National Park and individual park level. When combined with the potential effects of each alternative individually, this scenario forms the basis of the cumulative effects analysis for this topic.

The National Park Service provides interpretive services to visitors at over 350 units of the National Park System as well as through the internet. In recent years, NPS interpretive services have been most significantly improved by the implementation of Comprehensive Interpretive Plans (CIP) and the NPS Interpretive Development Program (IDP). Individual parks prepare CIPs to identify priorities for park interpretative and educational programs and informational services with the express purpose of improving visitor experiences. IDPs define professional standards for NPS interpreters through a national benchmark curriculum. Along with a companion training aid, “Meaningful Interpretation: How to Connect Hearts and Minds to Places, Objects, and Other Resources,” IDPs have greatly improved the quality of interpretive services provided to the public. IDPs identify elements necessary for effective interpretation including knowledge of the resource, knowledge of the audience and application of appropriate techniques for interpretation.

In addition, parks use partnerships to expand or improve their interpretive services, thus improving visitor experiences. For example, Yellowstone National Park recently convened a group of scientific experts to plan and review the content of displays for two new visitor centers. In 2001, 62 parks reported progress within such partnerships. The recently established NPS Education Council is charged with expanding the NPS’s existing educational partnerships and establishing new ones which is expected to further improve visitor experiences.

Overall, the cumulative impacts of the NPS programs and initiatives described in the cumulative scenario are expected to have a beneficial long-term impact on visitor experience and enjoyment in all contexts by improving NPS interpretive services.

#### **4.3.2.7 Cumulative impacts**

Benefits-sharing would not be implemented under Alternative A, therefore no change to NPS interpretive services or additional impact on visitor experience and enjoyment would result in the Servicewide, Yellowstone, or individual park context. Alternative A provides no demonstrable addition to the total beneficial cumulative impact on visitor experience and

enjoyment from actions outlined in the cumulative scenario.

### **4.3.3 Impacts to Social Resources: The Research Community**

Under Alternative A, any qualified researcher would be eligible to obtain an NPS research permit in accordance with NPS regulations and guidelines, regardless of whether the research activities might lead to commercially valuable discoveries.

#### ***4.3.3.1 Impacts to declared, inadvertent, and undeclared bioprospectors***

Under Alternative A, if valuable discoveries, inventions, and other developments resulting from study of research specimens lawfully collected from NPS units were commercially developed, the researcher's institution could realize economic gains without obligation to share any income with the NPS.<sup>12</sup> However, very few researchers—perhaps less than 0.5% of those holding NPS research permits—would be affected (*see* Chapter 3, Section 3.4). For this very small minority of researchers, the absence of a benefits-sharing obligation would be a long-term, negligible, beneficial impact (*see also* Section 4.4.4.1).

Under Alternative A, the Yellowstone–Diversa CRADA would be nullified and Diversa would have no benefits-sharing obligations to Yellowstone or the NPS. Accordingly, Diversa would experience a potentially long-term, negligible, beneficial impact.

#### ***4.3.3.2 Impacts to researchers who transfer or receive transferred NPS research specimens or other material originating as an NPS research specimen originally collected in a national park unit***

Under Alternative A, researchers who transfer or receive transferred NPS research specimens or other material originating as an NPS research specimen that is not suitable for permanent retention as a museum collection would continue to work with the different forms, processes, and requirements unique to each park. Even without a standardized Material Transfer Agreement (MTA), the specimen transfer process is expected to take considerably less time than the 1.6 hours estimated for completion of a research permit application and Investigator's Annual Report (IAR), and be similar to the work required to transfer park-cataloged specimens through loan agreements. Accordingly, implementation of Alternative A would have a long-term, negligible, adverse impact on third-party researchers as well as to any researchers who wish to supply third-party researchers with research specimens since these researchers would experience a slight but nearly undetectable change in their overall workload.

#### ***4.3.3.3 Impacts to all other researchers***

All other researchers would experience no impact from Alternative A's choice to not implement benefits-sharing.

#### ***4.3.3.4 Mitigation measures***

The NPS has not identified any additional mitigation measures (mitigation measures are described *in* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5).

#### ***4.3.3.5 Conclusion***

Implementation of Alternative A would have long-term, negligible, beneficial impacts on

researchers who make valuable discoveries during their research involving NPS scientific research specimens (some declared, some undeclared, and some inadvertent bioprospectors).

Implementation of Alternative A would have a long-term, negligible, adverse impact on researchers who transfer or receive transferred specimens or material originating as an NPS research specimen originally collected in an NPS unit.

Implementation of Alternative A would have no impact on all other researchers.

#### **4.3.3.6 Cumulative impact scenario**

The most important factor influencing researchers who study material originating as an NPS research specimen is whether their proposed research project receives funding. The federal government's research funding priorities have the most impact on NPS permitted researchers because most NPS research permittees (81% in 2001) are either affiliated with federal institutions or affiliated with academic institutions that receive the majority of their research funding from the federal government.<sup>13</sup> Future changes in funding availability cannot be foreseen in detail. Accordingly, funding changes could have either a beneficial or an adverse impact to the researchers described in this FEIS.

Nearly as important to researchers is the support offered them by the institution with which they are affiliated. Modern research is seldom conducted by a single individual in the field or at a desk. More often, research relies on sophisticated laboratories and the assistance of colleagues, students, and employees. Institutional support is usually essential for the performance of research. Because academic institutions are increasingly creating the infrastructure to translate research results into products that are distributed to the public through the marketplace, it is expected that institutional support of using NPS-related research results for commercial purposes will increase in the future, a beneficial impact to the researchers described in this FEIS.

Researchers are also influenced by the availability of scientifically significant resources for study. As home to relatively intact natural systems, the National Park System offers important opportunities for investigating scientific questions. The designation of 38 national park units as biosphere reserves and world heritage sites largely reflects the international scientific significance of these resources. The value of national parks as scientific laboratories will continue to grow in the face of accelerating local, regional, and global causes of environmental change and declining biological diversity, because the national parks contain precious information-gathering potentials that are not available anywhere else.<sup>14</sup> Researchers who are able to study park resources experience a beneficial impact from the availability of NPS-protected resources for scientific study.

The most important past, present or future action affecting the researchers described in this FEIS is the availability of funding for research. Both institutional support and park resource availability are expected to provide beneficial impacts for these researchers; however changes in funding availability, when combined with the impacts of other actions outlined in the cumulative scenario, could result in either a beneficial or adverse overall cumulative impact to the researchers described in this FEIS.

#### **4.3.3.7 Cumulative impacts**

The negligible impacts that result from the actions of Alternative A (negligible beneficial impacts to some declared bioprospectors, some undeclared bioprospectors, and inadvertent bioprospectors as well as negligible adverse impacts to researchers who participate in material transfers) would not demonstrably alter the cumulative impact of actions outlined in the cumulative scenario. The actions of Alternative A would have no impact to most researchers described in this FEIS, therefore there would be no demonstrable addition to the total cumulative impact these researchers experience from other sources.

### **4.3.4 Impacts to Social Resources: NPS Administrative Operations**

Under Alternative A, the requirement currently contained in the standardized NPS research permit General Conditions for negotiation of benefits-sharing agreements prior to any use of research results for commercial purposes would be deleted and not enforced. In addition, Alternative A would not provide a standardized MTA for use by parks when authorizing transfers of NPS research specimens or other material originating as an NPS research specimen originally collected in a national park unit (*see* Chapter 1, Section 1.3.1).

#### **4.3.4.1 Servicewide impacts**

Choosing not to implement benefits-sharing under Alternative A (No Benefits-Sharing/No Action) would have neither adverse nor beneficial impacts on NPS administrative operations.

Because Alternative A would not provide a servicewide standardized MTA for park use, it would not resolve the confusion some parks encounter regarding when to request specimen transfer authorizations and how to act upon such requests. There is no established systematic way to estimate the number of specimen transfer authorizations issued servicewide. However, the existing level of confusion appears to be minimal and does not constitute a significant adverse impact. Precise characterization of this impact is not essential to a reasoned choice among the alternatives. The impact of choosing not to standardize MTAs is expected to be long-term, adverse, and negligible on NPS administrative operations.

#### **4.3.4.2 Yellowstone-specific impacts**

Choosing not to implement benefits-sharing under Alternative A (No Benefits-Sharing/No Action) would have neither adverse nor beneficial impacts on Yellowstone National Park's administrative operations.

Alternative A does not provide a servicewide standardized MTA for individual park use. However, in the year 2000 Yellowstone National Park adopted a standardized MTA for authorization to transfer material originating as an NPS research specimen. Although Yellowstone has an existing administrative workload from executing MTAs, Alternative A would make no change to this workload, and as a result there would be no impact to Yellowstone administrative operations (*see* Section 4.2.4).

#### **4.3.4.3 Individual park impacts**

Choosing not to implement benefits-sharing under Alternative A (No Benefits-Sharing/No Action) would have neither adverse nor beneficial impacts on individual park administrative operations.

Alternative A does not provide a servicewide standardized MTA for individual park use and would not resolve the confusion some parks encounter regarding when to request specimen transfer authorizations and how to act upon such requests. There is no established systematic way to estimate the number of specimen transfer authorizations issued servicewide. However, the existing level of confusion appears to be minimal and does not constitute a significant adverse impact. Precise characterization of this impact is not essential to a reasoned choice among the alternatives. In the long term, the impact of choosing not to standardize MTAs is expected to be adverse and negligible on individual park administrative operations.

#### **4.3.4.4 Mitigation measures**

The NPS has not identified any additional mitigation measures (mitigation measures are described *in* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5).

#### **4.3.4.5 Conclusion**

Under Alternative A, the NPS would choose not to implement benefits-sharing nor to introduce a servicewide standardized MTA. The result would be long-term, adverse, negligible impacts servicewide, no impacts to Yellowstone, and long-term, adverse, negligible impacts to individual parks.

#### **4.3.4.6 Cumulative impact scenario**

The cumulative scenario discussed in this section focuses on past, present and reasonably foreseeable actions that could affect NPS administrative operations at the servicewide, Yellowstone National Park and individual park level. When combined with the potential effects of each alternative individually, this scenario forms the basis of the cumulative effects analysis for this topic.

Impacts to NPS administrative operations were evaluated in this EIS by examining staffing (expressed in FTE's) needed to administer benefits-sharing agreements and comparing the requirements of each alternative to available FTEs. The most important general influence on NPS administrative staffing at all levels is the funding made available by annual Congressional appropriations. In the recent past, the annual appropriation for the Operation of the National Park System (ONPS) has risen from \$1.36 billion in FY2000 to an estimated \$1.68 billion in FY2005. Although ONPS funding has risen in recent years, so have various costs including wages. It is reasonable to expect that ONPS funding levels will fluctuate in the future. In addition, the proportion of ONPS funds allocated to the various functions of NPS operations cannot be foreseen in detail. These factors complicate characterization of the impacts of the cumulative scenario. Given these uncertainties, the cumulative impact analyses that follow draw on past experience and reasonably foreseeable actions related to NPS staffing levels.

#### **4.3.4.7 Cumulative impacts**

The negligible adverse impacts of Alternative A servicewide and to individual parks would not demonstrably alter the cumulative impact of other actions outlined in the cumulative scenario. The actions of Alternative A would have no impact to administrative operations in Yellowstone National Park, therefore, Yellowstone would also experience no cumulative impacts associated with the actions of Alternative A.

### **4.3.5 Irreversible and Irretrievable Commitments of Resources**

Alternative A reveals the possible environmental impacts of choosing not to implement a certain type of contract; hence, the nature of this FEIS is such that its affected environment and impact topics relate primarily to administrative functions of the NPS, rather than to natural or cultural resources. Therefore, Alternative A would not result in the long-term or permanent loss of any resources.

### **4.3.6 Relationship Between Short-Term Uses of the Environment and Maintenance and Enhancement of Long-Term Productivity**

Alternative A applies to the role of the NPS in management of research results and not to the use or productivity of the environment. Neither short-term uses of the environment nor long-term productivity of the environment would be affected by actions proposed by Alternative A.

### **4.3.7 Adverse Effects that Cannot Be Avoided**

The action of this alternative will not result in any greater-than-negligible adverse impacts.

## **4.4 Alternative B: Implement Benefits-Sharing**

Under Alternative B, benefits-sharing could be expected to occur at Yellowstone National Park and other parks, especially those that are already aware of current or potential bioprospectors and those that have already hosted independent research activities (*see* Chapter 3, Section 3.5.3). Long-term impacts are analyzed over the 20-year period following implementation of the alternative. This FEIS considers any change that is evident for five years or less to be short-term.

The NPS has identified CRADAs as the agreement type for implementing benefits-sharing under Alternative B (*see* Chapter 2, Section 2.3).

### **4.4.1 Possible “Benefits” in Benefits-Sharing Agreements**

Under Alternative B, two different types of benefits could accrue to the NPS: non-monetary and monetary. Non-monetary benefits could include knowledge and research relationships, training and education, research-related equipment, or special services (such as laboratory analyses). Monetary benefits could generally take two forms: up-front funding for research projects that support the park’s research activities or performance-based payments paid as a percentage of any CRADA-related income received by a researcher’s institution.<sup>15</sup>

All benefits received by the NPS under any type of benefits-sharing agreement would be dedicated to the conservation of resources protected and managed by the NPS.

Individual park units that are federal laboratories would retain and use the benefits from a benefits-sharing agreement. The Federal Technology Transfer Act of 1986 (FTTA) provides for the disposition of royalties or other income resulting from developments arising from CRADA-related cooperative research.<sup>16</sup> Any funds received by the NPS from CRADA-related activities would be managed in compliance with these provisions.<sup>17</sup>

**Table 4.4.1. Potential benefit types and timing generated by a single CRADA**

	<b>Short-term</b>	<b>Long-term</b>
<b>Non-monetary</b>	Knowledge and research relationships, training or education, research-related equipment, or special services	Similar non-monetary benefits possible
<b>Up-front monetary</b>	Funding for park research (not expected in every agreement)	n/a
<b>Performance-based monetary</b>	Payment based on researcher’s “other license income” related to licensing of intermediate research results	Payment based on researcher’s income related to commercial use of research results (e.g., royalties on product sales)

Table 4.4.1. The potential benefits that could be generated by a benefits-sharing agreement are summarized in Table 4.4.1, discussed below in Sections 4.4.1.1–4.4.1.3, and discussed in more detail in Appendix C.

#### **4.4.1.1 Non-monetary benefits**

The NPS has identified four types of non-monetary benefits that could occur under some or all benefits-sharing agreements: knowledge and research relationships, training and education, research-related equipment, and special services (such as laboratory analyses).

The NPS expects that non-monetary benefits would be the primary benefit resulting from any benefits-sharing agreement. Non-monetary benefits could help address the goal of “science for parks” identified as a primary component of the Natural Resource Challenge. The NPS cannot afford to fund all of the research required for the problem-solving needs of the National Park System, some of which could be provided as non-monetary benefits (*see* Chapter 3, Section 3.2). For most parks, a benefits-sharing agreement that provided non-monetary benefits could represent a substantial increase in the amount of scientific knowledge either directly reported by independent scientists or discovered with their support (*see also* Chapter 3, Section 3.2). Each non-monetary benefit can add materially to a park’s ability to protect its resources and therefore meet the fundamental purpose of the National Park System, which begins with a mandate to conserve park resources and values.<sup>18</sup>

Non-monetary benefits, such as scientific equipment for research to answer management related questions and improve knowledge about park resources, would also be particularly useful for improving the NPS’s consideration of all reasonably foreseeable environmental effects of its proposed actions, as recommended by the Council on Environmental Quality (*see* Chapter 3, Section 3.2).

Each benefits-sharing agreement would be individually negotiated, and the particular knowledge and capabilities of the benefits-sharing researcher partner would determine the specific non-monetary benefits for each agreement. Accordingly, the expected values of non-monetary benefits in agreements were not assigned a hypothetical dollar equivalent value for this analysis.

Four types of non-monetary benefits were identified as likely to occur under some or all benefits-sharing agreements.

### ***Knowledge and research relationships***

The NPS believes that the benefits derived from the sharing of resource knowledge and the establishment of enhanced collaborative research relationships would be the most valuable component of a benefits package. The potential knowledge and research relationships from a benefits-sharing agreement could have both quantitative and qualitative dimensions. Quantitatively, the value of knowledge might be measured in dollars that the NPS otherwise would have had to expend to produce the same information. Qualitatively, the importance of information about park resources can be greater than the simple cost to produce information would indicate. In addition, the improved relationship between an independent researcher and the NPS that could be created by a benefits-sharing agreement could lead to unexpected and substantial benefits to the NPS. The value of these qualitative dimensions cannot be quantified.

### ***Training and education***

The value of training or education could have both quantitative and qualitative dimensions. Quantitatively, the value might be measured in dollars that the NPS otherwise would have had to expend to obtain the same training and education for its employees. Qualitatively, the value added to a park, or to the NPS, as a result of a person gaining training or education can be substantially greater than the initial cost of the training. For example, if an NPS employee attends a workshop about natural resource management, that employee might make a recommendation that saves a park many times the cost of the original training, because better decisions today can lower future costs. However, in terms of value added, the value of training and education, though substantial, cannot be quantitatively calculated.

### ***Research-related equipment***

The complete “value” of research-related equipment received by a park could have quantitative and qualitative dimensions. Quantitatively, its value might be measured in dollars that the NPS otherwise would have had to expend to obtain the same research-related equipment, and would be reported under Alternative B. Qualitatively, the value of research-related equipment can be greater than its initial retail value, because that equipment can be put to work on behalf of the park for a substantial amount of time. For example, a camera provided to a park and used to document wildlife migration could provide a resource management value many times greater than the retail cost of the camera. However, the additional value attributable to the use of otherwise unavailable research-related equipment, though substantial, cannot be quantitatively calculated.

### ***Special services***

Special services are specialized work functions for which the NPS has no equivalent function.

In such cases, the NPS either relies on contractors to produce these services when needed or foregoes their acquisition entirely. Common examples include DNA analysis and/or chemical and biochemical analysis. The value of these special services could have both quantitative and qualitative dimensions. Quantitatively, their value might be measured in dollars that the NPS otherwise would have had to expend to obtain the same special services through contracting. This quantitative retail value would be reported under Alternative B. However, the qualitative value of special services could be even greater. For example, the DNA analyses performed by Diversa on the Yellowstone wolf population had a retail cost equivalent, but the real value of these analyses included the production of new knowledge with substantial qualitative dimensions. New information was revealed about wolf reproductive relationships in the wild; managers can use that information to assess the genetic health of the population (*see* Appendix F).

#### **4.4.1.2 Monetary benefits**

Potential annual monetary benefits were estimated both in terms of a single benefits-sharing agreement and in cumulative terms for the entire proposed benefits-sharing program. Appendix C contains a detailed discussion of how these estimates were developed. The average potential monetary benefits displayed in Tables 4.4.1.2-1 and 4.4.1.2-2 should not be interpreted as a prediction of the specific monetary benefits that would result from any actual benefits-sharing agreement. Instead, they represent the range of potential monetary benefits that informs the impact analyses later in this chapter.

A single CRADA is estimated to yield between \$0 and \$24,000 annually in the short term and between \$0 and \$155,000 (and, though unlikely, could yield more than \$1,000,000) annually in the long term. The amount could vary considerably in any given year (*see* Table 4.4.1.2-1).

**Table 4.4.1.2-1. Estimated range of potential monetary benefits used to analyze the impacts of a proposed NPS benefits-sharing program on individual parks other than Yellowstone**

<b>Duration of potential impact</b>	<b>Potential annual payment</b>	<b>% of agreements likely to yield this average benefits level (see Appendix C, Section C.9.3)</b>	<b>See Appendix C (Sections referenced) for the derivation of this estimate</b>
<b>Short-term impact analysis</b>	0	29%	Model Two (Section C.8.2)
	\$700	22%	Model Two (Section C.8.2)
	\$24,000	50%	Model One (Section C.8.1)
<b>Long-term impact analysis</b>	0	77%	Both models
	\$4,000	12%	Model Two (Section C.8.2)
	\$155,000	12%	Model One (Section C.8.1)
	\$1,000,000	0.6%	High-value royalty analysis (Section C.8.3)

Cumulatively, the estimated potential monetary benefits under Alternative B would be larger with each succeeding year (*see* Table 4.4.1.2-2).

**Table 4.4.1.2-2. Range of potential cumulative monetary benefits used to analyze the potential impacts of a proposed NPS benefits-sharing program, servicewide and Yellowstone contexts**

Year	Low range estimated annual benefits	Mid-range estimated annual benefits	High range estimated annual benefits	High range with a high value annual royalty ( <i>see</i> Appendix C, Section C.8.3)
Year 1	\$24,313	\$48,626	\$97,252	no royalties expected this year
Year 5	\$121,565	\$243,130	\$486,260	no royalties expected this year
Year 10	\$268,178	\$536,357	\$1,206,803	\$2,206,803
Year 20	\$634,712	\$1,269,424	\$2,856,204	\$3,856,204

## 4.4.2 Impacts to Natural Resource Management

Under Alternative B, the potential impacts to natural resource management of implementing benefits-sharing agreements would be expected to focus primarily on biological resources, because all of the NPS-related research results known to have been used for commercial purposes relate to the field of biology. Accordingly, it is likely that the majority of benefits-sharing researchers would be biologists, and their assistance would be most suitable for natural resource management. These impacts could have both quantitative and qualitative dimensions.

### 4.4.2.1 *Impact analysis common to all contexts (servicewide, Yellowstone, and individual parks): research trends in the NPS*

During scoping, several commenters suggested that selection of the benefits-sharing alternative (Alternative B) could affect the quantity of research activities in parks by either attracting or discouraging scientific research activities by bioprospectors. Although these comments seemed generally based on a misassumption that bioprospecting activities are currently prohibited in parks, bioprospecting research in fact has always been possible in parks, allowed under the same regulations that control all types of scientific research activities. Implementation of benefits-sharing as proposed in Alternative B would not change the criteria by which all scientific research permit applications are evaluated. The following analysis addresses the potential foreseeable impact of Alternative B on research trends.

Four datasets were examined to determine whether there had been a measurable impact on the quantity of research in parks after the announcement of the Yellowstone–Diversa benefits-sharing agreement in 1997 (*see* Appendix E). These are the best available data with which to examine the possibility that researchers would be either attracted or discouraged by the selection of Alternative B. They were:

- The quantity of Scientific Research and Collecting Permits issued by Yellowstone, 1992–2001;
- The quantity of research reports (IAR) submitted to Yellowstone, 1992–2001;

- The quantity of research reports submitted to the 38 parks that received at least one research report each year from 1992 through 2001 (these parks accounted for half (50.3%) of all the research reports received by a total of 270 parks during this period); and
- The quantity of research reports submitted to the NPS servicewide, 1992–2001.

For each dataset, the number of research reports submitted (or, in one case, research permits issued) during the period 1992–1997 (prior to initiation of the Yellowstone–Diversa agreement) was compared to the number submitted during 1998–2001 (the post-benefits-sharing time period). No significant difference in the number of research projects conducted in any context was detected between the pre-benefits-sharing and post-benefits-sharing time periods. These data indicate that the announcement or publicity surrounding the 1997 Yellowstone–Diversa agreement did not result in either an increase or decrease in NPS research reports or permits.<sup>19</sup> Therefore, it is likely that implementing Alternative B would have no impacts on natural resource management relative to research trends, except in the case of Alternative B1 (*see* Section 4.4.2.2).

#### ***4.4.2.2 Impact analysis common to all contexts (servicewide, Yellowstone and individual parks): impacts specific to Alternatives B1, B2, or B3***

In response to public concerns, Alternative B provides three different ways that implementation of benefits-sharing could treat financial information such as royalty rates. The effects of these three variations on natural resource management are captured within the general impact analysis for Alternative B. However, their differences are analyzed in some detail here to provide a basis for choice among these variations.

##### ***Impacts specific to Alternative B1 (always disclose royalty rate and related information)***

Under Alternative B1, the NPS would treat the rate at which performance-based payments were made, as well as related financial information contained in a benefits-sharing agreement, as public information, not as confidential business information. Parties to potential agreements would be advised that all terms and conditions contained in the text of an agreement (including negotiated performance-based payment rates and other financial information) would be released to the public upon request. Accordingly, under Alternative B1, the NPS would not be privy to any financial information the researcher wished to keep confidential.

Alternative B1 could have five effects. It could (1) limit payment equitability, (2) create an artificial “rate ceiling,” (3) expose the NPS to litigation or other penalties, (4) discourage some research, and (5) discourage establishment of benefits-sharing agreements.

This mandatory disclosure would limit the NPS’s ability to negotiate “equitable” performance-based payment rates as specified by the National Parks Omnibus Management Act of 1998. Negotiations would depend heavily on a good-faith representation by the researcher’s institution of its ability to offer potential monetary benefits, because the researcher’s institution would not disclose financial information to the NPS that it wished to keep proprietary.

Disclosure of performance-based payment rates could result in possible establishment of an artificial “rate ceiling” without regard to factors that could justify higher or lower rates under specific facts and circumstances.<sup>20</sup> This could affect the amount and timing of monetary benefits actually provided to the NPS (*see* Chapter 4, Section 4.4.1.2, and Tables 4.4.1.2-1 and 4.4.1.2-2).

The NPS could face legal consequences and limitations regarding the release to third parties of certain business or commercial information received from benefits-sharing partners. A number of legal provisions of confidentiality and unfair business practice laws apply to a broad range of business, financial and commercial information including, but not limited to, trade secrets, royalty rates, sales data, customer lists, and accounting data and limit full disclosure of such information. Provisions in criminal code regarding the Trade Secrets Act state that unauthorized disclosure of trade secrets, confidential data, or protected financial information is punishable by fine, imprisonment of up to one year, or both, and removal from employment (18 USC 1905).<sup>21</sup> Additionally, the unauthorized release of trade secrets by the NPS could lead to misappropriation of trade secrets and breach of confidential relationship actions against the government under the Federal Tort Claims Act (28 USC 2671–2680). Release of information protected by the Freedom of Information Act (FOIA, 5 USC 552) could subject the agency to “reverse FOIA” litigation whereby a plaintiff might argue that the agency’s contemplated information release would violate the Trade Secrets Act and FOIA and thus would “not be in accordance with law” or would be “arbitrary and capricious” under the Administrative Procedures Act (5 USC 701–706).

These disclosure requirements could discourage both declared and undeclared bioprospectors from applying for NPS research permits to study park resources in anticipation of potential disclosure of negotiated royalty rates or other sensitive information normally considered to be proprietary financial information.<sup>22</sup> Any resulting reduction in research reports (IARs) submitted to parks could represent a potential loss of resource knowledge that would have been useful to natural resource managers.

Implementation of Alternative B1 could reduce the number of benefits-sharing agreements established in the NPS compared to Alternatives B2 and B3, because researchers might not want to expose themselves to potentially substantial economic and competitive harm resulting from mandatory disclosure of performance-based payment rates and related financial information that could otherwise be exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA), which requires federal agencies to withhold “trade secrets and commercial or financial information obtained from a person and privileged or confidential” when responding to FOIA requests.<sup>23</sup>

Alternative B1 could result in long-term impacts less beneficial for natural resource management programs than under Alternatives B2 and B3. Although the number of researchers who might refrain from studying park resources or from entering into benefits-sharing agreements under Alternative B1 cannot be derived from available information, the range of monetary benefits used to analyze impacts in Section 4.4.1.2 is broad enough to accommodate the variability between Alternatives B1, B2 and B3.

***Impacts specific to Alternative B2 (comply with confidentiality laws regarding disclosure of royalty rate or related information)***

Under Alternative B2, all benefits-sharing agreements would be made available to the public in their entirety upon request, unless one or more agreement parties objected to the release of any specific information for reasons satisfying one or more of the statutory disclosure exemptions provided under FOIA.<sup>24</sup>

Implementation of Alternative B2 would avoid the five effects of Alternative B1; it would not limit payment equitability, create an artificial “rate ceiling,” expose the NPS to litigation or other penalties, discourage some research, or discourage establishment of benefits-sharing agreements.

Alternative B2 would not limit the NPS’s ability to negotiate “equitable” performance-based payment rates or create an artificial “rate ceiling,” because the researcher’s institution would be free to disclose financial information to the NPS that it wished to keep proprietary without the concern of NPS releasing that information to the public (*see* previous discussion of Alternative B1). Implementation of Alternative B2 would have no impact on any researcher’s private proprietary interest otherwise entitled to protection under FOIA. Accordingly, in contrast to Alternative B1, Alternative B2 would not discourage either declared or undeclared bioprospectors from applying for NPS research permits to study park resources. Alternative B2 would not restrict the number of potential benefits-sharing agreements.

Alternative B2 could result in long-term impacts more beneficial for natural resource management than under Alternatives B1, and the same as Alternative B3. This could have some affect on the estimate of monetary benefits provided in this FEIS. The range of monetary benefits used to analyze impacts in Section 4.4.1.2 is broad enough to accommodate the variability between Alternatives B1, B2 and B3.

***Impacts specific to Alternative B3 (never disclose royalty rate or related information)***

Under Alternative B3, no royalty rate or related financial information would be released to the public under any circumstances. Therefore, implementation of Alternative B3 would avoid the five effects of Alternative B1; it would not limit payment equitability, create an artificial “rate ceiling,” expose the NPS to litigation or other penalties, discourage some research, or discourage establishment of benefits-sharing agreements (*see* previous discussion of Alternative B1).

Alternative B3 could result in long-term impacts more beneficial for natural resource management programs than under Alternative B1, and the same as Alternative B2. This could have some affect on the estimate of monetary benefits provided in this FEIS. The range of monetary benefits used to analyze impacts in Section 4.4.1.2 is broad enough to accommodate the variability between Alternatives B1, B2 and B3.

***4.4.2.3 Servicewide impacts***

***Qualitative impacts***

The NPS expects that the most significant potential impacts from implementing benefits-sharing agreements would be new knowledge about natural resources and new research

collaborations that would result from benefits-sharing agreements with members of the research community. Non-monetary benefits (*see* Section 4.4.1.1) could be used by the NPS to improve natural resource management activities, primarily in parks that entered into benefits-sharing agreements.

From a servicewide perspective, non-monetary benefits would work cumulatively with existing servicewide initiatives to increase and improve the use of science for natural resource management programs. Because the important role that microbes play in ecosystems is becoming more widely recognized, information that independent researchers could provide about park microbes would be particularly useful. For example, it is reasonable to expect that benefits-sharing partners could contribute to the NPS’s Inventory and Monitoring (I&M) Program and to individual park Vital Signs Monitoring. Accordingly, Alternative B’s impacts are expected to be long-term, beneficial, and negligible-to-major.

**Quantitative impacts**

It is expected that monetary benefits would increase over time as both the number of agreements and the value of research results increased (*see* Figure 4.4.2.3-1).

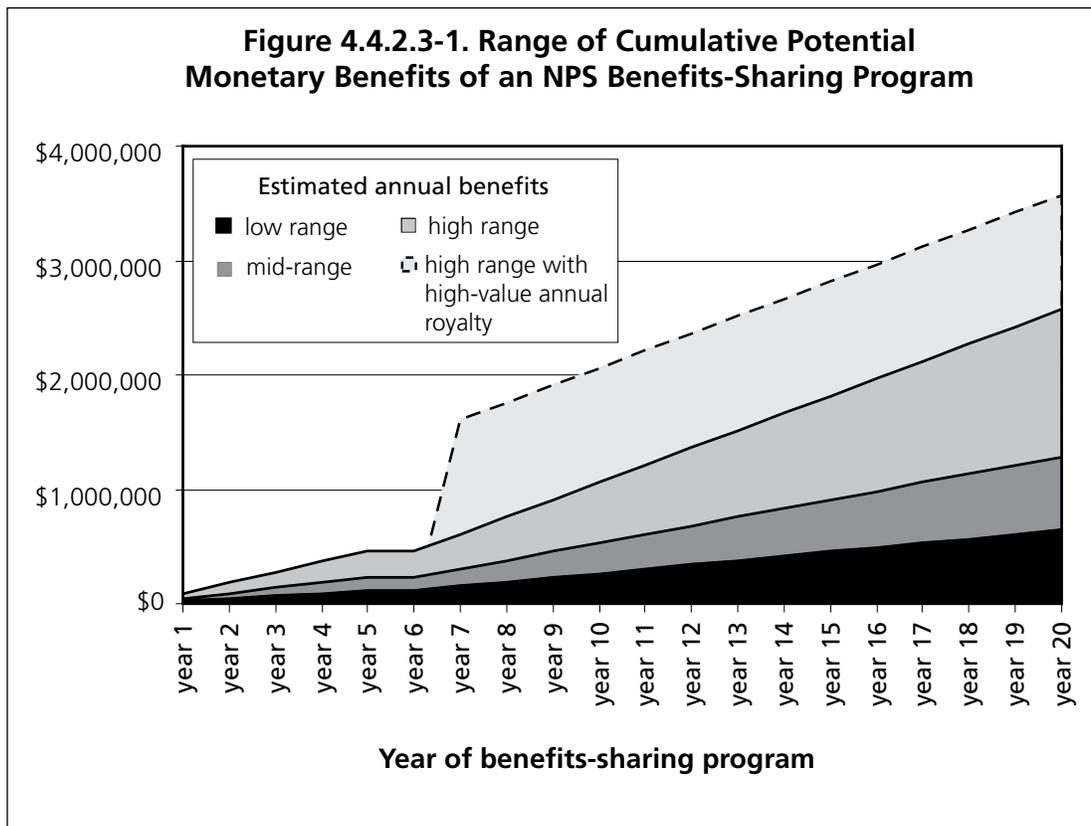


Figure 4.4.2.3-1. An NPS benefits-sharing program could generate monetary benefits that would increase over time because CRADAs would obligate researchers to make performance-based payments and such obligation would survive termination of the CRADA (*see* Appendix C).

To provide a servicewide perspective, the total amount of estimated monetary benefits was compared to the budget for the Natural Resource Challenge. In 2007, the Natural Resource

Challenge program accounted for approximately \$78 million of the NPS budget.<sup>25</sup> This comparison is presented in the table below.

**Table 4.4.2.3. All potential monetary benefits compared to the \$78 million NPS Natural Resource Challenge funding, FY2007**

Year	Low range estimated annual benefits	Mid-range estimated annual benefits	High range estimated annual benefits	High range with a high-value annual royalty (see Appendix C, Section C.8.3)
1	0.03%	0.06%	0.14%	no royalties expected this year
5	0.16%	0.31%	0.71%	no royalties expected this year
10	0.35%	0.69%	1.56%	2.85%
20	0.82%	1.65%	3.70%	4.99%

Table 4.4.2.3. The comparison of potential monetary benefits generated by an NPS benefits-sharing program to the FY2007 funding for the NPS Natural Resource Challenge is provided in this table (see also Appendix C).

In the short term (represented by year 5 in Table 4.4.2.3), it is expected that the monetary benefits from an NPS benefits-sharing program could range from approximately \$122,000 to \$547,000, which would be equivalent to no more than 0.75% of the funding derived from the Natural Resource Challenge in FY2007. Accordingly, potential short-term monetary benefits would represent short-term, beneficial, negligible impacts to servicewide natural resource management.

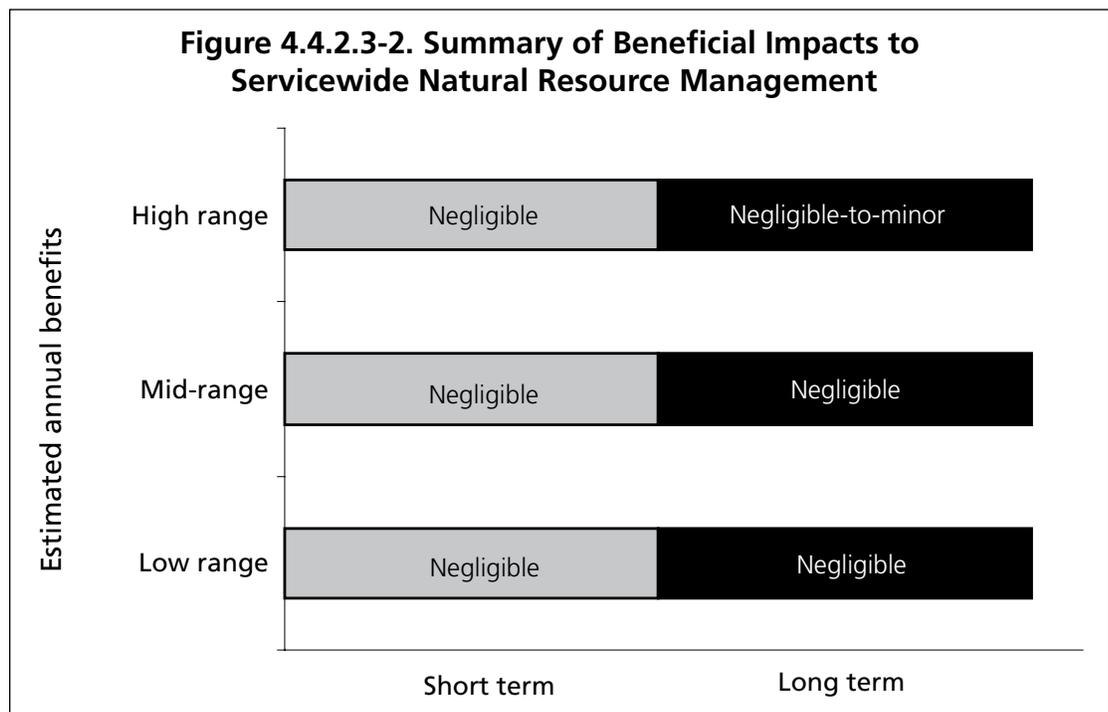


Figure 4.4.2.3-2. Monetary benefits could have a negligible and, in some instances, minor beneficial impacts on servicewide natural resource management.

In the long-term (year 20 in Table 4.4.2.3), it is expected that the monetary benefits from an NPS benefits-sharing program could range from approximately \$635,000 to more than \$3.8 million, which would be equivalent to a range of approximately 1–5% of the funding derived from the Natural Resource Challenge in FY2007. Accordingly, potential long-term monetary benefits would represent long-term, beneficial, negligible-to-minor impacts to servicewide natural resource management.

#### **4.4.2.4 Yellowstone-specific impacts**

Under Alternative B, it is possible that an estimated 2–9 new benefits-sharing agreements per year would be implemented in Yellowstone National Park (*see* Chapter 1, Section 1.2.4 and Chapter 3, Section 3.5.3). In addition, implementation of Alternative B would generate immediate non-monetary and monetary benefits to Yellowstone National Park as a result of implementation of the Yellowstone–Diversa CRADA, which has been suspended since March 1999 (*see* Appendix G).

##### ***Qualitative impacts***

The impact of non-monetary benefits to Yellowstone’s natural resource management program from an estimated 2–9 new benefits-sharing agreements per year cannot be foreseen in detail, because each benefits-sharing partner would have individual knowledge and capabilities to offer.

However, the Yellowstone–Diversa CRADA provides a single example of the kind of benefits that could result. Under the terms of that CRADA, Diversa used its proprietary techniques and databases to perform two genetic analyses needed for Yellowstone natural resource management at no cost to the park (*see* Appendix F). These types of analyses, which are hard for the NPS to accomplish because of the cost and the expertise required, are sometimes relatively easy for a private company to do. These non-monetary benefits, which were invaluable to Yellowstone’s wolf restoration program, occurred because of the working collaboration between park scientists and private scientists that had been fostered and required by the Yellowstone–Diversa CRADA. Accordingly, Alternative B’s impacts are expected to be long-term, beneficial, and minor-to-major.

##### ***Quantitative impacts***

Under Alternative B, the CRADA between Yellowstone National Park and Diversa Corporation, currently suspended, could become active, and Diversa could make payments of \$20,000 each year for five years to Yellowstone, as well as performance-based payments to the park resulting from development of Pyrolase 200™ (*see* Chapter 1, Section 1.2.4.2). The amount of these payments cannot be determined unless the CRADA is reinstated, because Diversa’s financial reporting obligations to Yellowstone under the CRADA are also currently suspended, as are its invention-disclosure and related reporting obligations. As a result, Yellowstone does not know whether Diversa has developed any additional products from its research activities at Yellowstone that might generate additional payment obligations.

The initial benefits period payment of \$100,000 over five years would be equivalent to 1.14% of the FY2002 operational funding for natural resource management that was identified in Yellowstone’s Business Plan (*see* Chapter 3, Section 3.2.2). Accordingly, this payment alone could have a short-term, beneficial, negligible impact on Yellowstone’s natural resource management program.

Individual natural resource management projects could be affected to a greater extent than this programmatic evaluation indicates. For example, Yellowstone’s natural resource managers have

identified a range of natural resource management activities that require approximately \$100,000 in funding to accomplish.<sup>26</sup> These include:

- One year of comprehensive parkwide air quality monitoring;
- Initiation and completion of the first complete cave inventory for the entire park;
- Four years of identifying, monitoring, and protection of the park’s fossil forests;
- Five years of operation and upgrading of the geothermal microbe database;
- Research related to the restoration of one new, wild population of imperiled westslope cutthroat trout;
- Five years of monitoring of bald eagle or peregrine falcon nesting success; and
- Funding one three-year PhD and one two-year MS studies on any desired resource topic.

Diversa’s payment obligations under the CRADA are both short- and long-term. The minimum \$100,000 payment would be short-term, reflecting the amount due for the initial five-year period provided by the CRADA, and would be paid whether or not Diversa used their research results for any commercial purpose. Any additional performance-based payments (e.g., royalties) would be paid for an indefinite, long-term future period, because the payment obligations resulting from development of valuable commercial applications from research results survive termination of the CRADA.

For purposes of this analysis, the estimated amounts shown in Table 4.4.1.3-1 were compared to Yellowstone’s natural resource management funding as presented in its Business Plan. In FY2002, Yellowstone had \$8.8 million available for natural resource management.

If all NPS CRADAs and resulting monetary benefits were received by Yellowstone alone (which is possible), and used entirely for research in support of natural resource management activities, the park could experience widely ranging monetary benefits of between \$0 and more than \$1 million annually. There could be short-term, beneficial, negligible impacts, represented by year 5 in Table 4.4.2.4 below, and long-term, beneficial, negligible-to-major impacts, represented by year 20. These conclusions are presented in the table below and summarized in Figure 4.4.2.4, below.

**Table 4.4.2.4. Potential monetary benefits equivalent to a percentage of Yellowstone natural resource management funding level, FY2002**

Year	Low range estimated annual benefits	Mid-range estimated annual benefits	High range estimated annual benefits	High range with a high value annual royalty (see Appendix C, Section C.8.3)
1	0.3%	0.6%	1.2%	no royalties anticipated this year
5	1.4%	2.8%	6.2%	no royalties anticipated this year
10	3.0%	6.1%	13.7%	25.1%
20	7.2%	14.4%	32.5%	43.8%

Table 4.4.2.4. If all of the NPS’s monetary benefits were received by Yellowstone alone and used entirely for natural resource management activities, they could represent the equivalent of less than 1–44% of Yellowstone’s FY2002 natural resource management funding level (see Appendix C).

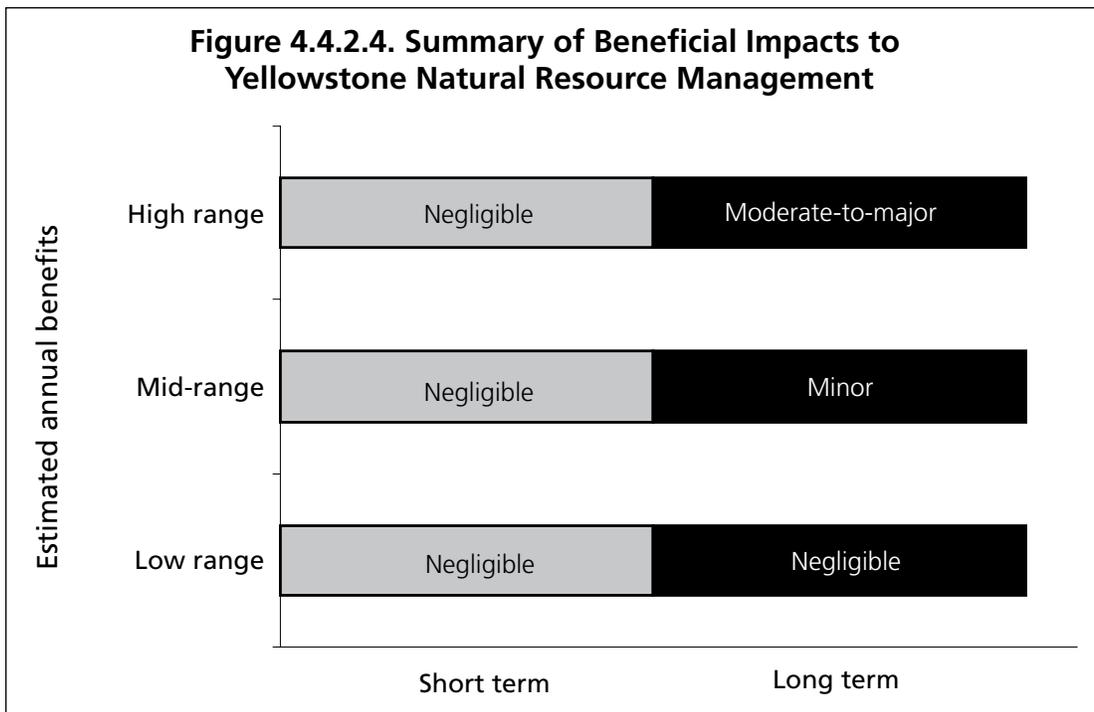


Figure 4.4.2.4. The monetary benefits derived from benefits-sharing program could have a negligible short-term beneficial impact on Yellowstone natural resource management and a long-term negligible-to-major beneficial impact.

#### **4.4.2.5 Individual park impacts**

Park-specific impact analysis was based upon the potential impact of a single benefits-sharing agreement on a park’s natural resource management program (*see* Section 4.2.1.2 and Chapter 3, Section 3.5.3).

#### ***Qualitative impacts***

The most significant non-monetary benefit that can be foreseen for most parks with a benefits-sharing agreement would be their ability to draw on the scientific expertise of benefits-sharing partners. Because all of the known park-related patents involve biology, it is likely that the majority of this expertise would be biological (*see* Chapter 1, Section 1.2.4).

Examples of expert provisions from which natural resource managers could benefit include genetic analyses of species of concern to park managers, research on wildlife diseases, impact assessments of proposed projects in parks, contributions to an individual park’s I&M program, and participation in planning for natural resource restoration projects (*see also* Chapter 3, Section 3.2.1). Accordingly, Alternative B’s impacts are expected to be long-term, beneficial, and negligible-to-major.

#### ***Quantitative impacts***

The potential income generated by a single benefits-sharing agreement and the potential timing of payments were characterized previously (*see* Table 4.4.1.2-1, above).

A park with a single benefits-sharing agreement could experience widely ranging monetary

benefits of between 0 and more than \$1 million annually. These estimates were compared to the funding levels for park natural resource management programs as presented in 43 Business Plans (see Chapter 3, Section 3.2.2). The potential impacts on natural resource management of the range of potential monetary benefits are shown in Table 4.4.2.5 below (see Appendix C for a detailed presentation regarding the derivation of the figures displayed in Table 4.4.2.5).

**Table 4.4.2.5. Beneficial impacts to natural resource management at 43 representative parks\***

If a park received:		Number of parks that would experience:				
		No impact	Negligible	Minor	Moderate	Major
Short-term annual payment	\$0	43	-	-	-	-
	\$4,000	-	42	1	-	-
	\$155,000	-	7	11	8	17
Long-term annual payment	\$0	43	-	-	-	-
	\$4,000	-	42	1	-	-
	\$155,000	-	7	11	8	17
	\$1,000,000	-	3	1	1	38

\*The potential annual monetary benefits of a single CRADA at a single park are compared to the natural resource management funding available per park. The levels of potential monetary benefits under analysis vary in their foreseeable likelihood. For example, 50% of agreements are expected to yield an average of \$24,000 annual monetary benefits during the first five years of the agreement (the short-term benefits period), but only 0.6% of agreements are expected to yield more than \$1 million annually (see Appendix C).

Table 4.4.2.5. Potential beneficial impacts of monetary benefits to individual park natural resource management programs ranges from no impact to major impact.

Impacts to parks that received monetary benefits during the immediate benefits period could range from negligible to major, with the majority of parks experiencing no more than negligible impacts. Impacts to parks that received monetary benefits during the deferred benefits period could also range from negligible to major. Accordingly, quantitative impacts to individual parks would be short or long-term, beneficial, and range from none to major, because not all of the parks studied would receive monetary benefits.

#### **4.4.2.6 Mitigation measures**

No mitigation is needed for potential beneficial impacts. The only adverse impacts to natural resource management that are anticipated are from a potential reduction in independent research under Alternative B1 and its accompanying reduction in the provision of scientific information to the NPS, but the extent or importance of such potential reduction cannot be estimated from available information. (Mitigation measures are described in EIS Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5)

#### **4.4.2.7 Conclusion**

Under Alternative B, the NPS could have additional scientific tools and knowledge to manage its natural resources. Additional opportunities could become available for supporting resource management-based cooperative research projects with independent researchers. Potential long-term impacts of Alternative B on NPS natural resource management could be more beneficial than Alternative A (No Benefits-Sharing/No Action) in every context.

Service-wide, the potential impacts of implementing benefits-sharing agreements to natural resource management could qualitatively be long-term, beneficial, and negligible-to-major. Quantitatively, they could be long-term, beneficial, and negligible-to-minor. From a resource conservation standpoint, the potential impacts of non-monetary benefits to NPS units could be of greater value than the quantitative monetary analysis suggests.

In Yellowstone, the potential impacts of implementing benefits-sharing agreements to natural resource management could qualitatively be long-term, beneficial, and minor-to-major. Quantitatively, they could be both short-term, beneficial, and negligible, and long-term, beneficial, and negligible-to-major.

At the individual park level, the potential impacts of implementing benefits-sharing agreements to natural resource management could qualitatively be long-term, beneficial, and negligible-to-major. Quantitative impacts to individual parks could be short or long-term, beneficial, and none-to-major (because not all of the parks studied would receive monetary benefits).

Alternative B1 could result in long-term, less beneficial impacts relative to natural resource management than Alternatives B2 and B3, because under Alternative B1, a small number of researchers could be expected to avoid park research and the mandatory disclosure would limit the NPS's ability to negotiate "equitable" performance-based payment rates. The intensity of such a reduction of beneficial impacts cannot be known from available information.

#### **4.4.2.8 Cumulative impacts**

The Cumulative Scenario was described in Section 4.3.1.6.

The cumulative impacts of the NPS programs and initiatives described in the cumulative scenario are expected to have a beneficial long-term impact on NPS natural resource management in all contexts by providing additional scientific knowledge for park natural resource management decision-making. Alternative B's impacts on natural resource management are also beneficial for this same reason. However, service-wide, the impacts that result from this alternative would make no demonstrable addition to the cumulative impact of other past, present and reasonably foreseeable actions outlined in the cumulative scenario. Individual parks with benefits-sharing agreements could experience a greater than negligible beneficial cumulative impact under this alternative.

### **4.4.3 Impacts to Visitor Experience and Enjoyment**

Park interpretation serves a primary resource preservation role by facilitating public understanding of and participation in the stewardship of park resources. Under Alternative B,

all benefits received through benefits-sharing agreements would be dedicated to conservation purposes. Accordingly, specific interpretive services designed to enhance visitors' understanding of and participation in meeting natural resource management goals would qualify for use of benefits.

### ***Qualitative impacts***

Potential qualitative impacts to visitor experience and enjoyment are related to the degree to which Alternative B would provide scientific knowledge and expertise to NPS interpreters.

### ***Quantitative impacts***

Monetary benefits derived under a CRADA would only be available to park interpretive divisions for research-related uses, and are captured in the impact analysis for natural resource management (*see* Section 4.4.2). An example of interpretive-related natural resource research could include site-specific research conducted to determine the effectiveness of various interpretive techniques in obtaining visitor compliance with park rules intended to protect natural resources.<sup>27</sup>

#### ***4.4.3.1 Servicewide impacts***

The NPS expects that the most significant potential impacts to visitor experience and enjoyment under Alternative B would result from non-monetary benefits, which could be used to improve interpretive services, primarily in the parks that entered into benefits-sharing agreements. These non-monetary benefits would include additional knowledge and information about park resources and increased recognition of the societal value associated with scientific research involving NPS units.<sup>28</sup> Interpreters could use this additional information and knowledge about park resources to improve interpretive services.

Alternative B would require researchers to provide a non-monetary benefit to the NPS by informing the NPS of all valuable discoveries developed under a benefits-sharing agreement.<sup>29</sup> Enhanced recognition of the value of NPS resources to ongoing scientific discoveries that can benefit humanity could help underscore for park visitors the value to society of conserving natural resources in an unimpaired condition NPS units. This type of recognition could improve visitor stewardship of natural resources. Additional non-monetary benefits would result from the enhanced research relationships developed between benefits-sharing partners and parks.

Accordingly, the servicewide impacts of Alternative B are expected to be long-term, beneficial, and at least negligible, with a possibility of being minor.

#### ***4.4.3.2 Yellowstone-specific impacts***

The impact of non-monetary benefits to Yellowstone interpretation cannot be foreseen in detail. Each benefits-sharing partner would have different knowledge and capabilities to offer. However, it is reasonably foreseeable that the majority of benefits-sharing partners would be microbiologists (*see* Chapter 1, Section 1.2.4).

Yellowstone National Park's Interpretation Division currently recognizes and explains to visitors the importance of the microbial components of the Yellowstone ecosystem. For example, recent planning for two new visitor education centers included consulting with

microbiologists, and Montana State University's Thermal Biology Institute recently agreed to help Yellowstone's education program with curriculum development.

Yellowstone's visitor interpretive services could also benefit from custom-designed reports from researchers detailing the significance of their discoveries in layperson's terms with photos or other visual aids. Additional non-monetary benefits would result from the enhanced research relationships developed between benefits-sharing partners and Yellowstone under Alternative B.

Alternative B's impacts to visitor experience and enjoyment in Yellowstone are expected to be long-term, beneficial, and negligible-to-minor.

#### **4.4.3.3 Individual park impacts**

Park-specific impact analysis was based upon the potential impact of a single benefits-sharing agreement on a park.

The impact of non-monetary benefits to park interpretation from a single benefits-sharing agreement cannot be foreseen in detail, because each benefits-sharing partner would have individual knowledge and capabilities to provide through benefits-sharing agreements under Alternative B.

The non-monetary benefits described in "servicewide impacts," above, could apply to any park with a benefits-sharing agreement. For certain parks, the value of potential non-monetary benefits could be moderate compared to their currently available resources. The most important non-monetary benefit that can be foreseen for most parks would be that parks could draw on the expertise of benefits-sharing partners. For example, it is reasonable to expect that benefits-sharing partners could provide site-specific information or visual aids about natural resources as well as actively participating in planning for interpretive services.<sup>30</sup> Accordingly, Alternative B's impacts to visitor experience and enjoyment are expected to be long-term, beneficial, and negligible-to-moderate.

#### **4.4.3.4 Mitigation measures**

No mitigation is needed for potential beneficial impacts. (Mitigation measures are described in EIS Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5).

#### **4.4.3.5 Conclusion**

Qualitatively, the impacts of Alternative B could be long-term, beneficial, and negligible-to-minor servicewide and for Yellowstone, and long-term, beneficial, and negligible-to-moderate for other individual parks.

The quantitative impacts of implementing benefits-sharing agreements on visitor experience and enjoyment derive from interpretive-related natural resource research that benefits-sharing could support. They are captured in the impact analysis for natural resource management (*see* Section 4.4.2).

#### **4.4.3.6 Cumulative impacts**

The cumulative impacts of the NPS programs and initiatives described in the cumulative scenario are expected to have a beneficial long-term impact on visitor experience and

enjoyment in all contexts by improving NPS interpretive services. The beneficial impacts that result from implementing benefits-sharing under Alternative B would add to the total beneficial cumulative impact outlined in the cumulative scenario. Servicewide and for Yellowstone, the negligible-to-minor beneficial impacts of Alternative B could add negligibly to the total cumulative impact. The negligible-to-moderate beneficial impacts of Alternative B to some other individual parks could result in a more than negligible beneficial cumulative impact to other parks that entered into a benefits-sharing agreement.

#### **4.4.4 Impacts to Social Resources: The Research Community**

The research community would be affected by Alternative B's requirement to enter into a benefits-sharing agreement before using research results for commercial purposes when research involved study of NPS specimens.

Under Alternative B, there would be no change in how research specimen collection is authorized. Parks would authorize research specimen collection the same way they do now: any qualified researcher would be eligible to obtain an NPS research permit in accordance with regulations and guidelines, regardless of whether the research activities might lead to commercially valuable discoveries. Therefore, under Alternative B, there would be no additional impacts to the research community related to the existing research permitting process.

A standardized MTA would be implemented for third-party transfers of research material.

##### **4.4.4.1 Impacts to declared bioprospectors**

Approximately 0.5% of NPS research permit holders in 2001 were declared bioprospectors (*see* Chapter 3, Section 3.4.3.2). Because the NPS proposal provides the non-monetary and monetary benefits obligated by benefits-sharing agreements would be negotiated and mutually agreeable to both parties, it is reasonable to expect that the potential economic impacts of an agreement would not rise above a negligible adverse effect on researchers or their institutions. It is anticipated that most declared bioprospectors would be affiliated with organizations such as academic institutions or corporations with experienced technology transfer offices. These researchers could rely on the technology transfer expertise already present in their institutions, thus reducing any adverse workload impacts on the researchers.

Benefits-sharing agreements would foster a collaborative relationship between researchers and NPS scientists that could have beneficial impacts for researchers. For example, the inadvertent bioprospector described as an example in Section 3.4.3.2 has explained that his discovery was based in part on a conversation with a park employee.

Overall impacts to declared bioprospectors are expected to be long-term, adverse, and negligible.

In addition, under Alternative B, the benefits-sharing agreement between Yellowstone National Park and Diversa Corporation would be amended to conform to the standardized CRADA provided in Appendix A of this FEIS should they wish to re-establish their partnership. This would not constitute any foreseeable additional impact to Diversa.

#### **4.4.4.2 Impacts to inadvertent and undeclared bioprospectors**

Few NPS research projects have been identified by park staff as undeclared bioprospecting (see Chapter 3, Section 3.4.3.2).<sup>31</sup>

Alternative B would have no impacts on inadvertent and undeclared bioprospectors until and unless they actually prepared to use their research results for commercial purposes. At that time, they would be required to declare their position as bioprospectors and enter into a benefits-sharing agreement with the NPS. Hence, they would become declared bioprospectors, and be subject to those impacts.

#### **4.4.4.3 Researchers who transfer or receive transferred NPS research specimens or other material originating as an NPS research specimen**

Currently, there is no standardized process or format for requesting NPS authorization of third-party transfers of research material originating as specimens collected under the authorization of an NPS research permit and not suitable for permanent retention as part of a museum collection. Standardization of MTAs is expected to reduce the workload associated with making such requests by streamlining the process and eliminating additional paperwork associated with multiple versions of MTAs issued by individual parks, thus providing a beneficial impact to researchers. The workload for researchers to complete an MTA would be substantially less than the 1.6 hours required to obtain an NPS research permit. The impacts to these researchers are considered to be long-term, beneficial, and negligible.

#### **4.4.4.4 All other researchers**

For all other researchers, implementing benefits-sharing agreements would result in no impacts.

#### **4.4.4.5 Impacts specific to Alternatives B1, B2, and B3**

##### ***Impacts specific to Alternative B1 (always disclose royalty rate and related information)***

During scoping, some members of the public advised the NPS to design a benefits-sharing program with full disclosure of all terms and conditions of benefits-sharing agreements, including all financial details. Under Alternative B1, there could be economic and competitive impacts to certain researchers and institutions whose otherwise confidential proprietary financial information was disclosed as required by the terms of the agreement.

The U.S. District Court for the District of Columbia ruled in 2002 that disclosure of otherwise confidential royalty rates in a CRADA over the objections of a CRADA party could constitute substantial harm that FOIA Exemption 4 was enacted to prevent. The court made its finding based on evidence presented by the National Institutes of Health that the overwhelming majority of its CRADA partners and other licensees objected to the release of otherwise confidential CRADA royalty rates based on demonstrations that the release of such information could cause substantial economic and competitive harm (see Chapter 1, Section 1.7.6). The court also found that many research firms would refuse to participate in CRADA-related research if otherwise confidential royalty rate information were disclosed.<sup>32</sup>

Accordingly, to avoid disclosing what they consider to be proprietary information, some proportion of declared and undeclared bioprospectors could abandon or never begin studies

involving NPS-related research specimens. In these ways, implementation of Alternative B1 could result in long-term impacts more adverse to the research community than under Alternatives B2 and B3.

***Impacts specific to Alternative B2 (comply with confidentiality laws regarding disclosure of royalty rate or related information)***

Under Alternative B2, all benefits-sharing agreements would be made available to the public in their entirety upon request, unless one or more agreement parties objected to the release of any specific information for reasons satisfying one or more of the statutory disclosure exemptions provided under FOIA. Accordingly, Alternative B2 would avoid any adverse impact to researchers from release of proprietary information that could be harmful to the researcher's interests.

Implementation of Alternative B2 would have no impact on any researcher's private proprietary interest otherwise entitled to protection under FOIA. Accordingly, in contrast to Alternative B1, implementation of Alternative B2 could result in long-term impacts less adverse to the research community than under Alternative B1, and the same as under Alternative B3.

***Impacts specific to Alternative B3 (never disclose royalty rate or related information)***

Under Alternative B3, no performance-based payment rate or related financial information would be released to the public under any circumstances. Therefore, implementation of Alternative B3 would have no impact on any researcher's private proprietary interest. Accordingly, Alternative B3 would avoid any adverse impact to researchers from release of proprietary royalty rate or financial information that could be harmful to the researcher's interests. Accordingly, in contrast to Alternative B1, implementation of Alternative B3 could result in long-term impacts less adverse to the research community than under Alternative B1, and the same as under Alternative B2.

**4.4.4.6 Mitigation measures**

Alternative B prevents greater-than-negligible adverse impacts to benefits-sharing partners by providing that terms of the non-monetary and monetary benefits obligated by benefits-sharing agreements would be negotiated and mutually agreeable to both parties. This would make it possible to produce agreements that are not unduly burdensome to researchers while still benefiting the NPS.<sup>33</sup>

**4.4.4.7 Conclusion**

Any potential for greater-than-negligible adverse impacts from benefits-sharing obligations would be prevented by adhering to mutually agreed terms negotiated for agreements consistent with the standardized terms provided in the CRADA proposed in Alternative B.

For declared bioprospectors, implementing benefits-sharing agreements would result in long-term, adverse, negligible impacts.

For inadvertent and undeclared bioprospectors, implementing benefits-sharing agreements would result in no impacts.

For researchers who transfer or receive transferred NPS research specimens or other material originating as an NPS research specimen, implementing benefits-sharing agreements would result in long-term, beneficial, negligible impacts.

For all other researchers, implementing benefits-sharing agreements would result in no impacts.

Alternative B1 could result in long-term, more adverse impacts to the research community than Alternatives B2 and B3.

#### **4.4.4.8 Cumulative impacts**

The negligible impacts that result from the actions of Alternative B (negligible beneficial impacts to researchers who participate in material transfers as well as negligible adverse impacts to declared bioprospectors) would not demonstrably alter the cumulative impact of actions outlined in the cumulative scenario. Alternative B would have no impact to all other researchers, therefore there would be no demonstrable addition to the total cumulative impact these researchers experience from other sources.

### **4.4.5 Impacts to Social Resources: NPS Administrative Operations**

Under Alternative B, individual parks would negotiate, implement, and monitor compliance with benefits-sharing agreements consistent with their current management of a variety of agreements with other entities. Although most monetary benefits would be dedicated to scientific activities promoting the conservation of natural resources protected and managed by the NPS, monetary benefits could also be used to offset administrative costs of a benefits-sharing agreement in accordance with the FTTA.<sup>34</sup>

The workload reported by the Association of University Technology Managers (AUTM) Annual Licensing Survey for personnel in university-based licensing offices can be used to indicate the potential administrative burden for managing NPS benefits-sharing agreements. Unlike the AUTM survey respondents, NPS personnel would not be responsible for soliciting benefits-sharing partners, marketing research results, or start-up activity efforts (starting a new company based on an academic discovery). Accordingly, the AUTM workload covers more functions than would be necessary for the NPS and provides a generous estimate of the work that would be required to administer benefits-sharing agreements.

In 2006, AUTM reporting institutions required a total of 910.7 FTE for a variety of activities associated with licensing. In that year, 4,963 new licenses were executed out of a total of more than 27,000 licenses administered. If all the reported FTE had simply been used for executing new licenses, then each new license would have averaged a 0.18 FTE workload. Because of the variety of activities included in the AUTM FTE figure, the 0.18 FTE is a generous estimate of the workload to execute a single new benefits-sharing agreement.<sup>35</sup>

#### **4.4.5.1 Servicewide impacts**

The potential servicewide impact of administering a benefits-sharing program was determined by examining the FTE needed to administer agreements utilizing 0.18 FTE

per new agreement, a figure based on AUTM data (see Section 4.4.5). The FTE required to administer an entire benefits-sharing program would range from 0.36 to 1.62 FTE per year, depending on the number of new agreements executed annually (see Table 4.4.5.1). Since the AUTM FTEs include functions that the NPS would not perform and activities related to managing ongoing active agreements, this is considered to be an adequate or possibly a slight overestimate of potential benefits-sharing program workload. For this reason, the potential impacts to servicewide NPS administrative operations would be long-term, adverse, and negligible in all reasonably foreseeable cases.

Yellowstone National Park has used MTAs since the year 2000, at an average workload of 1 hour and 30 minutes each to execute.<sup>36</sup> There is no established systematic way to estimate the number of specimen transfer authorizations issued servicewide. However, the existing level of confusion appears to be minimal and does not constitute a significant adverse impact. Precise characterization of this impact is not essential to a reasoned choice among the alternatives. The impact of adding standardization to the current requirement to authorize third-party transfers of NPS research specimens or other material originating as an NPS research specimen is expected to be long-term, beneficial, and negligible.

**Table 4.4.5.1. Potential servicewide benefits-sharing administrative burden**

	<b>2 new agreements annually</b>	<b>4 new agreements annually</b>	<b>9 new agreements annually</b>
<b>Number of FTE needed</b>	2 x 0.18 = 0.36	4 x 0.18 = 0.72	9 x 0.18 = 1.62
<b>Impact</b>	Negligible	Negligible	Negligible

Table 4.4.5.1. The administrative burden of executing benefits-sharing agreements remains low under every predicted level of program implementation.

#### **4.4.5.2 Yellowstone-specific impacts**

In 2002, Yellowstone National Park had 108.9 available FTE for administration and management. The potential impact to Yellowstone of administering a benefits-sharing program was determined by examining the FTE needed to administer agreements utilizing 0.18 FTE per new agreement, a figure based on AUTM data (see Section 4.4.5). The FTE required to administer an entire benefits-sharing program would range from 0.36 to 1.62 FTE per year, depending on the number of new agreements executed annually (see Table 4.4.5.1). Since the AUTM FTEs include functions that the NPS would not perform and activities related to managing ongoing active agreements, this is considered to be an adequate or possibly a slight overestimate of potential benefits-sharing program workload. For this reason, the potential impacts to NPS administrative operations of implementing benefits-sharing agreements in Yellowstone would likely be long-term, adverse, and negligible in all reasonably foreseeable cases.

Because Yellowstone National Park has used standardized MTAs since 2000, their servicewide introduction would have no impact in this context.

**Table 4.4.5.2. Potential Yellowstone benefits-sharing administrative burden**

	<b>2 new agreements annually</b>	<b>4 new agreements annually</b>	<b>9 new agreements annually</b>
Number of FTE needed	2 x 0.18 = 0.36	4 x 0.18 = 0.72	9 x 0.18 = 1.62
Percentage of available FTE (of 108.9)	0.3%	0.7%	1.5%
Impact	Negligible	Negligible	Negligible

Table 4.4.5.2. Under all predicted levels of benefits-sharing, the adverse impact to Yellowstone administration would be negligible.

#### **4.4.5.3 Individual park impacts**

Most parks would not enter into any benefits-sharing agreements, and would experience no impacts to park operations.

Other than Yellowstone, 31 of the 44 park Business Plans previously described include information about existing administrative resources.<sup>37</sup> The number of available administrative FTE per park varies considerably (*see* Table 4.4.5.3). If individual parks established a single benefits-sharing agreement, the FTE required for that purpose would represent, at most, 3.75% of available administrative FTE. Many parks may not have the expertise necessary to negotiate a benefits-sharing agreement. These parks would draw on the technical assistance resources described in Section 4.4.5.5. In some cases, a CRADA could provide up-front payments that could be used to offset administrative costs. For these reasons, the potential impacts of implementing benefits-sharing agreements to NPS administrative operations at the individual park level could be long-term, adverse, and negligible in all reasonably foreseeable cases.

The impact of adding standardization to the current requirement to authorize third-party transfers of NPS research specimens or other material originating as an NPS research specimen is expected to be long-term, beneficial, and negligible.

**Table 4.4.5.3. Potential individual park benefits-sharing administrative burden (one benefits-sharing agreement)**

Park code	Available administrative FTE	Percentage of available administrative FTE	Park Code	Available administrative FTE	Percentage of available administrative FTE
GUMO	4.8	3.75%	CAHA	16.1	1.12%
WWSA	5.1	3.53%	BIBE	16.4	1.10%
VICK	6.1	2.95%	VAFO	18.9	0.95%
WRST	6.9	2.61%	REDW	22.1	0.81%
TIMU	7	2.57%	GETT	22.2	0.81%
BAND	8	2.25%	CHOH	22.9	0.79%
APIS	8.5	2.12%	ZION	23	0.78%
BADL	9.5	1.89%	OLYM	26.5	0.68%
LAVO	9.7	1.86%	INDU	27.4	0.66%
VOYA	10.5	1.71%	EVER	31	0.58%
OZAR	10.6	1.70%	GRTE	31	0.58%
ISRO	10.6	1.70%	DENA	34.2	0.53%
BRCA	10.8	1.67%	GLCA	35.8	0.50%
VIIS	11.9	1.51%	GRCA	54	0.33%
JOTR	13.9	1.29%	GOGA	90.8	0.20%
ACAD	14.1	1.28%			

Table 4.4.5.3. Administration of a single benefits-sharing agreement would be a long-term, negligible, adverse impact for all parks studied.

Administration of a single benefits-sharing agreement would represent a long-term, adverse, negligible impact for most parks. The most time-consuming period for agreement administration would be in the period during which negotiations occurred and the agreement was established. Monitoring an agreement during the immediate benefits period (on average, five years) would require less administrative effort than establishing a new agreement. Monitoring an agreement during the deferred benefits period would require even less administrative effort. Accordingly, the actual potential impacts to individual parks may be less adverse than estimated here.

**4.4.5.4 Impacts specific to Alternatives B1, B2 or B3**

***Impacts specific to Alternative B1 (always disclose royalty rate and related information)***

Under Alternative B1, proprietary business information (including but not limited to the rate at which performance-based payments would be made to the NPS) in a benefits-sharing agreement would always be disclosed. Because researchers might not want to expose themselves to the potential substantial economic and competitive harm resulting from mandatory disclosure of royalty rates and related financial information that could otherwise be exempt from disclosure under FOIA Exemption 4 (see Section 4.4.4.5), they either might not provide that information to the NPS or they might decide not to conduct research involving study of NPS specimens. In addition, both declared and undeclared

bioprospectors considering park research proposals could be discouraged from applying for NPS research permits to study park resources in anticipation of a potential benefits-sharing agreement requirement to disclose what they consider to be proprietary financial information. Accordingly, implementation of Alternative B1 could reduce the effectiveness or number of benefits-sharing agreements established in the NPS when compared to Alternatives B2 and B3.

Additionally, under Alternative B1, the NPS could face legal consequences and limitations regarding the release to third parties of certain business or commercial information received from benefits-sharing partners as described in Section 4.4.2.2.

Due to the potential reduction in the number of research permits and benefits-sharing agreements, the impacts on NPS administrative operations of implementing Alternative B1 could be less adverse (require less work) than Alternative B2 or B3.

***Impacts specific to Alternative B2 (comply with confidentiality laws regarding disclosure of royalty rate or related information)***

Under Alternative B2, the NPS would consider individual requests to withhold or release proprietary business information regarding the rate at which performance-based payments would be made to the NPS or related financial information on a case-by-case basis. For example, FOIA Exemption 4 authorizes federal agencies to withhold “trade secrets and commercial or financial information obtained from a person and privileged or confidential” when responding to FOIA requests.<sup>38</sup>

Under Alternative B2, all benefits-sharing agreements would be made available to the public in their entirety upon request unless one or more agreement parties objected to the release of any specific information for reasons satisfying one or more of the statutory disclosure exemptions provided under FOIA.

Implementation of Alternative B2 would not reduce either the potential number of benefits-sharing agreements established in the NPS or the number of applications for NPS research permits compared to Alternatives B1 and B3. Alternative B2 also would have no additional impact on NPS administrative operations beyond that already identified for Alternative B.

***Impacts specific to Alternative B3 (never disclose royalty rate or related information)***

Under Alternative B3, proprietary business information (including but not limited to rates at which performance-based payments would be made to the NPS) in a benefits-sharing agreement would never be disclosed.

Implementation of Alternative B3 would not reduce either the number of benefits-sharing agreements established in the NPS or the number of applications for NPS research permits compared to Alternatives B1 and B2. In contrast to Alternative B1, Alternative B3 would have no additional impact on NPS administrative operations beyond that already identified for Alternative B.

#### **4.4.5.5 Mitigation measures**

Several mitigation measures would minimize adverse impacts to NPS administrative operations and prevent and avoid adverse impacts to the NPS research permit issuance decision procedures. Protecting research permit issuance decisions from being inappropriately influenced by benefits-sharing considerations will also protect park resources and values from potential adverse impacts by ensuring that such decisions continue to adhere to the strict standards in place for the issuance of NPS research permits.

##### ***Professional and financial assistance***

Mitigation measures would be applied to protect parks from undue impacts from excessive workloads associated with benefits-sharing or associated with a park's unfamiliarity with executing a benefits-sharing agreement. As provided in Alternative B, the NPS would provide technical assistance to parks with negotiation of benefits-sharing agreements and related issues.<sup>39</sup> Personnel with specialized benefits-sharing expertise would be available to park superintendents upon request in addition to the routine assistance available for every park contract or agreement from a Department of the Interior solicitor.

In addition, the authority in the FTTA to recover costs for administration of CRADAs would mitigate adverse impacts to NPS administrative operations.<sup>40</sup>

##### ***Workload***

NPS implementation of standardized MTAs to authorize third-party transfers of research material originating as specimens collected under the authorization of an NPS research permit and not suitable for permanent retention as part of a museum collection would help to minimize administrative burdens and, as such, any adverse impacts on NPS administrative operations.<sup>41</sup> The average workload associated with the proposed MTAs has not been established; however, Yellowstone National Park has used MTAs since the year 2000 at an average workload of 1 hour and 30 minutes each to execute.<sup>42</sup> No estimate has been made for this FEIS of the number of MTAs that would be executed servicewide, because no systematic way has been established to conduct, manage, or report on these authorizations.

##### ***Guarding against inappropriate influence (management accountability and control)***

In the absence of any mitigation measures, implementation of Alternative B could result in consideration of separate benefits-sharing issues at the time NPS research permits are issued, or at least in the perception of such consideration. For example, some people would allege that some park officials might be inclined to approve a permit based on the applicant's representation that valuable research results were likely, whereas other park officials might be inclined to disapprove permit applications involving commercial research firms for reasons not related to the scientific merits of the proposed research activity. Therefore, mitigation measures would be applied to protect permit issuance decisions from being inappropriately influenced by benefits-sharing considerations. This would protect park resources and values from potential adverse impacts by ensuring that park research coordinators continue to adhere to the strict standards in place regarding the issuance of research permits. Mitigation efforts would use management controls to manage the risk that benefits sharing might inappropriately influence research permitting decisions.<sup>43</sup> They would include the following:

### **Compliance with law**

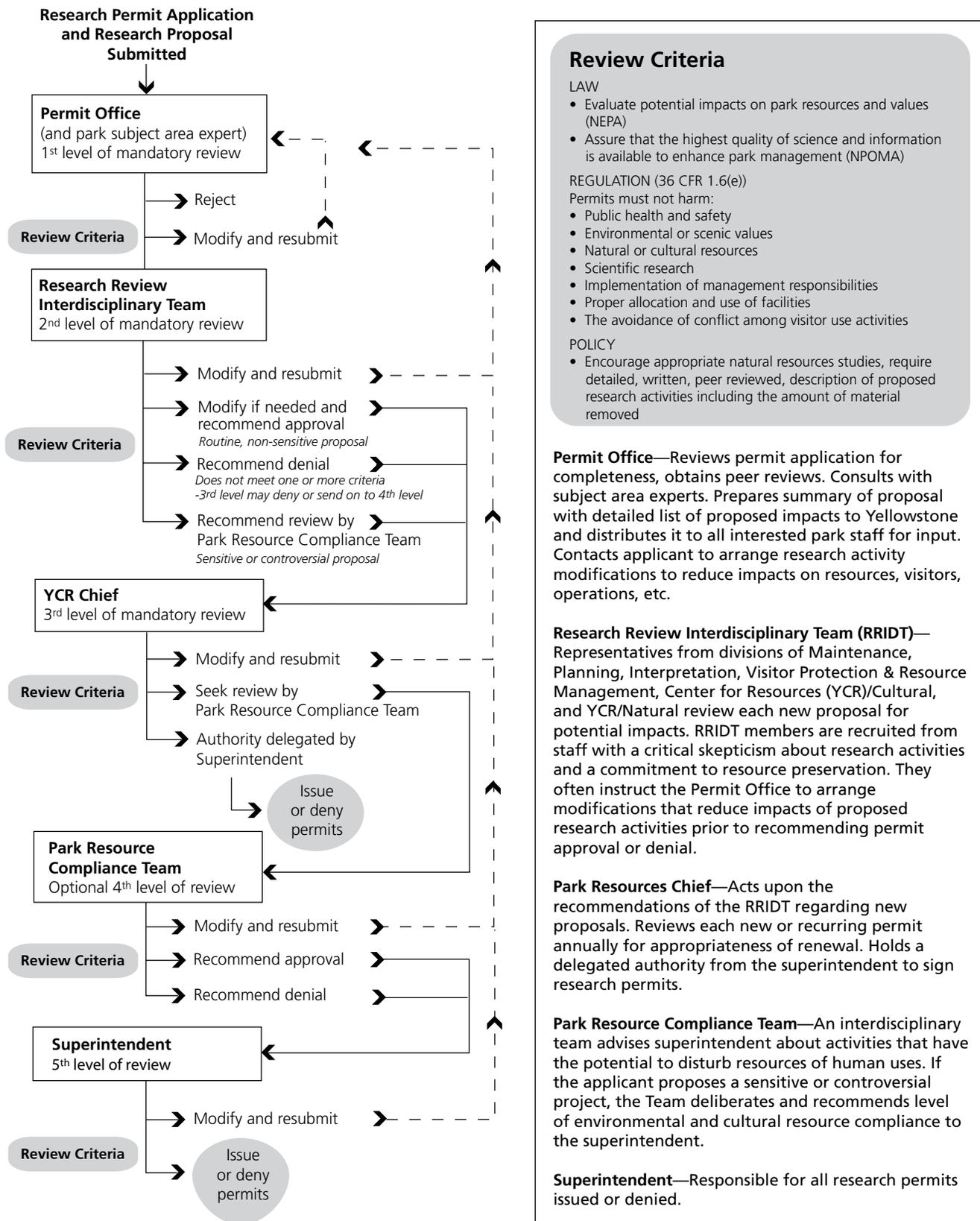
Current regulations guard against benefits-sharing having an inappropriate influence on research permitting decisions. Permits concerning activities that could impact NPS natural resources are issued by park superintendents pursuant to well-established NPS regulations (36 CFR 1.6 and 2.5) and NEPA guidance (Director's Order 12) that would not be affected by implementation of Alternative B. These regulations and policy directives would continue to protect NPS natural resources against impairment or other adverse impacts by applying the mitigation considerations provided in 36 CFR 1.6. These considerations provide that permits for the collection of research specimens from NPS units are issued to qualified applicants based on findings by park superintendents that issuance of a permit would not have adverse impacts on:

- Public health and safety;
- Environmental or scenic values;
- Natural or cultural resources;
- Scientific research;
- Implementation of NPS management responsibilities;
- Proper allocation and use of NPS facilities; or
- Avoidance of conflict among visitor use activities.

Furthermore, research permit applications are reviewed in accordance with NEPA, which provides additional protection against occurrence of adverse impacts to natural resources.

Alternative B would not change these regulations and practices that mitigate against improper issuance of NPS research permits. As an example of the way NPS research permit applications are reviewed, the procedures used by Yellowstone National Park are shown on the next page.

**Figure 4.4.5.5. Research permit review procedures, Yellowstone National Park**



### **Delegation of authority and organization; separation of duties and supervision**

As suggested by the U.S. Office of Management and Budget (OMB), appropriate organizational procedures and structure would be established to effectively carry out program responsibilities.<sup>44</sup>

Four organizational procedures would prevent consideration of benefits-sharing issues at the time of NPS decisionmaking regarding research permit applications:

- 1) Benefits-sharing agreements would not authorize specimen collection in parks.<sup>45</sup>
- 2) Although park superintendents would be the ultimate decisionmakers in both cases, separate individuals would manage preparation of research permit issuance decisions and benefits-sharing negotiations.
- 3) Prior to signature by the park superintendent and the researcher, all benefits-sharing agreements would be circulated for review and clearance along with a copy of the associated research permit and any supporting documentation (study proposal, environmental review forms, etc.), see details below.
- 4) Research permit issuance would precede and remain separate from negotiation of any benefits-sharing agreement.

This separation of the access (research permit) and benefits-sharing decisionmaking processes would ensure that there would be no inappropriate influence resulting from benefits-sharing considerations on the research permitting process.

During the negotiation phase, parks would be provided with technical assistance from personnel with specialized benefits-sharing expertise. Benefits-sharing negotiations would be a team effort including an appropriate mix of NPS staff (*see* the description of technical assistance that would be available to parks in Section 2.4.6.1). This team effort would lend a servicewide perspective in implementing benefits-sharing, thereby ensuring that benefits-sharing agreements would be consistent, equitable, and efficient throughout the National Park System. Before a benefits-sharing agreement could be signed by the park superintendent and the researcher, the agreement and the associated research permit documentation would be recommended for approval by the appropriate regional director and reviewed by the Department of Interior Solicitor's Office and the NPS director. The standardized terms of the General Provisions could not be changed in a specific benefits-sharing agreement without the approval of the Department of the Interior's Office of the Solicitor. As suggested by OMB, these procedures would function as a guard against individuals exceeding or abusing their assigned authorities.<sup>46</sup>

These mitigation measures also would be applied to any future actions that are guided by this FEIS. The NPS would comply with appropriate environmental review requirements under NEPA and any other relevant legislation for any future actions.

#### **4.4.5.6 Conclusion**

Entering into benefits-sharing agreements would be likely to produce long-term, adverse, negligible impacts to administrative operations in all contexts: servicewide, Yellowstone, and individual parks. Implementation of mitigation measures could prevent adverse impacts from rising to a minor level for parks with small staffs.

The implementation of mitigation measures that separate permit decisionmaking from benefits negotiation would prevent the NPS from making decisions about issuance of research permits based upon speculative consideration of possible benefits-sharing.

Impacts from using MTAs would be long-term, beneficial, and negligible servicewide and in individual parks, and would have no impacts in Yellowstone.

Implementation of Alternative B1 would result in fewer benefits-sharing agreements and accordingly less adverse impacts than B2 or B3 in all three contexts.

#### **4.4.5.7 Cumulative impacts**

The negligible adverse impacts of entering into benefits-sharing agreements under Alternative B in all contexts would not demonstrably alter the cumulative impact of other actions outlined in the cumulative scenario. In addition, technical assistance to parks and the cost-recovery provisions of the FTTA are anticipated to mitigate adverse impacts to the administrative workload associated with benefits-sharing agreements (see Section 4.4.5.5).

The negligible beneficial impacts of using standardized MTAs under Alternative B servicewide and in other parks would not demonstrably alter the cumulative impact of other actions outlined in the cumulative scenario. Using standardized MTAs would have no impact to administrative operations in Yellowstone National Park, therefore, Yellowstone would also experience no cumulative impacts associated with this action of Alternative B.

#### **4.4.6 Irreversible and Irrecoverable Commitments of Resources**

Alternative B would not result in the temporary or permanent loss of any resources.

#### **4.4.7 Relationship Between Short-Term Uses of the Environment and Maintenance and Enhancement of Long-Term Productivity**

Alternative B applies to the management of research results. Long-term productivity of the environment would be unaffected by actions proposed by Alternative B.

#### **4.4.8 Adverse Effects that Cannot Be Avoided**

The action of this alternative will not result in any greater-than-negligible adverse impacts.

### **4.5 Alternative C: Prohibit Research Specimen Collection for Any Commercially Related Research Purposes**

Alternative C would prohibit specimen collection for commercially-related research and prohibit commercial development of research results involving NPS research specimens unless determined by the NPS director to be in the public interest. These prohibitions would

not be retroactive; therefore, there would be no impacts related to NPS Scientific Research and Collecting Permits signed before Alternative C’s proposed regulatory change (*see* Chapter 2).

Alternative C would also provide standardized MTAs to parks for completing third-party transfers of research material originating as specimens collected under the authorization of an NPS research permit and not suitable for permanent retention as part of a museum collection.<sup>47</sup> Impacts from the use of MTAs are analyzed in Sections 4.5.4 and 4.5.5.

For purposes of this analysis, the estimated number of potential future research projects that would not be undertaken under Alternative C was estimated based on 1992–2001 park research activity. The NPS is not aware of data or other information that is inconsistent with these findings and projections. The loss of scientific knowledge that could have been obtained from research projects that may be abandoned or never begun under Alternative C cannot be predicted in detail. Long-term impacts are analyzed over the 20-year period following implementation of the alternative. This FEIS considers any change that is evident for five years or less to be short-term.

### 4.5.1 Analysis Common to All Impact Topics

In order to illustrate the potential impacts of Alternative C, information from 2001 was analyzed.

Alternative C would prohibit specimen collection for commercially-related research. The number of research permit applications that would have been denied if Alternative C had been in effect in 2001 is presented in Table 4.5.1. These research projects involved collection of research specimens and were conducted by scientists who informed or acknowledged to the NPS that their research results could be used for some commercial purpose. These 12 research projects could have been conducted without park specimens. However, the level of difficulty in obtaining non-NPS specimens would have varied, as would each project’s specific research results, because NPS units contain relatively intact natural systems and offer research opportunities that may not be available outside the NPS. Table 4.5.1 shows the percentage of 2001 research permit applications that would have been denied for each context under analysis (servicewide, Yellowstone National Park, and other individual parks). In addition, some unknown number of researchers would likely have avoided the potential adverse impacts of Alternative C entirely by not beginning future research involving specimens collected from NPS units.

**Table 4.5.1. Potential consequences of Alternative C**

	<b>Servicewide</b>	<b>Yellowstone</b>	<b>Individual parks</b>
Number of 2001 research permit applications that would have been denied	12	7	5 applications involving 7 parks
% of 2001 research projects	0.6%	3%	1% to 20%

Table 4.5.1. Under Alternative C, research specimen collection for research involving any potential commercial applications would be prohibited. In order to illustrate the potential impacts of Alternative C, information from 2001 was analyzed.

## 4.5.2 Natural Resource Management

Alternative C could result in impacts from the loss of current and future research projects in the NPS. In addition, although the ratio of bioprospectors to all researchers who study park resources is very small, Alternative C could cause some loss of potential research discoveries and scientific data that could have improved understanding of the natural resources that the NPS protects and manages.<sup>48</sup> This impact has both quantitative (number of researchers, research projects, and resulting data) and qualitative (sophistication of the science, relevance to NPS natural resource management, and quality of data) dimensions.

The specific data and discoveries useful for natural resource management that might be lost cannot be known. However, particular losses could be expected in microbiology because almost every known patent related to the study of biological material originating in the NPS has been developed from microbiological research. Because it is becoming increasingly clear that ecosystem processes are largely mediated by microorganisms, and because NPS resource managers generally lack expertise in microbiology, this loss of potential knowledge could be substantial in the future.<sup>49</sup>

Information developed by microbiologists, whether or not they are bioprospectors, can add substantially to natural resource managers' knowledge base. In 2001, at least 72 research reports (IARs) were submitted to the NPS by microbiologists. During that year, the NPS identified 6 of those 72 projects (8% of microbiologists and less than 1% of all researchers) as declared bioprospecting. Under Alternative C, that small proportion of microbiologists would have been denied permission to collect research specimens because under Alternative C, these scientists could have been expected to inform or acknowledge to the NPS that their research results could be used for some commercial purpose. It is reasonably foreseeable that a few additional microbiologists would consider themselves to be undeclared bioprospectors and would therefore avoid applying for an NPS research permit.

### 4.5.2.1 Servicewide impacts

Based on past data, such as the potential loss of less than 1% of research projects servicewide (see Table 4.5.1), the qualitative impacts to servicewide natural resource management from the loss of potential future research projects would likely be long-term, adverse, and would appear to be negligible servicewide, because there would likely be slight change in the availability of new scientific knowledge about park resources servicewide. Quantitatively, there would appear to be long-term, adverse impacts to natural resource management of a negligible intensity servicewide, in light of the relatively small number of research projects affected and the quality of scientific information otherwise available to the NPS as a whole. For example, a potential loss of 8% of permitted microbiologists as described above would appear to have a negligible adverse impact on the quality of knowledge about NPS microbial resources servicewide.

### 4.5.2.2 Yellowstone-specific impacts

Based on past data, the number of potential future research projects that would be lost under Alternative C would likely be small. However, the impacts resulting from the loss of a single high-quality scientific study revealing important new information about Yellowstone's natural resources could be meaningful.

For example, because Yellowstone has recognized that inventories of thermal life are important, it has authorized several research projects to conduct such inventories, including one conducted by a declared bioprospector.<sup>50</sup> The loss of microbial inventory data caused by a reduced number of inventories could have a moderate impact on Yellowstone's understanding and management of its hot spring environments. Although natural resource managers recognize the importance of such biological inventories, park funding for such inventories is limited.

Under Alternative C, the CRADA between Yellowstone National Park and Diversa Corporation, currently suspended, would be nullified, and all monetary benefits provided to Yellowstone by Diversa pursuant to the CRADA before its suspension would be returned to Diversa. In addition, Diversa also would not make any performance-based payments to the park from development of Pyrolase 200™ or from any other product Diversa has developed from its research activities at Yellowstone (*see* Section 4.4.2.4 and Chapter 1, Section 1.8.1.1). Loss of the CRADA's previously arranged up-front payment of \$100,000, equivalent to 1.14% of the FY2002 operational funding for natural resource management that was identified in Yellowstone's Business Plan (*see* Chapter 3, Section 3.2.2), represents a short-term, adverse, negligible impact on Yellowstone's natural resource management.

The number of research projects that would be eliminated under Alternative C is expected to be small. However, if a substantial proportion of researchers studying topics related to Yellowstone's natural resource management priorities abandoned or did not begin park-related research under Alternative C, it would constitute a long-term, major, adverse impact to Yellowstone natural resource management. For these reasons, although past data indicate that the potential loss of at least 3% of independent research projects in Yellowstone would appear to result in long-term, adverse, negligible quantitative impacts, the qualitative impacts to natural resource management at Yellowstone resulting from such a loss could be long-term, adverse, and negligible-to-major.

#### **4.5.2.3 Individual park impacts**

Because there could be a reduction in the number of research projects conducted in some parks, the potential for loss of valuable scientific information that could impact natural resource management is greatest in parks where a large proportion of research projects would either be denied authorization or would never be proposed because researchers avoided park research under Alternative C.

If Alternative C had been in effect in 2001, between 1% and at least 20% of independent research projects potentially would have been lost in the eight individual parks where declared bioprospectors held NPS research permits (*see* Chapter 3, Section 3.4.3). Such losses would represent quantitatively long-term, adverse, and negligible-to-moderate impacts to natural resource management.

The impact of the loss of a single research project in a typical park with few independent research projects is illustrated by examining NPS research in 62 parks that received six or fewer research reports from independent scientists in 2001. The loss of a single research project in any of those parks would have represented a 17–100% decrease in independent research activity, resulting in quantitatively long-term, adverse, moderate-to-major impacts on natural resource management.

Qualitative impacts in both cases could be more adverse than quantitative impacts, depending upon the specific park projects or goals that could be affected.

In sum, quantitative and qualitative impacts to natural resource management for individual parks could be expected to be long-term, adverse, and negligible-to-major.

#### **4.5.2.4 Mitigation measures**

The NPS has not identified any additional mitigation measures (mitigation measures are described *in* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5).

#### **4.5.2.5 Conclusion**

There would likely be a reduction in the number of research projects authorized under Alternative C compared to Alternatives A and B. Accordingly, there could be a reduction in the scientific information that would be generated from such projects that could impact NPS natural resource management. The impacts of Alternative C on NPS natural resource management are thus likely to be long-term and adverse in all three contexts. Qualitatively, these long-term, adverse impacts appear to be negligible servicewide, negligible-to-major in Yellowstone, and negligible-to-major at the individual park level. Because the relative number of such projects that would be affected servicewide is very low (perhaps as low as 0.5%), and because the NPS has access to a great deal of scientific information from many sources, quantitatively, these long-term, adverse impacts appear to be negligible servicewide, negligible in Yellowstone, and negligible-to-major at the individual park level.

#### **4.5.2.6 Cumulative impacts**

The Cumulative Scenario was described in Section 4.3.1.6.

The many variables that can affect future research trends prohibit a meaningful assessment of the number, quality and location of future research projects or reliable determination of whether the current trends in research will continue. Only as new permit applications are submitted to the NPS will it become possible to identify with greater certainty any measurable level of adverse impacts to natural resource management resulting from Alternative C.

The cumulative impacts of the NPS programs and initiatives described in the cumulative scenario are expected to have a beneficial long-term impact on NPS natural resource management in all contexts by providing additional scientific knowledge for park natural resource management decision-making. However, these beneficial impacts could be offset under Alternative C since some researchers would be denied permission to collect NPS research specimens. Bioprospectors often use the newest and most advanced scientific techniques, and discouraging bioprospectors from studying park resources by denying them permission to collect park specimens would decrease the rate at which new science becomes available to parks.

At the Servicewide level, Alternative C is likely to result in only a slight change in the availability of new scientific knowledge about park resources. As a result, this alternative would not demonstrably alter the cumulative impact to actions outlined in the cumulative scenario for natural resources at the servicewide level.

These impacts to natural resource management could be less favorable to certain parks or specific natural resource management projects. The potential reduction in research projects under Alternative C cannot be defined quantitatively, however for specific parks, the loss of certain scientific knowledge could impact a park's natural resource management program.

Most parks have not identified any declared bioprospectors and therefore are less likely to experience a reduction in research under Alternative C. For these parks, no cumulative impacts would result from this alternative.

Yellowstone National Park and other parks that could deny some researchers permission to collect specimens under Alternative C may experience negligible-to-major adverse impacts to the management of park natural resources. In some cases, these adverse impacts could offset the beneficial impacts described in the cumulative scenario. In other cases, the actions described in the cumulative scenario could be expected to replace some of the specialized scientific knowledge no longer available from bioprospectors under Alternative C. When Alternative C's adverse impacts are combined with the beneficial impacts of actions outlined in the cumulative scenario, the cumulative adverse impacts that result could range from negligible (if there is only a slight overall loss of scientific information) to minor (if scientific information relating to a natural resource management priority could not be practically acquired otherwise).

### **4.5.3 Visitor Experience and Enjoyment**

Alternative C could result in impacts to visitor experience and enjoyment resulting from a potential reduction in the amount of available scientific research results and the number of collaborative interactions with researchers that the NPS uses to develop interpretive services for visitors.

#### **4.5.3.1 Servicewide impacts**

The servicewide impacts to visitor experience and enjoyment from loss of potential future research projects can only be examined in general terms, because the specific data and discoveries that would have been useful for interpretation targeted towards natural resource management goals cannot be known in advance of potential future research projects. However, because the estimated number of research permit applications that would be denied is so small (*see* Table 4.5.1), the servicewide impacts appear to be long-term, adverse, and negligible.

#### **4.5.3.2 Yellowstone-specific impacts**

Similarly to servicewide impacts, the impacts to Yellowstone visitor experience and enjoyment from the loss of potential future research projects can only be examined in general terms. In particular, the specific data and discoveries that would have been useful for interpretation targeted toward resource protection cannot be known in advance of potential future research projects. However, one of the co-investigators in a 2001 research project that would not have occurred if Alternative C had been in effect was also a member of the scientific review panel for the new Old Faithful Visitor Education Center. It is reasonable to expect that this researcher would not have been conducting research in the park, and therefore would not have been in a position to participate on this scientific review panel, if Alternative C had been in effect.

Accordingly, although the potential loss of at least 3% of independent research projects in Yellowstone appears to be quantitatively long-term, adverse, and negligible for visitor experience and enjoyment overall, for specific projects the loss could be qualitatively long-term, adverse, and negligible-to-minor.

#### **4.5.3.3 Individual park impacts**

Again, the impacts to park-specific visitor experience and enjoyment from loss of potential future research projects can only be examined in general terms (*see also* Section 4.5.2.3). In all cases, impacts would be long-term and adverse. Qualitative impacts in any park could range from negligible-to-major relative to specific goals related to visitor experience and enjoyment. For certain parks, the resultant loss of information for interpretation of science from a key research project would be substantial. Impacts in parks with few independent researchers would be quantitatively more adverse than in parks with many independent researchers, ranging from negligible-to-major.

#### **4.5.3.4 Mitigation measures**

The NPS has not identified any additional mitigation measures (mitigation measures are described *in* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5).

#### **4.5.3.5 Conclusion**

Under Alternative C, there would be long-term, adverse effects related to a small reduction in the number of researchers at work in parks in all three contexts. Qualitatively, these long-term, adverse impacts could be negligible servicewide, negligible-to-minor in Yellowstone, and negligible-to-major at the individual park level. Quantitatively, these long-term, adverse impacts appear to be negligible servicewide, negligible in Yellowstone, and negligible-to-major in other specific parks.

#### **4.5.3.6 Cumulative impacts**

The cumulative impacts of the NPS programs and initiatives described in the cumulative scenario are expected to have a beneficial long-term impact on visitor experience and enjoyment in all contexts by improving NPS interpretive services. The negligible adverse impacts to visitor experience and enjoyment that result from Alternative C's small reduction in the number of researchers at work in parks would not demonstrably alter the cumulative beneficial impact to servicewide or Yellowstone visitor experience and enjoyment. The negligible-to-major adverse impacts to visitor experience and enjoyment that could result from the loss of partnership opportunities with researchers under Alternative C in some other individual parks could effectively reduce the beneficial cumulative impact of actions described in the cumulative scenario in a few individual parks.

### **4.5.4 Social Resources: The Research Community**

Under Alternative C, certain researchers would be prohibited from collecting research specimens in national park units, and all researchers would be prohibited from commercial development of their research results, barring a select few, case-by-case exceptions as determined by the NPS director (*see* Chapter 2, Section 2.5.1).<sup>51</sup>

#### **4.5.4.1 Impacts to declared bioprospectors**

Under Alternative C, researchers who identified or acknowledged that their research results

could have some commercial application (declared bioprospectors) and were qualified in all other respects could be issued a research permit, but would not be authorized to collect research specimens.

If Alternative C had been in effect in 2001, approximately 23 of the 4,568 total permitted researchers registered in RPRS (0.5% of researchers) could have been denied permission to collect NPS research specimens by the 8 parks in which they conducted research. These 23 researchers conducted 12 of the 2,160 total research projects (0.6% of projects) registered in RPRS in 2001. The 23 researchers could have continued to conduct research without park specimens, thus avoiding a major adverse impact. However, the level of difficulty in obtaining non-NPS specimens would vary. Some of the 23 researchers could find more or less similar specimens outside of parks. Others would have more difficulty; for example, researchers who study thermophilic microorganisms might have no readily accessible alternative sites outside of parks for collection of research specimens from similar or identical biological, chemical and thermal environments that have not been degraded by human activity. Other thermophilic microorganism specimens could be collected in extremely remote areas (e.g., in the deep ocean), but at a significant expense. In all cases, an NPS specimen might have had more desirable attributes for study than its non-NPS substitute and the researcher might have discovered a commercially applicable research result studying a park specimen that would not have been discovered otherwise. Accordingly, declared bioprospectors (approximately 0.5% of the research community) would experience long-term, adverse, minor-to-moderate impacts under Alternative C.

Alternative C responds to public advice to prohibit commercialization of NPS-related research by denying permission to collect research specimens if there is any connection between proposed specimen collection and an identified or acknowledged commercial use of research results. Accordingly, some researchers who are not usually considered to be bioprospectors could also be affected by Alternative C. For example, a research project that the researcher acknowledged would result in the development of commercially valuable software to interpret scientific data would be prohibited from studying NPS research specimens. The number of such researchers who would be affected in this way by Alternative C, although likely very small, cannot be determined from available data. Accordingly, potential adverse impacts to the research community may involve more than the 0.5% of the research community identified in the paragraph above.

#### **4.5.4.2 Impacts to inadvertent and undeclared bioprospectors**

Impacts to undeclared and inadvertent bioprospectors would be only slightly discernible in the NPS research community as a whole, because less than 1% of NPS-permitted researchers perform such research (*see* Section 3.4.3).

Some undeclared bioprospectors could prefer to keep their options open for commercialization by refraining from proposing or conducting research involving research material originally collected in an NPS unit. As described for declared bioprospectors, the level of difficulty in obtaining non-NPS specimens would vary, as would each researcher's specific research results, because NPS units contain relatively intact natural systems and offer research opportunities that may not be available outside the NPS.

Under Alternative C, inadvertent bioprospectors would be prohibited from developing any discoveries resulting from research involving NPS research specimens that could have some valuable commercial application unless such development was determined in writing by the NPS director to be in the public interest. Inadvertent bioprospectors whose discoveries were not determined to be in the public interest and therefore were not permitted to use their research results for commercial purposes could be prevented from having the opportunity to realize economic gains from their research results. In addition, because some research projects require long-term, historical, site-specific data, a researcher involved in such a project might not welcome the inadvertent realization that his research results could have commercial applicability. Such inadvertent bioprospectors who considered themselves basic researchers with no intention for their studies to have commercial application would experience a major adverse impact if they had to discontinue long-term study of NPS specimens when they recognized and acknowledged a foreseeable commercial use for their research results.

Accordingly under Alternative C, inadvertent bioprospectors and some undeclared bioprospectors, a small minority of the research community, could experience long-term, adverse, negligible-to-major impacts.

#### ***4.5.4.3 Impacts to researchers who transfer specimens or material originating as an NPS research specimen to others, researchers who receive transfers, and all other researchers***

Currently, there is no standardized process or format for requesting NPS authorization of third-party transfers of research material originating as specimens collected under the authorization of an NPS research permit and not suitable for permanent retention as part of a museum collection. Standardization of MTAs is expected to reduce the workload associated with making such requests by streamlining the process and eliminating additional paperwork associated with multiple versions of MTAs issued by individual parks, thus providing a beneficial impact to researchers. The workload for researchers would be substantially less than the 1.6 hours required to obtain an NPS research permit.

In addition, use of the standardized MTA would clearly subject third-party transfer recipients to Alternative C's prohibition of commercialization of research results and likely would induce undeclared bioprospectors to consider foregoing conducting their research using NPS specimens. Accordingly, Alternative C's impacts to bioprospectors, as described previously, could apply to more researchers than those who personally collect research material from NPS units under NPS research permits. Overall, the impacts to these researchers are considered to be long-term, beneficial, and negligible.

#### ***4.5.4.4 Mitigation measures***

Under Alternative C, the burden of identifying and declaring potential commercial applications for research results would be placed on the researcher rather than the park. This would serve to protect researchers from being unfairly denied permission to collect specimens. Therefore, researchers who have no plans or expectations of making commercial use of their research results and who meet all of the other qualifications for an NPS research permit could be granted permission to collect specimens regardless of whether or not they study specific topics with recognized commercial potential.

#### **4.5.4.5 Conclusion**

Adverse impacts would occur to somewhat more than 0.5% of the research community.

All researchers would be prohibited from using their research results for commercial purposes and would thereby be prevented from seeking economic gain from them (unless such use was determined in writing by the NPS director to be in the public interest, in the case of inadvertent bioprospectors). Declared bioprospectors also would be denied permission to collect research specimens from national park units. As such, they could experience short-to-long-term, adverse, minor-to-moderate impacts.

Inadvertent bioprospectors would experience long-term impacts under Alternative C that could be adverse, minor-to-major impacts in the event that they were prevented from performing research based on past studies or from realizing economic gain from research results.

Some undeclared bioprospectors could be expected to discontinue conducting or planning studies under NPS research permits, which would have long-term, adverse, negligible-to-major impacts on those researchers.

Researchers who transfer or receive transferred specimens or material originating as an NPS research specimen, and all other researchers, would experience long-term, beneficial, negligible impacts from the institution of standardized MTAs. They would also be subject to Alternative C's prohibition of commercialization of research results and the impacts described for bioprospectors.

#### **4.5.4.6 Cumulative impacts**

Under Alternative C, some researchers would be excluded from studying material originating as a park specimen and others would choose not to study such material (estimated to be somewhat more than 0.5% of the research community described in this FEIS). For this minority of the research community, Alternative C's adverse impacts combined with the impacts described in the cumulative scenario could result in either a less beneficial or a more adverse cumulative impact than the impact of the cumulative scenario alone. For researchers who participate in material transfers, the negligible beneficial impact of Alternative C would not demonstrably alter the cumulative impact of other actions outlined in the cumulative scenario. The actions of Alternative C would have no impact to all other researchers, therefore there would be no demonstrable addition to the total cumulative impact these researchers experience from other sources.

### **4.5.5 Social Resources: NPS Administrative Operations**

Under Alternative C, there would be no benefits-sharing agreements to administer. Some researchers would not conduct studies in NPS units, and NPS authorization of third-party transfers of research material originating as specimens collected under the authorization of an NPS research permit and not suitable for permanent retention as part of a museum collection would occur through standardized MTAs.

#### **4.5.5.1 Servicewide impacts**

Somewhat more than 0.5% of researchers would be expected to drop plans for conducting studies under NPS research permits. Such a reduction in the number of researchers working in

parks would represent a long-term, beneficial, negligible impact on the administrative burden associated with managing research permits.

Based on Yellowstone National Park data, the time required to execute an MTA is 1 hour and 30 minutes.<sup>52</sup> There is no established systematic way to estimate the number of specimen transfer authorizations issued servicewide. However, the existing level of confusion appears to be minimal and does not constitute a significant adverse impact. Precise characterization of this impact is not essential to a reasoned choice among the alternatives. The impact of adding standardization to the current requirement to authorize third-party transfers of NPS research specimens or other material originating as an NPS research specimen, particularly for material that is unsuitable for permanent retention as a museum collection, is expected to be long-term, beneficial, and negligible.

#### **4.5.5.2 Yellowstone-specific impacts**

Somewhat more than 3% of researchers in Yellowstone would be expected to abandon or not begin park-related studies. Processing a research permit application requires approximately 0.03 FTE (*see* Chapter 3, Section 3.5.2). If the seven declared bioprospectors identified for Yellowstone in 2001 stopped conducting research in the park, 0.21 fewer FTE (0.2% of the available FTE identified in Yellowstone's Business Plan) would be necessary to process research permit applications. Such a reduction in the number of researchers working in Yellowstone would represent a long-term, beneficial, negligible impact on the administrative burden associated with managing research permits.

Because Yellowstone National Park has used standardized MTAs since 2000, their servicewide introduction would have no impact in this context.

#### **4.5.5.3 Individual park impacts**

A reduction in the number of researchers working in parks would represent a long-term, beneficial impact on the administrative burden associated with managing research permits in individual parks. Because only a single declared bioprospector was identified in 2001 in any individual park (other than Yellowstone), it is anticipated that 0.03 fewer FTE would be required for any park that would avoid processing a single research permit application (*see* Chapter 3, Section 3.5.2).

Other than Yellowstone, 31 of the 44 park business plans previously described include information about existing administrative resources.<sup>53</sup> The number of available administrative FTE per park varies considerably (*see* Table 4.4.5.3). If individual parks avoided processing a single research permit application, the FTE no longer required for that purpose would represent, at most, 0.6% of available FTE. For this reason, the potential impacts to NPS administrative operations of Alternative C's reduction in the number of researchers applying for research permits at the individual park level would be long-term, beneficial, and negligible in all reasonably foreseeable cases.

The impact of adding standardized MTAs to the current processes to authorize third-party transfers of NPS research specimens or other material originating as an NPS research specimen is expected to be long-term, beneficial, and negligible.

#### **4.5.5.4 Mitigation measures**

The NPS has not identified any additional mitigation measures (mitigation measures are described *in* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5).

#### **4.5.5.5 Conclusion**

The impacts of Alternative C on NPS administrative operations in all contexts (servicewide, Yellowstone National Park and other individual parks) would be long-term, beneficial and negligible.

#### **4.5.5.6 Cumulative impacts**

Under Alternative C, potential reductions in the number of research proposals and implementation of standardized MTAs would have a negligible beneficial impact on administrative operations in all contexts. These negligible beneficial impacts would not demonstrably alter the cumulative impact of other actions outlined in the cumulative scenario for all contexts.

### **4.5.6 Irreversible and Irretrievable Commitments of Resources**

Alternative C would not result in the temporary or permanent loss of any resources.

### **4.5.7 Relationship Between Short-Term Uses of the Environment and Maintenance and Enhancement of Long-Term Productivity**

Alternative C would slightly restrict specimen collection activities from NPS units. Long-term productivity of the environment would be unaffected by Alternative C.

### **4.5.8 Adverse Effects that Cannot Be Avoided**

The FEIS reveals the possible environmental impacts of choosing whether or not to implement a certain type of contract. Hence, the nature of this FEIS is such that its affected environment and impact topics relate primarily to administrative functions of the NPS. The actions of this alternative that will result in adverse impacts that cannot be fully mitigated or avoided are related to these administrative functions. Alternative C would prohibit some researchers from studying NPS research specimens, some of whom would not find appropriate specimen collection sites outside the NPS. Other adverse impacts of the alternative would be mitigated by the beneficial actions described in the cumulative scenarios.

# Notes

## Section 4.1 Introduction

<sup>1</sup> National Park Service Organic Act, 16 USC 1.

<sup>2</sup> The Federal Technology Transfer Act of 1986 (FTTA) requires that benefits generated for parks be used for research and development consistent with a park's mission. The FTTA also allows the use of benefits for scientific education and training or scientific exchange among the parks as well as for administration of the CRADA (15 USC Section 3710a; *see also* Chapter 4, Section 4.4.1).

## Section 4.2 Methodologies for Evaluating Impacts

<sup>3</sup> *See, e.g.*, C. J. Widner, "Reducing Theft of Petrified Wood at Petrified Forest National Park," *Journal of Interpretation Research* 5(1):1–18.

<sup>4</sup> Any specific discoveries that could be used for commercial purposes cannot be known in advance of the actual discovery. In addition, proprietary information about any current commercial use of research results also is unavailable. In the absence of the supplemental reporting requirements that would be in effect pursuant to a CRADA, the NPS does not have access to proprietary information concerning any income resulting from any researcher's commercial uses of research results.

<sup>5</sup> National Park Service, *National Park Service Management Policies 2006* (Washington, D.C.: U.S. Department of the Interior, 2006).

<sup>6</sup> *See* 40 CFR 1508.7.

## Section 4.3 Alternative A: No Benefits-Sharing/No Action

<sup>7</sup> Diversa scientists have continued to study Yellowstone resources. In 2004, they applied for and obtained a research permit to explore the microbial diversity in Yellowstone Lake. Their preliminary results almost doubled the known number of microbe species in the lake and provided a proof-of-concept for a new biodiversity assessment model melding classic Linnaean taxonomy with genomic inventories (Eric Mathur, "Biomolecular Diversity in Yellowstone National Park," NPS Investigator's Annual Report, 2004), available online at <<http://rprs.nps.gov/research/ac/iars/search/iarView?reportId=32666>>, last accessed April 18, 2006.

<sup>8</sup> National Park Service, *Funding the Natural Resource Challenge: A Report to Congress, FY 2001,12*, available online at <<http://www.nature.nps.gov/challenge/congress/congressreport2001.pdf>>, last accessed March 20, 2006.

<sup>9</sup> For additional information and materials, see <<http://www.cesu.psu.edu/default.htm>>.

<sup>10</sup> National Science Foundation, Division of Science Resources Statistics, National Patterns of Research and Development Resources: 2003, NSF 05-308, Brandon Shackelford (Arlington, VA 2005). *see also* Rapoport, A. I. 1999. How has the field mix of federal research funding changed over the past three decades? National Science Foundation/Division of Science Resources Studies Issue Brief.

<sup>11</sup> Personal experience of the IDT gained from reviewing hundreds of park research proposals. Data regarding funding sources for NPS permitted research projects service-wide has not been compiled. (*see also* Section 4.3.3.6)

<sup>12</sup> Analysis of the intensity of potential beneficial economic impacts was limited to potential income related to licensing of research results. Proprietary business information about other forms of income related to the commercial use of research results, such as income related to patent right sales or from actual product sales, was unavailable for analysis. The record of licensing income to universities and federal laboratories indicates that income to a researcher's institution from licensing of research results generates between \$0 and more than \$1 million per license. (More detailed analysis of such license income is presented in this chapter, Section 4.4.1.3 and in Appendix C.)

<sup>13</sup> AUTM 2003 reports that 66% of research expenditures that year were funded from federal sources.

<sup>14</sup> NPS Natural Resource Year in Review 2004. *see also* United States, Committee on Improving the Science and Technology Programs of the National Park Service, *Science and the National Parks* (Washington, D.C.: National Academy Press, 1992).

## Section 4.4 Alternative B: Implement Benefits-Sharing

<sup>15</sup> The FTTA authorizes private-sector research partners to provide funds through CRADAs to be used to support the participating federal laboratory's research activities consistent with its mission. This FEIS terms such payments "up-front payments." Not all benefits-sharing agreements would generate up-front payments. The FTTA also authorizes private-sector research partners to provide performance-based payments that would likely be due to the NPS whenever (and if) the researcher's institution derived any kind of income from research results. Income can be generated in a number of ways in addition to

product sales. For example, income can be produced by the performance of contract research, such as screening compound libraries. Income can also be produced if intermediate research results are licensed to another institution. Licenses can generate income for the researcher's institution through license issue fees, annual minimum payments, milestone payments (payments based on successful completion of certain R&D stages, described in Chapter 3, Section 3.4.3), or royalties.

<sup>16</sup> See 15 USC 3710c.

<sup>17</sup> See 15 USC 3710a(d)(1) and 3710c.

<sup>18</sup> The fundamental purpose of the National Park System is established by the NPS Organic Act, and reaffirmed by the General Authorities Act, as amended and interpreted for the NPS by NPS Director's Order #55.

<sup>19</sup> A chi-square test was performed to determine if the null hypothesis ("There was no change in the number of reports/permits before 1997 and after 1997") could be rejected. In each case, there was no evidence of a significant difference in the number of reports submitted (or, in one dataset, permits issued) before and after NPS announced the benefits-sharing agreement between Yellowstone and Diversa. In other words, the null hypothesis could not be rejected (see also Appendix E).

<sup>20</sup> See, e.g., A. Artuso, *Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing* (Binghamton, New York: The Haworth Press, 1997); W. H. Lesser and A. F. Krattiger, "The Complexities of Negotiating Terms for Germplasm Collection," *Diversity* 10(3).

<sup>21</sup> 18 USC 1905. Disclosure of confidential information generally. Whoever, being an officer or employee of the United States or of any department or agency thereof, . . . publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; . . . shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.

<sup>22</sup> *Public Citizen Health Research Group v. National Institutes of Health, et al.*, Civil Action No. 00-1847 (DDC 2002) (Memorandum Opinion dated March 11, 2002). See also 5 USC 552 (b)(4).

<sup>23</sup> Ibid.

<sup>24</sup> For example, Exemption 4 requires federal agencies to withhold "trade secrets and commercial or financial information obtained from a person and privileged or confidential" when responding to FOIA requests (see 5 USC 552 (b)(4)).

<sup>25</sup> Although potential monetary benefits were compared to Natural Resource Challenge funding, such benefits might not be useable by the same programs funded by the Challenge.

<sup>26</sup> Yellowstone National Park, *Resource Management Plan* (1995).

<sup>27</sup> See, e.g., Widner, "Reducing Theft of Petrified Wood at Petrified Forest National Park."

<sup>28</sup> For example, Article 4.1 of the standardized CRADA proposed by Alternative B authorizes the park superintendent to require research reports containing whatever level of detail the superintendent requests (see Appendix A).

<sup>29</sup> See Appendix A, Article 7.1, requiring the benefits-sharing partners to disclose all inventions.

<sup>30</sup> Similar assistance has recently been given by researchers to Yellowstone National Park.

<sup>31</sup> About 90 researchers were identified by the NPS between about 1990 and 2002 as possible declared or undeclared bioprospectors. About 80 of these scientists actually held NPS research permits; the remainder made inquiries only. During a similar time frame (1992–2001), the NPS received more than 20,500 research reports from permitted researchers.

<sup>32</sup> See *Public Citizen Health Research Group v. National Institutes of Health*, Civil Action No. 00-1847 (DDC Memorandum Opinion dated March 12, 2002 (Colleen Kollar-Kotelly, J.)).

<sup>33</sup> Such negotiations would meet the requirement for benefits-sharing agreements to be equitable as mandated by the National Parks Omnibus Management Act (16 USC Chapter 79, Section 5935(d)).

<sup>34</sup> 15 USC 3710c.

<sup>35</sup> In addition to those activities listed in the text, other work associated with the AUTM-reported FTE include technology valuation and license agreement drafting and negotiation.

<sup>36</sup> C. Hendrix, Yellowstone Research Permit Coordinator, pers. comm. to A. Deutch, November 2003.

<sup>37</sup> Most Business Plans that were prepared in 1999 (the first year of the Business Plan Initiative) did not include FTE information.

<sup>38</sup> See 5 USC 552 (b)(4).

<sup>39</sup> Such assistance would be consistent with the guidelines relating to development of CRADAs first published by the Department of the Interior in May 1996.

<sup>40</sup> 15 USC 3710c(a)(1)(B)(iv).

<sup>41</sup> The proposed MTA and related procedures described in Alternative B are based on the Uniform Biological Material Transfer Agreement developed by the National Institutes of Health in 1995, in part to minimize

administrative burden. Accordingly, any adverse impacts on NPS administrative operations also would be minimized.

<sup>42</sup> C. Hendrix, Yellowstone Research Coordinator, pers. comm. to A. Deutch, November 2003.

<sup>43</sup> See OMB Circular A-123, Management Accountability and Control (1995).

<sup>44</sup> Ibid.

<sup>45</sup> The potential mitigation impacts of this distinction on specimen collection activities in NPS units have been recognized and affirmed on judicial review. See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, at 70 (DDC 2000) (“[W]hile in certain respects the CRADA may impose restrictions on [the research firm’s] research activities over and above those provided by a permit alone, the research permit, not the CRADA, provides the legal basis for [the research firm] to collect specimens. For example, the CRADA may give Park officials *greater* control of specimen extraction. . . .” (emphasis added)).

<sup>46</sup> See OMB Circular A-123.

#### **Section 4.5 Alternative C: Prohibit Research Specimen Collection for Any Commercially Related Research Purposes**

<sup>47</sup> Material Transfer Agreements (MTAs) are not “benefits-sharing” agreements, because they do not contain revenue-sharing or other benefits-sharing terms or obligations.

<sup>48</sup> About 90 researchers were identified by the NPS between about 1990 and 2002 as possible declared or undeclared bioprospectors. About 80 of these scientists actually held NPS research permits and the remainder made inquiries only. During a similar time frame (1992–2001) the NPS received more than 20,500 research reports from permitted researchers.

<sup>49</sup> For example, on the Colorado Plateau, the ecosystem role of biological soil crusts, composed entirely of microorganisms and non-vascular plants, has been recognized to be so important that federal land managers on the plateau usually consider potential impacts to crusts in their environmental assessments of proposed Colorado Plateau projects (M. Nijhuis, “Getting under the desert’s skin: Biologist Jayne Belnap,” *High Country News*, 36:2, January 19, 2004; see also R. Constanza et al., “The Value of the World’s Ecosystem Services and Natural Capital,” *Nature* 387:253–260).

<sup>50</sup> In 2001, Yellowstone permitted a microbiologist to begin a study of thermophilic viruses with two objectives: (1) to discover new information about these seldom-studied viruses, and (2) to discover “various applications” for the new discoveries. This study, partly motivated by bioprospecting, evolved into a thorough inventory of all the microscopic life forms in a single hot spring (T. Schoenfeld, “Viral Populations in Thermal Environments,” NPS Investigators’ Annual Report, 2001, available online at <<http://rprs.nps.gov/research/ac/iars/search/iarView?reportId=20842>>; T. Schoenfeld, “Microbial Life in Thermal Environments,” NPS Investigators’ Annual Report, 2002, available online at <<http://rprs.nps.gov/research/ac/iars/search/iarView?reportId=23913>>; T. Schoenfeld, “Microbial Life in Thermal Environments,” NPS Investigators’ Annual Report, 2003, available online at <<http://rprs.nps.gov/research/ac/iars/search/iarView?reportId=27141>>, all last accessed October 24, 2008.

<sup>51</sup> The NPS director could authorize commercial development of an inadvertent or otherwise unexpected valuable discovery based on a finding by the director that refusal to authorize such development could be harmful to public health or other overriding public interest (such as discovery and development of an important new medicine).

<sup>52</sup> C. Hendrix, Yellowstone Research Permit Coordinator, pers. comm. to A. Deutch, November 2003.

<sup>53</sup> Most Business Plans that were prepared in 1999 (the first year of the Business Plan Initiative) did not include FTE information.

# **Chapter 5**

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## **Consultation and Coordination**

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## **5.1 Introduction**

This chapter describes the consultation and coordination that has occurred during the preparation of the Benefits-Sharing Environmental Impact Statement (EIS). Consultation, coordination, and public involvement have been integral to identifying relevant issues and concerns and to make sure these issues are addressed. This was accomplished primarily through newsletter mailings, individual contacts, website postings, news releases, and Federal Register notices.

### **5.1.1 History of Public Involvement**

#### ***5.1.1.1 Initial public scoping***

Public involvement for the Benefits-Sharing Environmental Impact Statement began in June 2001 with a public scoping process. Scoping is an early and open process for determining the scope of environmental issues and alternatives to be addressed in a NEPA document. Chapter 1, Section 1.8 contains a summary of the process and the major issues and concerns identified through this process, key to development of the DEIS. The NPS published a notice of intent to prepare an environmental assessment (EA) in the Federal Register on June 25, 2001.<sup>1</sup> Scoping comments received from the public persuaded the NPS that an EIS would be more appropriate. The NPS published a notice of intent to prepare an EIS in the Federal Register on April 12, 2002.<sup>2</sup>

#### ***5.1.1.2 DEIS public notification***

The Benefits-Sharing Draft Environmental Impact Statement (DEIS) was released for public review on September 22, 2006 (71 Federal Register [FR] 184), initiating the formal public comment period for the DEIS. Due to print omissions and delays in delivering the draft, the comment period was extended on December 15, 2006 (71 FR 241). The comment period concluded on January 29, 2007, and totaled 130 days.

Approximately 12,000 people were notified by mail or email about the availability of the DEIS for public review, including all NPS superintendents, all researchers who entered their contact information into the NPS Research Permit and Reporting System website, and every person who contacted the EIS team. Notification about the availability of the DEIS for public review was also made through press releases and by posting on the NPS Planning, Environment and Public Comment (PEPC) web site at <http://parkplanning.nps.gov> and also the benefits-sharing project website at [www.nature.nps.gov/benefitssharing](http://www.nature.nps.gov/benefitssharing). More than 450 hard copies or compact disks (CDs) of the DEIS were distributed and the DEIS was also posted for download from the PEPC web site. A complete list of individuals, agencies, tribes and organizations that received the project scoping materials and/or the draft EIS and/or the final EIS is on file at Yellowstone National Park. The following is a partial list of the agencies, offices, and organizations to whom the DEIS was sent.

#### ***5.1.1.3 List of DEIS recipients***

Alliance for the Wild Rockies  
Advisory Council on Historic Preservation  
Biotechnology Industry Organization  
Bureau of Land Management

Bureau of Reclamation Office of Science and Technology  
Center for Urban Ecology  
Cubist Pharmaceuticals, Inc.  
Defenders of Wildlife  
Department of Interior Deputy Secretary  
Department of Interior Assistant Secretary for Fish and Wildlife and Parks  
Diversa Corporation  
Ecology Center  
Edmonds Institute  
George Wright Society  
International Center for Technology Assessment  
Minerals Management Service  
National Agricultural Library  
National Biodiversity Institute, Costa Rica  
National Cave and Karst Research Institute  
National Conference of State Historic Preservation Officers  
National Institutes of Health Office of Technology Transfer  
National Marine Fisheries Service  
National Parks and Conservation Association  
Native Forest Network  
Public Employees for Environmental Responsibility  
Sierra Club  
Sierra Club Genetic Engineering Committee  
US Army Corps of Engineers Office of Policy and Compliance  
US Environmental Protection Agency  
US Fish and Wildlife Service  
US Department of State, Office of Ecology and Terrestrial Conservation  
US Geological Survey  
US Geological Survey Office of Technology Transfer  
USDA Forest Service  
USDA NRCS Agricultural Research Coordinator  
Washington Biotechnology Action Council  
Yellowstone Research Coordinating Network, Montana State University

#### ***5.1.1.4 Organizations and agencies consulted***

During the NEPA decision-making processes, the NPS is required to consult with certain American Indian tribes, as well as with federal and state agencies and entities with jurisdictional responsibilities (40 CFR 1502.25). This section documents these consultation and coordination efforts. Consultation will be an ongoing effort through completion of a final document and agency decision. Letters received from various organizations and agencies are included in the Representative Correspondences section of Chapter 5.

All American Indian Tribal Governments and Alaska Native Groups were notified about potential NPS benefits-sharing because this decision could affect any national park unit in the United States. Three tribes commented on the EIS. All correspondence received from tribes is reproduced in Chapter 5. Issues identified by tribes included cautioning against allowing any extraction of park natural resources for direct commercial use, and cautioning against allowing research to adversely impact park resources or spiritual values. The Shoshone-

Bannock Tribes also clarified their social and spiritual connection to Yellowstone National Park and made suggestions about research permitting procedures in Yellowstone.

The 1966 National Historic Preservation Act, as amended in 1992, requires federal agencies to consult with the state historic preservation officer and the Advisory Council on Historic Preservation (Council) regarding undertakings that may affect historic properties. Because the Benefits-Sharing EIS is about a servicewide proposal, formal consultation letters were sent to both the Council and the National Conference of State Historic Preservation Officers. Both the Council and the National Conference determined that the benefits-sharing proposal is not an undertaking as defined in the National Historic Preservation Act and its implementing regulations, “Protection of Historic Properties” (36 CFR Part 800). Accordingly, pursuant to 36 CFR 800.3(a)(1) and 800.16(y), the NPS has no further obligations for compliance with Section 106 for the development and implementation of benefits-sharing policy and agreements with scientists who conduct research in NPS units.

The Endangered Species Act of 1973, as amended, directs every federal agency to ensure that any action it authorizes, funds, or carries out is not likely to jeopardize the existence of any federally-listed species or destroy or adversely modify critical habitat (50 CFR 400). In compliance with Section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et. seq.), a formal letter was sent to the U.S. Fish and Wildlife Service (USFWS) in May 2007 regarding the DEIS. The USFWS replied in June 2007 with a caution that some specific research activities could require additional consultation in the future. Although research activities are out of scope of the Benefits-Sharing EIS, the NPS agrees and continues to review research activities for impacts to endangered species under a separate process. The USFWS determined that the benefits-sharing proposal (Alternative B) would be “not likely to adversely affect” threatened or endangered species.

The United States Department of State Office of Ecology and Terrestrial Conservation also provided comments on the DEIS. The NPS was advised that any benefits-sharing program should first and foremost encourage research and scientific innovation, not discourage it.

#### **5.1.1.5 DEIS public response**

About 9,600 individuals and organizations chose to participate in the comment process by submitting correspondence during the public review period.<sup>3</sup> The correspondence included form and non-form letters, both mailed and submitted over the internet at the NPS Planning Environment and Public Comment (PEPC) website. Only 190 individual or organization correspondents submitted non-form letters. Form correspondence (e.g., a form letter) is defined as a correspondence whose content is essentially duplicated by several commenters. Form correspondences are typically copied from material distributed by organizations.

The Comments and Responses section of Chapter 5 contains a summary of comments received on the Benefits-Sharing Draft Environmental Impact Statement. It also contains responses to comments as appropriate under CEQ regulations.

## 5.2 Responses to Comments on the Draft Benefits-Sharing EIS

### 5.2.1 Introduction

Section 5.2.3 contains a summary of all comments received on the NPS Benefits-Sharing Draft Environmental Impact Statement. Section 5.2.2 contains an overview of the process and a breakdown of comment types, numbers, and content. Sections 5.3.1 through 5.3.15 contain excerpts from correspondence that summarize the content of all correspondences received. Sections 5.3.1 through 5.3.15 also contain responses to comments as appropriate under CEQ regulations. Section 5.4 contains correspondences that are representative of the body of comment as a whole.

In preparing a final EIS (FEIS), an agency is required to assess and consider comments both individually and collectively. The agency has several options to respond by one or more of the following means, while stating its response in the final statement (40 CFR 1503.4). Possible responses include:

- Modify alternatives
- Develop and evaluate alternatives not given serious consideration
- Supplement, improve, or modify analyses
- Make factual corrections
- Explain why comments do not warrant further agency response

All substantive comments received on a draft EIS (DEIS) (or summaries thereof where the response has been voluminous), should be attached to the final statement whether or not the comment is thought to merit individual discussion by the agency in the text of the statement.<sup>4</sup> Substantive comments are defined as those that do one or more of the following:

- (a) question, with reasonable basis, the accuracy of information in the EIS
- (b) question, with reasonable basis, the adequacy of environmental analysis
- (c) present reasonable alternatives other than those presented in the EIS
- (d) cause changes or revisions in the proposal

In other words, substantive comments raise, debate, or question a point of fact or policy. Comments in favor of or against the proposed action or alternatives, or comments that only agree or disagree with NPS policy, are not considered substantive.<sup>5</sup>

Public comments on the Benefits-Sharing Draft EIS consisted of three main types: 1) copies of two form correspondences (e.g., form letters), 2) correspondences not subscribing to a form but clearly based on one of the websites that generated form correspondences, and 3) other correspondences that examine the DEIS in some detail. The entire body of comment is summarized in this chapter and all comments are responded to. For the most part, responses consist of explanations. Where a response also consists of some action reflected in the FEIS, it is noted.

Many comments shown in this summary are not substantive, but they are included in an attempt to portray what the public has stated. The correspondences in Section 5.4 contain statements that help provide a context for any substantive remarks in the correspondence. It is appropriate to refer to these correspondences as “representative” because they are representative of the content and substance of the entire body of comment.

## 5.2.2 Overview of the Comment Analysis Process

About 9,600 individuals and organizations chose to participate in the comment process by submitting correspondence during the public review period.<sup>6</sup> The correspondence included form and non-form letters sent both via regular mail and submitted over the internet at the NPS Planning Environment and Public Comment (PEPC) website. Only 190 individual or organization correspondents submitted non-form letters. Form correspondence (e.g., a form letter) is defined as a correspondence whose content is essentially duplicated by several commenters. Form correspondences are typically copied from material distributed by organizations. The content of form correspondences and non-form correspondences can be very similar. Non-form correspondences are in many cases distinguished by the personal remarks, expressions of concern, or other comments that are demonstrably individual in nature.

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**Table 5.2.2. Summary of correspondence received**

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	<b>Form Correspondence</b>	<b>Non-form Correspondence<sup>7</sup></b>
Support benefits-sharing in general or support Alternative B	7,222	45
Oppose “commercial bioprospecting” or support Alternative C	2,150	142

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All correspondences were sorted by general topic or category of concern. Each correspondence was reviewed for potential substantive comments. The content of the correspondences was recorded using a coding system. Each comment was then reviewed by at least one member of the NPS planning team.

Due to the volume of correspondence received, and the large amount of repetition in the correspondences, summaries of the comments were compiled, as allowed by regulation.<sup>8</sup> In every case, the actual wording of the correspondent has been used. Where more than one excerpt has been compiled from a single correspondence, the text that was skipped is indicated by ellipses (...). The NPS does not consider all of the information contained in the correspondence summaries as substantive. In addition, some correspondences contained personal anecdotal information which, though of interest to decision makers, is not regarded as pertinent to the content of the EIS and is not reproduced in Section 5.4.

CEQ regulations require the agency to respond to all comments, as a minimum, by explaining why those comments do not warrant further agency response, citing the sources, authorities, or reasons that support the agency's position and, if appropriate, indicating those circumstances that would trigger agency reappraisal or further response.

### **5.2.3 Correspondence Content and Response**

The majority of comments on the DEIS consisted of one of two form letters. The two form letters can be traced to common roots in two websites published by advocacy groups either favoring benefits-sharing or opposing "commercial bioprospecting." These two form letters are reproduced in full in Section 5.3 of this chapter. Many correspondents who sent in form letters also took the time to write additional thoughts or concerns. These additional expressions have been summarized in Section 5.2.4.

Most of the 190 non-form letter correspondences also shared phrases and terminology found on the same two websites. Letters in this category differ from form letters in that they expressed thoughts that were not part of a mass-produced letter. The non-form letters generally expressed individual thoughts, concerns and experiences. However, for the most part they did not contain relevant new information or scientific data that would necessitate changes in the final EIS. While letters of this type are not particularly informative to the NEPA process, they are of importance to decision makers.

The concepts and concerns surrounding benefits-sharing are complex and many correspondences were received from people who made comments based on simple summaries of the EIS provided on non-NPS websites. Correspondences such as these are still important to decision makers because they indicate that the majority of correspondents simply want the national parks to be protected under all circumstances.

For the most part, comments fell into two categories, based on information from one of two advocacy group websites. Correspondents motivated by a National Parks and Conservation Association (NPCA) website urged the NPS to adopt benefits-sharing with certain conditions. Correspondents motivated by a website entitled "Parks Not For Sale" responded to an interpretation of potential "commercial bioprospecting" activities and impacts created and publicized by the former plaintiffs in the court case that precipitated this EIS.<sup>9</sup> The latter correspondences were difficult to interpret since they responded to the "Parks Not For Sale" website material and not the actual proposal or content of the DEIS. For example, the phrase "commercial bioprospecting" was not used or defined in the DEIS. As a result, the correspondents assumed that "commercial bioprospecting" would ultimately lead to harvest and sale of park resources, activities that are prohibited by federal regulation and which were not proposed in the EIS.

The correspondences that are summarized and responded to in Sections 5.3.1 through 5.3.15 are best described as representative. The content of this representative group of correspondences, with respect to substance in particular, encompasses the content of the entire body of comment. In the summaries, the commenters' own words were used. The representative correspondences are duplicated in their entirety in Section 5.4.

Although the correspondence analysis process attempted to capture the full range of public concerns, it is acknowledged that comments from people who chose to respond do not necessarily represent the sentiments of the entire public. Further, the NEPA process emphasizes the content of the comment rather than “vote counting” or the number of times a comment was received.

To locate a response to a representative comment, refer to the Index to Comments and Responses. All correspondence received will be kept in the NPS PEPC database and at Yellowstone National Park headquarters.

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# **Comment Summaries and Responses**

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## 5.3 Comment Summaries and Responses

### 5.3.1 Comments Regarding Legal or Procedural Matters— National Park Service Laws, Regulations, and Policies

#### 5.3.1.1 *Benefits-sharing is in keeping with or contrary to the NPS Mission/Organic Act*

*Comment #83:* Furthermore, I would like to note that I view bioprospecting as being consistent with the NPS mandate, that is, to preserve and conserve (in not so many words). The knowledge gained through bioprospecting activities far outweighs its environmental “impact” (if it can be stated as such) and in a world slowly falling to the loss of microbial diversity, bioprospecting does well to work against these decreases while at the same time providing for sustainable solutions to a number of industry problems (including but not limited to the development of alternative fuels and efficient, non-synthetic industrial processes).

*Comment Form Letter #96:* I believe that allowing commercial bioprospecting runs counter to the mission of our National Parks. The natural resources on our public lands must be preserved, protected and – most importantly – remain public for the public’s benefit.

*Comment #6719:* To allow commercial research in the parks goes expressly against the original purpose of the Park Service, which is to protect these areas from exploitation.

*Response:* The proposal in Alternative B is not a “commercial bioprospecting” proposal, it is a proposal to require benefits-sharing, when appropriate, with researchers who have already studied material originating as lawfully collected NPS research specimens (see Section 5.3.8.2). NPS research permits may only authorize specimen collection for projects with scientific or resource management goals.<sup>10</sup> See Section 5.3.7.2 for a detailed answer explaining that NPS does not allow research that is for purely commercial purposes. NPS research permitting procedures would remain unchanged under the benefits-sharing proposal.

The NPS Mission as stated in the NPS Management Policies is:

The National Park Service preserves unimpaired the natural and cultural resources and values of the national park system for the enjoyment, education, and inspiration of this and future generations. The National Park Service cooperates with partners to extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.<sup>11</sup>

NPS Management Policies provide guidance to the agency in interpreting the NPS mission. The benefits-sharing proposal (Alternative B) is in accordance with the mission, as interpreted by the management policies, in the following ways:

The NPS encourages research in parks as part of the fundamental purpose of parks.

The NPS evaluates research permit applications under NEPA.

The NPS does not allow sale or commercial use of park resources.

The benefits-sharing proposal abides by all of these policies.

The NPS recognizes that research involving the study of park specimens can sometimes result in discoveries with commercial applications. The proposal does not include any new research or bioprospecting initiatives. It was developed to respond to commercially applicable discoveries that have been and are being made as a result of research involving specimens collected from parks pursuant to a research permit.

Public Comment:	Commenter:	Affiliation:
83, 96, 6719		Individuals

### **5.3.1.2 Research specimen laws, regulations and policies**

***The NPS does not own research specimens collected under the authority of an NPS research permit. Researchers own the samples they have collected from parks.***

*Comment #7418:* The NPS has maintained, in discussions with the scientific community pertaining to the ownership of specimens taken from the parks under NPS-issued research permits, that it has, but cannot transfer ownership of specimens.

NPS does not, according to the Supreme Court, have ownership and because there are no laws barring transfer of ownership...

Nonetheless, the fact remains that in allowing the researcher to remove a specimen from the park, to study it with methods that may destroy or modify all or part of the specimen, and to retain the specimen permanently, the NPS has, in fact, transferred ownership of the specimen.

*Response:* Under the Organic Act, NPS has broad authority to promote and regulate the national parks to conserve the scenery and wildlife therein in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.<sup>12</sup> In addition to this broad authority, NPS is authorized to assure that management of units of the National Park System is enhanced by the availability and utilization of a broad program of the highest quality science and information.<sup>13</sup> Under this mandate, the primary purpose of study within park units is to more effectively achieve the mission of the National Park Service and to enhance management and protection of park resources and use information gathered for management purposes.<sup>14</sup> Scientific study within park units must be consistent with applicable laws and National Park Service management policies and must be conducted in a manner as to pose no threat to park resources or public enjoyment from those resources.

NPS has not asserted that the United States has any ownership in wild animals. NPS does allow the collection of research specimens pursuant to its statutory authority and federal regulation.<sup>15</sup> Based on property law, NPS takes the position that research specimens, once collected from lands owned by the United States and reduced to possession, are property of the United States.

Regarding authority to convey ownership, we refer the commenter to the response of Michael Soukup, Associate Director, Natural Resource Stewardship and Science (May 17, 2004) responding to letters received from the commenter dated February 18, 2003, and January 8, 2004. We quote from the letter below.

“Congress and NPS have determined that certain natural and cultural specimen collections are permissible pursuant to specific statutes and regulations. Scientific natural resource activities, including specimen collection, are governed by 36 CFR 2.5. A very limited number of other types of natural resource collecting is governed by 36 CFR 2.1.

Specimens collected pursuant to 36 CFR 2.5 are treated as NPS museum objects or collections. NPS museum objects and collections are subject to the statutory provisions in 16 USC 18f and 18f2-3. This statute defines “museum objects” and “museum collections” as “objects that are eligible to be or are made part of a museum, library, or archive collection through a formal procedure, such as accessioning. Such objects are usually movable and include but are not limited to prehistoric and historic artifacts, works of art, books, documents, photographs, and natural history specimens” 16 USC 18f-3(b).

Originally enacted in 1955 to allow NPS to accept donations and loans, the statute was amended in 1996 to provide NPS with additional management tools. However, Congress did not give NPS unfettered discretion to transfer or convey museum specimens. Rather, it prescribed specific conditions and parameters for donations, exchanges, loans, transfers and conveyances. “Transfers” to qualified Federal agencies may occur when the Secretary determines that museum objects or collections are no longer needed for museum purposes. Items transferred under this authority remain in federal ownership. “Conveyances” to private 501(c)(3) institutions and to non-federal governmental entities may occur if the Secretary determines that the collections are no longer needed for museum purposes, and the recipient is dedicated to the preservation and interpretation of natural or cultural heritage and is qualified to manage the property. A conveyance under 16 USC 18f-2(a)(2) would result in a change of ownership from NPS to the receiving entity.

Such conveyances are subject to the review and approval process outlined in 16 USC 18f-2(b). Under current NPS policy, deaccessioning is only accomplished on a case-by-case basis. (See NPS Museum Handbook II, Ch. 6, “Deaccessioning,” <[www.cr.nps.gov/publications/MHII/mushbkII.html](http://www.cr.nps.gov/publications/MHII/mushbkII.html)>.

36 CFR 2.5 requires that specimens collected under this regulation, if retained in museum displays or collections, bear official NPS museum labels and their catalog numbers be registered in the NPS National Catalog. Specimens collected under 36 CFR 2.5 and retained for museum collections are needed for museum purposes and future resource management decision-making. Therefore, they are not eligible for conveyance to other institutions. The strong interest of other museums in these specimens further demonstrates the importance of these specimens for museum purposes.”

The DEIS indicates that originally collected research specimens that are not destroyed or consumed in analysis and not authorized to be discarded are cataloged and retained in the NPS museum collection. The cataloged specimen is on loan when not in NPS custody. In a minority of cases, portions of originally collected microbial specimens can be successfully cultured (grown in the laboratory). In these cases, the culture may be suitable for permanent maintenance and retention by a qualified “culture collection” and is then accessioned as an NPS museum collection.

Public Comment:	Commenter:	Affiliation:
7418	The Ornithological Council	Organization

***The USGS Organic Act dictates where NPS specimens may be deposited.***

*Comment #7461:* Provisions in the USGS Organic Act of 1879 which clearly outline the responsibility of the NPS to deposit research collections at the Smithsonian or other repositories.

*Response:* The United States Geological Survey (USGS) Organic Act states: “All collections of rocks, minerals, soils, fossils, and objects of natural history, archaeology, and ethnology, made by the National Ocean Survey, the United States Geological Survey, or by any other parties for the government of the United States, when no longer needed for investigations in progress, shall be deposited in the National Museum.”<sup>16</sup>

Subsequent legislation as noted below, established NPS authority over collections of rocks, minerals, soils, fossils, and objects of natural history in areas managed by the National Park Service. This legislation, in certain instances, supersedes the USGS Organic Act provision stated above.

The National Park Service Organic Act of 1916 (16 USC 1-4) states: “The service thus established shall promote and regulate the use of the Federal areas known as national parks, monuments, and reservations hereinafter specified, except such as are under the jurisdiction of the Secretary of the Army, as provided by law, by such means and measures as conform to the fundamental purpose of the said parks, monuments, and reservations, which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.”

This law gives NPS authority to regulate the natural objects and wild life in parks, such as by permitting research and collection of natural objects and wildlife, and their conversion to natural history specimens through the collection process.

The Museum Act of 1955 (16 USC 18f) clarifies NPS management authorities for park museums and museum collections. It addresses “museums established within the individual areas administered by the Secretary of the Interior through the National Park Service as a means of informing the public concerning the areas and preserving valuable objects and relics relating thereto.” It states “‘museum objects’ and ‘museum collections’ mean objects that are eligible to be or are made part of a museum, library, or archive collection through a formal procedure, such as accessioning. Such objects are usually movable and include but are not

limited to prehistoric and historic artifacts, works of art, books, documents, photographs, and natural history specimens.”

The Museum Act further gives the Secretary of the Interior discretion to determine when collections are no longer needed for NPS purposes and to transfer them to other federal agencies, including the Smithsonian Institution, or convey them to other eligible parties. The law states:

“[T]he Secretary of the Interior may perform the following functions in such manner as he shall consider to be in the public interest: 1) Transfer museum objects and museum collections that the Secretary determines are no longer needed for museum purposes to qualified Federal agencies, including the Smithsonian Institution, that have programs to preserve and interpret cultural or natural heritage. . .”<sup>17</sup>

Public Comment:	Commenter:	Affiliation:
7461		Individual

***NPS loan policies create undue burdens on repositories and discourage repositories from accepting NPS specimens.***

**Comment #7459:** Reference note 27 (cited on page 13 of Chapter One and explained on page 32) states, “Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property.” Aside from the non-scientific and anti-science implications in that statement, current National Park Service policy requires that the specimens must be kept with National Park Service labels and apart from other collections.

**Comment #7461:** Most natural history collections currently will not take NPS collections under the conditions which Headquarters insist upon. NPS loan policies are expensive, create additional unfunded mandates, and for control purposes (to avoid misappropriation which might reduce benefit sharing as mentioned above) mandate dual systems of storage, curating, reporting and monitoring of the collections.

**Comment #7464:** Some...of the specific potential ramifications ... include... the need to obtain permission from the NPS to allow qualified scientists to examine such specimens, or to make available data from such specimens to other parties; and the inability to transfer such specimens to third party scientists or scientific institutions.

**Response:** NPS museum specimen loan policies are long-standing and were developed without regard to any benefits-sharing considerations. Specimens that are not consumed in analysis or discarded after analysis remain federal property, and must be labeled and cataloged into the NPS catalog system.

With respect to NPS collections on loan to repositories for management, NPS procedures require that NPS catalog the collections in the NPS cataloging system. Permittees may have responsibility for seeing that collected specimens are cataloged in the NPS system as a condition of the permit. The borrowing repository has responsibility for storage, curation, reporting, and monitoring of the collections. NPS allows, but does not require, the repository

to catalog the collections in the repository's catalog system. NPS asks the repository to provide data for the NPS annual inventory or have an equivalent system in place.

NPS does not mandate dual systems of storage, curating, reporting, and monitoring. Such dual systems are the option of the repository manager, but NPS does not require that they be kept apart from other collections. For example, NPS herbarium specimens may be integrated into the taxonomically ordered storage of a designated repository's herbarium.

In the interest of protecting irreplaceable and priceless specimens in perpetuity and following widely accepted professional procedures, NPS collections managers give permission for qualified researchers to access specimens in NPS custody. NPS authorizes repositories that manage NPS specimens to provide qualified researchers access to NPS specimens consistent with the repository's procedures as authorized in the NPS loan agreement with the repository.

NPS outgoing loan agreements, such as with a repository, may specifically authorize third party loans. The outgoing loan conditions prohibit third-party loans, unless specifically authorized in the loan agreement.<sup>18</sup>

Data derived from the RPRS (the NPS's Research Permit and Reporting System) system indicate that many non-NPS entities are willing to become repositories for NPS specimens. For example, in 2006, 64% of repositories designated on NPS permits were non-NPS repositories (36% were NPS repositories). On the permit application, proposed non-NPS repositories agree to accept collections on loan from NPS. RPRS has designated over 800 non-NPS repositories in the U.S. and other countries.

The 2006 RPRS data are as follows:

Out of 1,065 permits to collect specimens, 455 permits authorized the researcher to retain collected specimens. These researchers placed their specimens in 470 repositories. Of the 470 repositories, 302 were non-NPS facilities and 168 were NPS facilities. For that year, there were a total of 855 non-NPS repositories available for use by NPS research permittees.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7459	American Society of Mammalogists	Organization
7461		Individual
7464	Systematic Collections Committee American Society of Mammalogists	Organization

**Removing park resources for profit is prohibited by law.**

**Comment #7261:** The specific language in the creation acts for Yellowstone and the National Park Service clearly prohibits the removal of park resources for profit.

**Response:** NPS agrees that removal of park resources for sale or commercial use is prohibited by law (36CFR 2.1). This prohibition also applies to any natural resource that is authorized for collection as a research specimen. Additionally, research specimens remain federal property and transfer to any other party without prior written authorization from the NPS is also prohibited.

Commercial use of research results is different from commercial use of park resources. Inventions and intellectual property derived from research results involving park research specimens may be commercially used. This distinction was upheld on judicial review in April 2000 when a federal court ruled against the assertion that the Yellowstone–Diversa CRADA was a commercial use of Yellowstone National Park resources by saying, “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources...[A]ny ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.”<sup>19</sup>

This chapter includes a more detailed description of some of the requirements for NPS research permit issuance that call for research projects to have scientific or educational goals in Section 5.3.7.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

**Why are researchers who collect specimens subject to different rules than anglers or subsistence hunters?**

**Comment #7424:** To see specimen-based scientists treated fundamentally differently than other consumptive users of NPS flora and fauna is insulting, and it operates against the interests of NPS itself in obtaining an improved understanding of these resources. And these are renewable resources. Fishermen, subsistence hunters, berry pickers, and now commercial developers of NPS biological resources are apparently all more important to NPS in this regard than scientists who collect specimens to learn more about our public resources. This has to change! It clearly discriminates unfairly between user groups that have similar consumptive effects on Park resources.

**Response:** Differences in who, when, and how much certain park users may collect are attributable to the different NPS regulations, ultimately derived from laws enacted by Congress. Under NPS enabling legislation, the NPS has a great deal of discretion in promulgating regulations for use of the national parks. Certain uses, such as subsistence

hunting and gathering, are mandated by federal law. The correspondent is based in Alaska, where the Alaska National Interest Lands Conservation Act and regulations apply to legally-qualified subsistence users and activities.<sup>20</sup> Hunting, trapping, or any other methods of harvesting wildlife by the public is only allowed where it is specifically authorized, either on a mandatory or discretionary basis, under federal law.<sup>21</sup> Recreational fishing is allowed in parks when it is authorized by federal law or not specifically prohibited by federal law and determined to be an appropriate use.<sup>22</sup>

Use of national park units for research purposes is governed by law and regulation.<sup>23</sup> The NPS encourages scientific research. To this end, NPS regulations provide that researchers may be given special permission to collect material that other park visitors may not collect. For example, in many parks, pursuant to regulation 36 CFR 2.1(c)(1) and a park’s compendium, visitors are allowed to collect and eat berries and they are only permitted to collect what they can use immediately for personal consumption. On the other hand, researchers are allowed to collect and remove a wide array of material pursuant to the conditions of their research permits. In most NPS park units, permitted researchers are allowed to collect and remove more natural materials than visitors. No distinction or special collecting privileges are extended to “commercial developers of NPS biological resources” as the commenter suggests, nor is NPS proposing any.

Research specimens collected pursuant to 36 CFR 2.5 are treated as NPS museum objects or collections. NPS museum objects and collections are subject to the statutory provisions in U.S. Code.<sup>24</sup> Because research specimen collections are governed by this specific statute, issues involving commercial hunting, fishing and trapping are not analogous.

Public Comment:	Commenter:	Affiliation:
7424	University of Alaska, Museum of the North	Organization

### 5.3.2 Comments Regarding Legal or Procedural Matters—The Wilderness Act

#### 5.3.2.1 Research with foreseeable commercial application for research results is contrary to the Wilderness Act

*Comment #7261:* The vast majority of national park lands are subject to wilderness laws and policies, which place these lands off-limits to commercial bioprospecting.

*Comment #7485:* Commercial enterprise in wilderness is prohibited by the Wilderness Act. Bioprospecting is a commercial activity. Parks are to manage recommended wilderness the same as designated wilderness. There is so little of our natural heritage left and it needs to be guarded and preserved, not sold off for any reason.

*Response:* The EIS does not propose commercial enterprises in designated wilderness or

elsewhere. Commercial use of research results is distinct from commercial use of park natural resources. Inventions and other intellectual property derived from research results involving park research specimens may be commercially used. This distinction was upheld on judicial review in April 2000 when a federal court ruled against the assertion that the Yellowstone–Diversa CRADA was a commercial use of Yellowstone National Park resources by saying, “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources...[A]ny ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.”<sup>25</sup>

The statutory purposes of wilderness include scientific activities, and these activities are encouraged and permitted when consistent with NPS’s responsibilities to preserve and manage wilderness.<sup>26</sup>

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7485		Individual

### 5.3.3 Comments Regarding Legal or Procedural Matters—The National Parks Omnibus Management Act (NPOMA)

#### 5.3.3.1 *The NPS must use the authority of the National Parks Omnibus Management Act (NPOMA) to benefits-share instead of the FTTA*

*Comment #7492:* The DEIS, by relying on the FTTA and CRADAs, implicitly posits that Congress acted superfluously when it enacted NPOMA section 205(d).

The NPS must leave behind the inappropriate CRADA tool found in the FTTA and use the most relevant, current and park-specific law -- NPOMA.

*Response:* In April 2000, a federal court found that by enacting section 205(d) of the National Parks Omnibus Management Act (NPOMA) in 1998, Congress “reinforce[d] the conclusion that application of the FTTA to [NPS benefits-sharing] is consistent with Congressional intent regarding cooperative scientific research agreements with units of the National Park System... [T]he CRADA . . . plainly constitutes an ‘equitable, efficient benefits-sharing arrangement’ with a private entity for the purposes of scientific study.”<sup>27</sup> NPOMA clarified that NPS had the authority to enter into benefits-sharing agreements but did not specify what mechanism should be used for benefits-sharing. If the NPS decides to implement benefits-sharing as proposed in the EIS, it will comply with the requirements of the FTTA to the extent applicable and appropriate to the NPS’s specific circumstances and legislated mandates.

Public Comment:	Commenter:	Affiliation:
7492	Public Employees for Environmental Responsibility	Organization

#### 5.3.3.2 *NPOMA would allow parks to withhold information about “commercially valuable” specimen collection from the public*

*Comment #7261:* NPOMA § 207 states: “Information concerning the nature and specific location of a National Park System resource which is endangered, threatened, rare, or commercially valuable, may be withheld from the public in response to a request under section 552 of title 5, USC.” ... Even the very geographic location of the activity may be made secret, and, under FOIA, kept secret. Thus, the public and independent scientists may have no way to objectively judge a project’s impact on the environment ... The public will not be able to judge whether its own “free access” to certain areas will be precluded for unannounced commercial reasons.

*Response:* Section 207 of the National Parks Omnibus Management Act of 1998 (NPOMA) provides NPS with the option to withhold information concerning “the nature and specific location of a National Park System resource which is endangered, threatened, rare, or commercially valuable, of mineral or paleontological objects within units of the National Park System, or of objects of cultural patrimony...” The Act goes on to specify the information “may be withheld from the public unless the Secretary [of Interior] determines that (1) disclosure of the information . . . would not create an unreasonable risk of harm, theft, or destruction of the resource or object, including individual organic or inorganic specimens; and (2) disclosure is consistent with other applicable laws protecting the resource or object.”

NPOMA attempts to balance the availability of information to the public and the NPS’s mandate to protect park resources. The statute is intended to thwart illegal activities, such as poaching of plants and animals, the looting of archeological sites and removal of fossils and minerals, where many times the objects have a high commercial value and will be immediately sold on the black market. With the exception of NPOMA-protected resources, the nature and location of research projects and specimens collected is public information as most are not “commercially valuable” resources protected by NPOMA. Instead, it is often the information learned from a research specimen after long and skilled study that may be valuable.

Although it is the general NPS policy to share information widely, the Service also realizes that providing information about the nature and location of park resources may sometimes place those resources at risk of harm. NPS managers use these exemptions sparingly, and only to the extent allowed or required by law.

NEPA analyses for specific research permits and projects must take NPOMA confidentiality considerations into account in a manner that provides as much information about the resources to the public as possible.

In an additional protection against the scenario proposed by the correspondent, the example CRADA (Appendix A) includes the requirement to append a copy of the associated research permit, which discloses the location of specimen collection as well as the maximum allowable quantity of collections. An NPS research permit does not grant exclusive rights to individual researchers. Additionally, the NPS research permit General Condition #17 states: “Expiration date—Permits expire on the date listed. Nothing in this permit shall be construed as granting any exclusive research privileges or automatic right to continue, extend, or renew this or any other line of research under new permit(s)” (see Scientific Research and Collecting Permit in Appendix H of the EIS).

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

## 5.3.4 Comments Regarding Legal or Procedural Matters—The Federal Technology Transfer Act (FTTA)

### 5.3.4.1 NPS cannot consider parks to be laboratories under the definition provided by the Federal Technology Transfer Act (FTTA)

*Comment #7261:* As the District Court noted, the Park Service could find no statutory authority for commercial bioprospecting and, struggling to find a shoe that might fit, began to creatively stretch the language and the imagination in order to allow it by claiming that Yellowstone and other national parks are “federal laboratories” under the meaning of the Federal Technology Transfer Act (FTTA) of 1986 . While the Court ultimately accepted this interpretation, in the minds of the public, such an interpretation was at odds with basic logic and commonsense. Moreover, the legislative history of the FTTA would indicate that Congress enacted the law for the named “national laboratories”, such as Los Alamos National Laboratory, Oak Ridge National Laboratory, National Institutes of Health, etc. Nowhere does FTTA history suggest that the law was enacted for the purpose of declaring the units of the National Park System as national laboratories under the definitions of the FTTA.

*Comment #7492:* Nothing in that Act’s (Federal Technology Transfer Act) language or its legislative history refers to a national park system or its areas as “laboratories.” A review of the legislative history reveals that Congress enacted the FTTA for the named “national laboratories.”

*Response:* In 1997, some of the authors of comment #7261 filed a lawsuit against the NPS claiming, among other things, that the NPS could not consider Yellowstone National Park to be a laboratory under the FTTA. The court found that the NPS provided a reasoned basis for concluding that the broad, statutorily assigned definition of laboratory in the FTTA encompasses Yellowstone National Park’s research facilities and ruled firmly in NPS’ favor.<sup>28</sup> The court’s explanation of its decision is summarized here.

When Congress passed the FTTA, it assigned a particular definition to the term “laboratory.” Although the court agreed that a national park does not immediately remind people of a laboratory, neither courts nor government agencies are allowed to cast congressional definitions aside in favor of a term’s “ordinary” meaning. The FTTA defines a laboratory as “a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.”

The legislative history of the FTTA also provided guidance to the NPS in determining whether parks could be considered laboratories. Congress intended that the term should be “a broad definition which is intended to include the widest possible range of research institutions operated by the Federal Government.”<sup>29</sup> As the court explained in its April 2000 decision, the dictionary definition of facility is “something that is...established to perform some particular function or to serve or facilitate some particular end.” Therefore, as the court determined, a national park meets the dictionary definition of facility, and can meet the congressional definition of laboratory if a “substantial purpose of [the park] is the performance of research.”

Like other federal facilities that carry out research activities, units of the National Park System that satisfy the FTTA definition of a laboratory are eligible to enter into CRADAs. With regard to Yellowstone specifically, the court determined that Yellowstone meets the FTTA criteria as a laboratory. If benefits-sharing is implemented, NPS will determine whether or not other parks meet these criteria on a case-by-case basis, as needed.

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7492	Public Employees for Environmental Responsibility	Organization

**5.3.4.2 The NPS must adopt all of the requirements in the Federal Technology Transfer Act (FTTA) before entering into any benefits-sharing agreements**

*Comment #7492:* If the FTTA governs the national park system as laboratories, the NPS has been in substantial noncompliance with several provisions of that law. In brief the FTTA did the following:

- Made technology transfer a responsibility of all federal laboratory scientists and engineers.
- Mandated that technology transfer responsibility be considered in employee performance evaluations.
- Established principle of royalty sharing for federal inventors (15% minimum) and set up a reward system for other innovators.
- Legislated a charter for Federal Laboratory Consortium for Technology Transfer and provided a funding mechanism for that organization to carry out its work.
- Allowed current and former federal employees to participate in commercial development of the research fostered by the CRADA, to the extent there is not conflict of interest.

The National Park Service ... has yet to implement a single one of the above actions:

- Where is the “technology transfer responsibility” found in the performance evaluations of employees? The answer, in short, is “NOWHERE.”
- Does the NPS Director sit as a member of the Federal Laboratory Consortium for Technology Transfer? NO.
- Has the NPS set up a mechanism to allow current and former federal NPS employees to participate in commercial development of the research fostered by the CRADA? NO

In short, the NPS disregards the CRADA provisions of the FTTA, expect for that portion that may provide a revenue stream or monetary benefits to the negotiating park (“laboratory”).

The FTTA language on CRADAs also requires that “an agency shall make separate

determinations of the mission or missions of each of its laboratories.” 15 U.S.C. 3710a(e). Where is the NPS determination of the mission or missions of the Yellowstone National Park Laboratory, or the Sequoia National Park Laboratory? The NPS has never made the required FTTA determinations of the mission or missions of each of its nearly 400 separate “laboratories.” ...

Ethics issues relating to the FTTA are complex and numerous. Agencies that are actually governed by the FTTA (not, like the NPS, which imagines that it is) have developed such ethics standards. The NPS has not even thought about it. That is but one indication that the NPS never actually believed the FTTA applied to it until the DIVERSA Agreement led it to grasp this flimsy rationale.

Before entering into a single benefits-sharing agreement, including the DIVERSA-Yellowstone CRADA, the NPS must adopt standards to implement these parts of the FTTA that guard against conflicts of interest or corruption. The ethics standards must be reviewed by the Department of Justice and be placed before the public.

*Response:* If the NPS decides to implement benefits-sharing, it will comply with the requirements of the FTTA to the extent applicable and appropriate to the NPS’s specific circumstances and legislated mandates. Taking action towards implementing benefits-sharing, such as those described above, prior to completion of this EIS would be inappropriate and potentially violate CEQ regulations.

The “technology transfer responsibility” is not in the performance evaluations of NPS employees because the NPS does not currently have a technology transfer function. Completion of this EIS must precede any decision by the NPS to implement “technology transfer.” If benefits-sharing is adopted by the NPS, employees could be assigned technology transfer tasks, as appropriate, which would be reflected in their performance evaluations.

The NPS Director does not sit as a member of the Federal Laboratory Consortium for Technology Transfer. The membership requirements of the Consortium is established by 15 USC 3710(e)(2). If benefits-sharing is implemented, the NPS will review the FTTA and determine whether it is appropriate for a senior representative from the NPS to be appointed to the Consortium.

The NPS has not set up a mechanism to allow current and former federal NPS employees to participate in commercial development of the research fostered by CRADAs. This type of action would be inappropriate prior to completion of the EIS. If benefits-sharing is implemented, the NPS will review the FTTA provision 15 USC 3710a(b)(3)(C), which states “to the extent consistent with any applicable agency requirements or standards of conduct, [the laboratory may] permit an employee or former employee of the laboratory to participate in an effort to commercialize an invention made by the employee or former employee while in the employment or service of the Government.” Note that the establishment of such a mechanism is not a requirement of the FTTA, it is an option.

The NPS has not set up a mechanism to distribute royalties or other payments received by the NPS. NPS does not currently receive royalties or other payments and this type of action would be inappropriate prior to completion of the EIS.

The missions of Sequoia National Park and Yellowstone National Park are derived from the NPS’s Organic Act of 1916 (16 USC 1) and each park’s respective enabling legislation. NPS Management Policies require every park to prepare a Strategic Plan, beginning with a mission statement (NPS Management Policies, Chapter 2, Section 2.3.3). The FTTA does not strictly govern the manner in which a laboratory mission determination is made. This could be done separately from the Strategic Plan mission statement, or if a park is in the process of developing their Strategic Plan, the laboratory mission could be incorporated. Yellowstone did make a determination regarding its laboratory mission prior to entering into the Yellowstone–Diversa CRADA. With regard to other parks needing a laboratory mission determination, this has not occurred as benefits-sharing activities were halted pending completion of this EIS.

In terms of ethics considerations, the EIS discusses the most probable potential conflict of interest related to benefits-sharing (identified during public scoping and internal NPS reviews), that benefits-sharing considerations might inappropriately influence research permitting decisions. The EIS mitigates against this including the following examples from the EIS (Sections 2.4.6.4 and 4.4.5.5)

- CRADAs would be negotiated only with researchers who had already been issued a research permit. Thus, issuance of a research permit would precede negotiation of a benefits-sharing agreement, thereby separating the timing of the decision about access to research specimens (the research permit) from any decision about entering into a benefits-sharing agreement (the CRADA).
- Separate individuals would manage preparation of benefits-sharing arrangements and research permit issuance decisions. If a park could not provide separate individuals to supervise the separate benefits-sharing and research permit reviewing processes, as may be the case in some smaller parks, the superintendent would seek assistance from another park, a regional office, or national headquarters.
- Parks would not negotiate and execute CRADAs in a vacuum. After a CRADA was prepared, it would be recommended for approval by the appropriate regional director and reviewed by the Department of Interior Solicitor’s Office and the NPS director before it was signed by the park superintendent and the researcher.

Public Comment:	Commenter:	Affiliation:
7492	Public Employees for Environmental Responsibility	Organization

### 5.3.5 Comments Regarding Legal or Procedural Matters—The National Environmental Policy Act (NEPA)

#### ***5.3.5.1 The EIS failed to analyze cumulative impacts, include specific mitigation measures, or incorporate opposition to benefits-sharing***

*Comment #7261:* Inexplicably, the DEIS only describes cumulative impact relative to interpretive services provided by the NPS to park visitors.

The DEIS does not contain a discussion of opposing views. It simply states they have been incorporated into one of the alternatives, without identifying the specific opposing views or how they have been addressed within the given alternatives.

NPS provides only an inadequate mention of mitigation measures, simply stating that they will be developed.

*Response:* The CEQ defines “cumulative impacts” as the impacts to the environment that result from the incremental impact of each action when added to other past, present, and reasonably foreseeable future actions, regardless of what agency (federal or non-federal) or person undertakes such actions. The cumulative scenario, describing the past, present, and reasonably foreseeable future actions, for each impact topic was described in EIS sections 4.3.1.6, 4.3.2.6, 4.3.3.6, and 4.3.4.6. The cumulative impacts of each alternative, if any, are described in the EIS for each impact topic in the following EIS sections: Sections 4.3.1.7, 4.3.2.7, 4.3.3.7, 4.3.4.7, 4.4.2.8, 4.4.3.6, 4.4.4.8, 4.4.5.7, 4.5.2.6, 4.5.3.6, 4.5.4.6, and 4.5.5.6.

Specific mitigation measures associated with the benefits-sharing proposal were explained in detail in the DEIS in sections 2.4.6, 2.4.6.1, 2.4.6.2, 2.4.6.3, 2.4.6.4, 4.4.4.6, and 4.4.5.5.

The CEQ requires agencies to “make every effort to disclose and discuss at appropriate points in the draft statement all major points of view on the environmental impacts of the alternatives including the proposed action.”<sup>30</sup> The DEIS described how opposition to benefits-sharing was incorporated into the alternatives in Sections 1.9 and 2.6. Section 1.9 in the final EIS has been edited to clarify that Alternative C, “Prohibit Specimen Collection for Any Commercially Related Research Purposes,” was developed in response to comments opposing benefits-sharing and opposing commercialization of research discoveries.

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

### 5.3.6 Comments Regarding Legal or Procedural Matters— Issues from the Edmonds Institute, et al. v. Babbitt, et al. Court Decisions

#### 5.3.6.1 Edmonds Institute highlights several issues from the first District Court ruling in Edmonds Institute, et al. v. Babbitt, et al.

***The court’s first ruling told the NPS there is a difference between ordinary research in parks and research involving a CRADA***

*Comment #7261:* The Judge rejected the Park Service position that bioprospecting is no different than other research conducted in the parks ... The judge went on to point out that, “There is an undeniable reality that commercial activity is qualitatively different than scientific

and educational activity of a similar nature, due to the very different forces and motivations that drive them.”

The Court wrote “... the introduction of commercial bioprospecting into the nation’s parks represents a dramatic change in Park Service policy ...”

*Response:* The authors quote the court’s March 1999 decision without reference to the related April 2000 decision by the same court (both court decisions are provided in Appendix I of this EIS). In its April 2000 decision, the court clarified the difference between the CRADA and Diversa’s pre-existing research permits, saying “Since 1994, prior to its entry into the CRADA, Diversa, under its previous name Recombinant Biocatalysis, Inc., had already been conducting the same sort of sampling from Yellowstone, pursuant to [research and collecting] permits issued in accordance with Park regulations. The main difference, however, is that prior to the CRADA, the company was under no obligation to share any of the economic or other benefits that might result from its research on Park resources.” The dramatic change in park policy the court referred to in its March 1999 decision was the first use of a CRADA by a national park, hence benefits-sharing agreements (CRADAs) are the subject examined in this EIS.

In April 2000, the court clarified that the NPS made a reasoned decision when it considered commercial use of research results to be distinct from commercial use of park resources, saying “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources ... [A]ny ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.”<sup>31</sup>

### ***The Yellowstone–Diversa CRADA authorized specimen collection.***

*Comment #7261:* The CRADA allowed Diversa to remove biological samples including microbes, soils, fungi, trees, plants, rocks and other natural features.

The Court wrote: “... With regard specifically to Yellowstone, the defendants have offered no persuasive counter to plaintiffs’ assertion that the CRADA, on its face, allows for a tremendously broad range of activities spanning a broad range of ecosystems.”

*Response:* The CRADA did not authorize any collection of park natural resources. The authors quote the court’s March 1999 decision without reference to the related April 2000 decision by the same court (both court decisions are provided in Appendix I of this EIS). The court’s ruling (April 2000) against the commenter (former plaintiffs) firmly corrected their misunderstanding about what the Yellowstone–Diversa CRADA authorized. To quote the court’s April 2000 decision, the Yellowstone–Diversa CRADA “does not grant Diversa the right to collect any research specimens at all. Indeed, contrary to plaintiffs’ assertion, neither the CRADA nor its Scope of Work authorizes Diversa to take any natural materials from Yellowstone. Rather, the CRADA outlines the rights and responsibilities of Yellowstone and Diversa with respect to information and inventions developed after the conclusion of research specimen collection and analysis.”<sup>32</sup>

### ***The DEIS failed to analyze the topics ordered by the court.***

*Comment #7261:* It is our position that the DEIS does not fulfill or comply with the instructions contained in the District Court’s Order.

*Response:* The District Court’s March 1999 decision declined to specify exactly what topics were to be studied in a NEPA analysis. Instead, the Court indicated that the Yellowstone–Diversa CRADA was a precedent-setting agreement and should require an intensive deliberation by the NPS through the NEPA process. The Court deferred to this process, rather than substitute its own judgment for that of the agency without the benefit of a well developed record. That decision further stated that the NPS should “suspend operation of the Yellowstone–Diversa CRADA and prepare an environmental assessment in accordance with the requirements of the NEPA.”<sup>33</sup>

NPS complied with the court’s order to suspend the Yellowstone–Diversa CRADA. NPS began an environmental assessment of benefits-sharing agreements that ultimately merged with this EIS. NPS believes it has fully complied with the court’s order by taking a “hard look” and providing a full and fair discussion of the significant environmental impacts associated with benefits-sharing agreements to inform decision-makers and the public of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment, as required by NEPA.

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

### 5.3.7 Correspondents Discuss “Commercial Bioprospecting”

#### 5.3.7.1 NPS should prohibit “commercial bioprospecting”

*Comment #112:* Bioprospecting in our National Parks is a horrible idea! These lands are supposed to be protected from commercial, natural resource exploitation.

*Comment #6724:* I do not want any bioprospecting in our country’s national parks. I hope you do not approve any plan which permits this no matter what the financial benefits. Our parks have been set aside to protect them from exploitation of any kind including bioprospecting.

*Comment #7473:* I oppose any commercial exploitation by any commercial bioprospecting. Park resources should not be used at all for commercial purposes. National parks are for the protection of their natural resource, not commercial uses.

*Response:* Although many correspondents wrote of bioprospecting as if it were a new activity invented as a part of modern biotechnology, examples of early bioprospecting include the first development of crop plants and herbal medicines. Despite the lack of extractive or consumptive aspects of the proposal and the existing measures that protect national park resources during research activities, some correspondents said that bioprospecting is an unethical exploitation of nature that should be prohibited in the national parks.

The NPS received correspondence on the draft EIS discussing “commercial bioprospecting” and focusing on the motivations and intentions of “commercial bioprospectors.” Correspondents also seemed to assume that large numbers of commercially motivated researchers are poised to target a commercial product and then search for naturally occurring compounds to use in manufacturing that product. In preparing the EIS, the NPS monitored research permits for examples of declared bioprospecting and has not found any example of that kind of product-targeted research. Instead, declared bioprospectors who have been issued NPS research permits have identified scientific or resource management goals in their research permit applications.

All research permit applications are reviewed pursuant to NEPA as well as NPS policies and regulations. Permits are only issued if the proposed research activities are determined to be acceptable for park research under NPS’s long-standing Scientific Research and Collecting Permit protocols.

The NPS has concluded that the benefits-sharing proposal is not likely to attract researchers who fit the public’s expressed perception of “commercial bioprospecting.” For more information about the way NPS research policies protect parks, please see Section 5.3.8.

Public Comment:	Commenter:	Affiliation:
112, 6724, 7473		Individuals

### **5.3.7.2 NPS should not allow research that is for purely commercial purposes**

*Comment #39:* Research conducted on publicly-owned lands should not have the profit motive as its paramount concern.

*Comment #7261:* Research for purely commercial purposes is inconsistent with the original purposes of the park system and individual park creation acts. The specific language in the creation acts for Yellowstone and the National Park Service clearly prohibits the removal of park resources for profit.

*Comment #7488:* The Sierra Club is very supportive of scientific research occurring in our national parks and aware that on occasion biological resources will inevitably result in discoveries with may have economic, social and environmental values. However, the Sierra Club believes that wildlife and biological resources of the national parks should not be exploited for purely commercial purposes.

*Comment #7492:* Alternative C differs from Alternative B in that it disallows agreements with entities whose research is commercial in nature, motive and purpose.

*Response:* NPS research permits are issued pursuant to regulations 36 CFR 1.6 and 2.5 and in compliance with NEPA, which afford strict resource protection provisions. Currently, neither NPS policy nor regulations prohibit research or collections associated with the development of commercial products. See Section 5.3.8.2 for a detailed answer explaining that NPS

does not allow research that is for purely commercial purposes. Research permits may only authorize specimen collection for projects with scientific or resource management goals.<sup>34</sup> NPS Management Policies (2006) section 4.2.4 state, “Extractive use of park resources for commercial purposes is prohibited except when specifically authorized by law or in the exercise of valid existing rights.”

Commenters frequently confused and blurred the line between research permitting and benefits-sharing. As NPS proposed in the EIS, these are two very distinct and separate processes which the EIS indicates need to remain distinct and separate (EIS section 2.4.6.3). Factors that contribute to this separation are described in detail in EIS Section 4.4.4.5 Mitigation for potential impacts to NPS Administrative Operations.

Additionally, commercial use of research results is very different from commercial use of park resources. This distinction was upheld on judicial review in April 2000 when a federal court ruled firmly against the assertion that the Yellowstone–Diversa CRADA was a commercial use of Yellowstone resources. “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources...[A]ny ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.”<sup>35</sup>

Current NPS research permitting instructions have been added to the EIS as Appendix H. These two documents are the “Guidelines to Researchers for Study Proposals” and the “Application Procedures and Requirements for Scientific Research and Collecting Permits.” These documents describe the requirements researchers must satisfy as part of their research permit applications. In addition, a sample research permit is included in Appendix H illustrating typical restrictions placed on researchers regarding their conduct and activities while in a park unit.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
39		Individual
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7488	Sierra Club	Organization
7492	Public Employees for Environmental Responsibility (PEER)	Organization

## 5.3.8 Correspondents Support Protecting Park Resources

### 5.3.8.1 Research and bioprospecting should not harm park resources

*Comment #32:* In principle I support allowing commercial bioprospecting in our National Parks. However, any such scheme must make protection and preservation of the wild ecosystem an utmost priority. This includes requiring whatever environmental impact statements and field oversight are necessary to ensure the collecting is done in an ecologically sensitive manner.

*Comment #72:* National Parks, as places for self-willed nature and humans to interact in non-consumptive ways must not be compromised with for profit activities that most likely will harm biological diversity, ecological integrity and ecosystem integrity.

*Comment #83:* The impact to our environment in regards to bioprospecting is negligible; in some cases, it is nonexistent.

*Comment #84:* There should be no bioprospecting in national parks. The mission of the NPS is to protect parks and everything they consist of for future generations.

*Comment #105:* I vehemently oppose commercial bioprospecting in our National Parks. These are natural treasures that should be allowed to remain pristine for the public and wildlife.

*Comment #150:* You, the National Park Service, are supposed to protect our parks instead we find you trying to exploit them. Is there any government official that can be trusted?

*Comment #6718:* We favor the use of national parks for research that draws upon the natural organisms and ecosystems that are protected in the parks, as long as it does not compromise the protection of the parks. We believe the benefits flowing from that research should be shared with the national parks to advance their conservation.

*Comment #6721:* I must strongly protest and oppose any move to allow any commercial 'bioprospecting' in our national parks. The National Parks Service has been assigned stewardship of our precious lands, to preserve and to protect them.

*Comment #7492:* For example, Exxon-Mobil researchers could approach a park manager seeking a BSA [benefits-sharing agreement] to conduct seismic surveys in a park to determine oil deposits in and around the park ... Without a doubt, this type of BSA [benefits-sharing agreement] could occur under Alternative B. If we are wrong, the Final EIS must state so and explain why.

Seismic research is only one of many conceivable scenarios where research by commercial interests could impinge on park values and public enjoyment of those values.

*Comment #7502:* Park resources should not be directly or indirectly adversely affected by the research or specimen collection process. Also, visitors and their experience and enjoyment of parks should not be adversely affected by research conducted within parks. Park resources must remain unimpaired for future generations.

*Response:* Many correspondents reminded the NPS of the importance of preserving

its resources “unimpaired for future generations.” The NPS agrees that this is the most important consideration when deciding among the alternatives in the EIS.

The NPS agrees that park resources and values must not be harmed by research activities. Authorization to conduct scientific research in national parks is subject both to well-established NPS regulations and to separate NEPA compliance procedures. The long-standing review procedures associated with research permitting are designed to identify and then mitigate, minimize, or avoid adverse impacts to park resources and values. Federal actions analyzed in this EIS would not change these review procedures.

Objective 3 of the EIS (section 1.4.3) expressed the NPS’s desire to: “Ensure that the NPS research permitting process is independent, objective, and unaffected by actions proposed in this DEIS.” To this end, Alternative B (the benefits-sharing proposal in this EIS) includes mitigation measures to separate research permitting and benefits-sharing functions to prevent research activities from being evaluated with regard to any benefits-sharing considerations (EIS Section 4.4.5.5). Research permit issuance would precede and remain separate from negotiation of any benefits-sharing agreement (EIS Section 2.4.6.3). Separate individuals would manage preparation of benefits-sharing arrangements and research permit issuance decisions (EIS Section 2.4.6.4).

Additionally, benefits-sharing would not change NPS research permitting procedures or policies (EIS section 2.4.6.3) nor would it circumvent or supersede any NPS planning process, permitting authority, or other regulatory procedure or policy. For example, benefits-sharing agreements would not authorize any research activities in parks that otherwise require a permit (EIS Section 2.4.2.2). This means that every scientific proposal that would currently require a research permit would still require the same permit, including a NEPA review, if benefits-sharing were implemented.

The seismic study example, as described in comment #7492, could not be authorized by a benefits-sharing agreement. A research permit application for such a project would need to be analyzed for its potential impacts before a permit was issued or denied. In general, research permit applications proposing use of seismic methods could potentially impact natural and cultural resources as well as visitors, therefore such a research permit application would be subject to strict site-specific evaluation under NEPA before a decision could be reached about whether or not to issue a permit. No benefits-sharing agreement could permit such an activity.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
32, 72, 83, 84, 105, 150, 6718, 6721		Individuals
7492	Public Employees for Environmental Responsibility (PEER)	Organization
7502	Greater Yellowstone Coalition	Organization

### **5.3.8.2 Benefits-sharing must not authorize harvest, extraction or sale of park resources**

*Comment #37:* In the event of a viable discovery, how will the park protect its philosophical and physical mission to the public when extraction begins?

*Comment #71:* Please preserve our national parks as havens rather than as raw material for commercial exploitation. Do not allow such an invasion of our publicly safeguarded areas to occur under any circumstances.

*Comment #74:* The truth of the matter is that the NPS has no legal right to sell off the natural resources that it holds in the public interest.

*Comment #92:* I do not think that the Benefits sharing program will be beneficial to the parks ecosystems. The whole point of the National Parks is to preserve the natural beauty of this country. Letting logging and mining happen will destroy this natural beauty.

*Comment #152:* Alternative B sets a bad precedent that will open the door to more extractive activities for commercial purposes.

*Comment Form Letter #167:* No benefits sharing agreement should be developed that results in resources being used for commercial purposes. Any research contemplated under Benefits Sharing agreements cannot result in the direct commercial use of those samples removed from parks.

*Comment #7116:* Sirs, these parks are national treasures belonging to the American people. Please defend them from the 'biomining' that would inevitably result from the initial 'bioprospecting', and leave a bio-devastation in our parks comparable to that left by mineral mining throughout the West.

*Comment #7261:* Potentially, the public may not even be able to know ... whether the project will involve what is precluded in § 3 of the National Park Service Act, notably the lease, rental, or grant of natural curiosities, wonders, or objects of interest "on such terms as to interfere with free access to them by the public."

*Comment #7477:* Environmental impact analysis of roads, impacts of equipment on the soil, wildlife, soluble and non' soluble trash, and future development can never be adequately predicted once prospecting begins.

*Comment #7487:* I am completely opposed to the NPS allowing private corporations to have access to the park for profit making exploration.

*Response:* Many correspondents seemed to be responding to what they read on a web site entitled "Parks Not For Sale" rather than the content of the DEIS or newsletters or websites provided by the NPS. Benefits-sharing would only apply to research results and would not authorize harvest, use or sale of NPS natural resources for product production or any other commercial purpose. The EIS does not propose sale of natural resources, "biomining," logging, or any kind of mining or extractive processes. Benefits-sharing agreements and

research permits would not authorize any resource extraction; no harvest of natural resources could occur under the guise of “research” because the strict resource protection provision of NPS regulations would not allow it and NPS Management Policies reinforce this prohibition. Benefits-sharing agreements, as proposed in the EIS, would not grant or authorize “the lease, rental, or grant of natural curiosities, wonders, or objects of interest.”<sup>36</sup> Research permits issued by the NPS do not violate 16 USC 3 as they do not lease, rent, or grant natural curiosities, wonders, or objects of interest in a manner that interferes with free access to them by the public. All specimens collected under the authority of an NPS research permit remain federal property.

By regulation, a specimen collection permit may be issued only when the superintendent determines that the collection is necessary to the stated scientific or resource management goals of the institution or agency conducting the research. In addition, a research permit that authorizes the collection of living organisms for destructive analysis “may be issued only when the superintendent approves a written research proposal and determines that the collection will benefit science or has the potential for improving the management and protection of park resources.”<sup>37</sup> NPS Management Policies prohibit the repeated collection of materials to ensure a continuing source of supply for research or propagation.<sup>38</sup>

Public Comment:	Commenter:	Affiliation:
37, 71, 74, 92, 152, 7116, 7477, 7487		Individuals
167 (form letter)	National Parks and Conservation Association	Organization
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

### 5.3.9 Correspondents Suggest NPS Units Should Be “The Commons”

#### 5.3.9.1 All details about research involving study of NPS resources should be in the public domain

*Comment #36:* Our government has an honorable history of making its scientific research available to all citizens, in the public domain, like the USGS survey maps I use often. Opening our National Parks to private economic gain, with no thought of the public good, is directly opposed to this tradition. Scientific research is a laudable endeavour, but only if conducted in the open so the knowledge gained may be shared by all, and not locked away by private greed.

*Comment #88:* It [Alternative C] will assure that the results all research in the Park system will be placed in the public domain.

*Comment #4602:* National parks belong to all of us - all their resources. Therefore all individuals should have the benefit of any research conducted in the park.

*Comment #7261:* It [NPS] ignores the example of such agencies as the Centers for Disease Control, where public service scientists search for vaccines against such threats to public health and safety as the avian flu, and conduct extensive research in the public interest.

*Response:* The NPS benefits-sharing proposal stipulates that all information generated under a benefits-sharing agreement be shared freely with the NPS. The NPS would have unlimited rights to share most of this information with the public, in accordance with confidentiality and unfair business practice laws (see Section 4.4.2.2) which limits disclosure of certain business and commercial information such as trade secrets.<sup>39</sup> The benefits-sharing proposal provides for access to research information above and beyond the requirement placed on other NPS research permittees, who by comparison are required to provide only a brief annual report.<sup>40</sup> A benefits-sharing agreement would assure that the public had more, not less, access to the information generated by scientific research involving the study of park specimens.

Both government agencies referenced by correspondents, the United States Geological Survey (USGS) and the Centers for Disease Control (CDC) conduct publicly funded research in the public interest. Both agencies also enter into CRADAs and support the patenting and commercial development of research results. Of note, the USGS CRADA policy, like the NPS benefits-sharing proposal, requires that information about projects conducted under CRADAs be in the public domain, but also allows patenting and other forms of intellectual property protection for research results.<sup>41</sup> The CDC’s Technology Transfer Office “is wholly focused on translation of CDC’s research findings into practical application for the benefit of health and safety of the American public and the world.”<sup>42</sup> To date, more than 70 CRADAs have been formed between the CDC and industry. The CDC patents the inventions of its scientists and licenses inventions to provide income to the CDC.

Public Comment:	Commenter:	Affiliation:
36, 88, 4602		Individuals
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

**5.3.9.2 NPS should prohibit patenting of any intellectual property related to study of park resources**

*Comment #61:* Privatization has been gaining strength for past number of years in the Park Service ... We do not want corporations to patent genetic codes, plant, and animal life from public lands for their own benefits.

*Comment #68:* I used to work on intellectual property (IP) issues for the National Center for Supercomputing Applications and have some familiarity with how businesses manage IP. Bioprospecting transfers value from the public domain to private hands. What is in the public domain should remain in the public domain, therefore no private IP should be allowed from bioprospecting in national parks. Bioprospecting effectively takes public assets and limits access to their benefits so that some individual and institutional investors can benefit. That is an unfair tradeoff which does not serve the public interest. If the science is really compelling, leave the resulting IP in the public domain to maximize public benefit.

*Comment #69:* The very idea that genetic codes can be patented is unethical to begin with, and the practice should not be encouraged or facilitated.

*Comment #71:* Ample experience has shown that large corporations trying to patent life forms and biological/genetic material do not have the interests of the public at heart, but are seeking to maximize profits at almost any cost.

*Response:* The Constitution of the United States gives Congress the power to promote the progress of science by securing for limited times to inventors the exclusive right to their discoveries. The issuance of patents is exclusively governed by the Patent Act, 35 USC 101-376. The NPS does not have the authority to determine what is or is not patentable in the United States, nor may it preclude inventors from pursuing patents for their discoveries.

Correspondent #68 suggests that what is in the public domain should remain in the public domain. Research specimens collected through a research permit remain federal property subject to the statutes and regulations governing the NPS. A patented discovery based on study of natural resources does not preclude study of those same resources by others. An absolute prohibition against the development and protection of intellectual property derived from research involving specimens collected from NPS units would be contrary to the policies of the United States as expressed through the intellectual property rights and other laws that encourage discovery and technological innovation.

Public Comment:	Commenter:	Affiliation:
61, 68, 69, 71		Individuals

**5.3.9.3 Do not cede control of parks to corporations; beware of patents that might restrict access to resources within parks**

*Comment #69:* If a corporation obtains patents on genetic patterns of plants and animals that live in the national parks, then they could attempt to enforce those patents and monopolize access to the plants and animals possessing the genetic patterns. This would effectively remove or restrict public access to the national parks. This is not acceptable.

*Comment #154:* I am concerned that increasing privatization of “public” interests will further erode the public’s already fragile control of our resources ... It is necessary that the NPS be in full

control of research, if we are to avoid handing over the resources to corporations ...  
Corporate control of public resources is an irreversible trend, and a very slippery slope.

**Comment #7466:** I am aware of the existing system for limited ‘prospecting’ of natural species within the parks, with friends who deal with academic biological studies, and with research from private corporations. The system that is currently in place admittedly works well, as stated within the DEIS. This allows low-impact surveys, with any beneficial results spread across the public. Commercialized bio-prospecting will entail a ‘lock,’ in the form of limited licensure or a patent on a specific natural process or item.

**Response:** U.S. patents cannot be issued for naturally occurring organisms or natural processes. If a researcher patents his research results related to study of a park organism, the patent does not control or affect the park organism or limit or prohibit other researchers from attempting to collect identical park specimens. The commercialization of park-related research results would not affect park management or visitor access to parks.<sup>43</sup>

Correspondent #7466 indicates that the system for allowing research and associated collecting in parks works well and then assumes that, if benefits-sharing were selected, that system would change. The benefits-sharing proposal would make no changes to the way that research permit applications are evaluated and issued or denied by the NPS. The correspondent further assumes that currently all research results remain entirely in the public domain but would become private under the proposal. Laws already allow researchers to protect their intellectual property and research results. The proposal would have no impact on intellectual property rights as recognized in U.S. intellectual property rights laws.

Public Comment:	Commenter:	Affiliation:
69, 154, 7466		Individuals

#### **5.3.9.4 NPS should prohibit any commercial use of research results involving study of specimens collected from NPS units**

**Comment #56:** I am writing to support the alternative that prohibits scientific research involving NPS specimens if associated with the development of commercial products. The parks are not meant to be commercial resources, nor are they meant to be self-supporting in any way.

**Comment #59:** Why is there no option to rule out bioprospecting altogether?

**Comment #72:** Cease all commercialization of park biodiversity including but not limited to soil organisms, plants, insects, amphibians, reptiles, birds, mammals, bacteria, fungi, protists, algae and minerals. This is part of the Commons, held and protected in perpetuity for future generations of humans and non-humans.

**Comment #7241:** Velcro, metallic paints, the least toxic EPA approved herbicide, biological weed control, and light without heat (glow-in-the-dark sticks and accessories) were all invented from the study of nature. Industry increasingly turns to the wonders of nature to meet society’s wants and needs.

*Response:* As the DEIS stated in Section 2.7, the option to rule out bioprospecting altogether was considered but was deemed unreasonable, as described below. NEPA does not require unreasonable alternatives in an EIS.

An absolute prohibition against the development of any commercial use of research results involving specimens collected from NPS units would be contrary to the policies of the United States as expressed through the intellectual property rights and other laws that encourage discovery and technological innovation. To prohibit any commercial use of research results that involved specimens collected from NPS units could arbitrarily deprive society of important discoveries and also have a chilling effect on research in units of the National Park System. Such consequences would be contrary to a wide range of NPS policies as well as National Parks Omnibus Management Act (NPOMA).

Commercial use of research results is distinctly different from commercial use of park resources. This distinction between commercial use of research results and commercial use of park resources was upheld on judicial review in April 2000 when a federal court ruled against the assertion that the Yellowstone–Diversa CRADA was a commercial use of Yellowstone resources. “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources...[A]ny ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.”<sup>44</sup>

Under Alternative C the NPS proposed a prohibition on the collection of specimens for research that was identified or acknowledged by the researcher to have potential for commercial development (EIS Section 2.5).

Public Comment:	Commenter:	Affiliation:
56, 59, 72, 7241		Individuals

### ***5.3.9.5 NPS should not allow private interests to profit from the study of public resources***

*Comment #71:* The purpose of the national park system, the public interest, and the public trust would be violated by allowing private interests to exploit the resources of our national parks for their own gain.

*Comment #102:* NPS’s decision on the subject of benefits-sharing will support the spread of privatization -- or it can affirm the value of the Commons. Each time we give our Commons to corporations, we get further locked in to the market mindset. The mandate of the NPS asks us to be more creative than that: to find a solution that will foster the common good.

*Comment #150:* I object to research in national parks that is commercial and for private profit. These parks belong to the citizens and any profit from the parks should be put back into the parks’ upkeep.

*Comment #7455:* I strongly oppose opening up the parks for business partnerships. Also, I want to see profits from research or applications of research conducted in the parks to be shared with the parks...

*Comment #7476:* I am very proud of our National Parks System, the finest in the world, and I believe overwhelmingly seen as havens of natural resources to be enjoyed as Nature--not as commercial resources!

*Response:* Some correspondents advised the NPS to prevent any private enterprises from profiting on projects related to the study of public resources, including correspondents who differed on whether NPS-related research results ought to be used for commercial purposes. However, the application of new knowledge to useful public purposes depends largely upon actions by business. For example, many potentially useful inventions made by university scientists are simply waiting for a business to express an interest in developing these inventions further so that they could actually be used by the public.

Various laws, regulations and policies, such as The National Parks Omnibus Management Act of 1998 (NPOMA), encourage the NPS to extend the benefits of natural resource conservation to the public. If research on the resources preserved in parks might lead to beneficial discoveries, generally speaking, the NPS supports research efforts of this type as long as they meet stringent resource protection standards and requirements of the NPS research permitting process and are appropriate for a park environment. Conserving park resources is of critical importance to the NPS, and both public and private entities have demonstrated the ability to comply with and adhere to strict park protection standards for research and collecting activities, while benefiting management of park resources through enhanced understanding of the resources they study.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
71, 102, 150, 7455, 7476		Individuals

## 5.3.10 Correspondents Discuss Benefits-Sharing Details

### 5.3.10.1 Benefits-Sharing agreements and public disclosure

***The public should know who has entered into a benefits-sharing agreement with the NPS***

*Comment #4:* As a member of the public I have the absolute right to know who is making money off our parks. Secret arrangements, behind our backs, does not do justice to the American people!

*Response:* The NPS agrees. Section 2.4.4.1 of the EIS specifies that all benefits-sharing agreements and the associated research permit would be made available to the public upon request.

Public Comment:	Commenter:	Affiliation:
4		Individual

***All non-monetary and monetary benefits received by the NPS should be disclosed to the public***

*Comment #7463:* We would also like to see a detailed description of the non-monetary benefits provided to the NPS to be included in the CRADA.

*Comment #7492:* Under that alternative [B1], there must be full public disclosure of the benefits, monetary or non-monetary, that are exchanged between the parties to the BSA [benefits-sharing agreement].

There is no legitimate justification for keeping secret the benefits, monetary or non-monetary, that are exchanged between the parties to the BSA.

*Response:* The NPS agrees that all monetary and non-monetary benefits received by the NPS should be disclosed to the public, as allowed by law, and the final EIS has been edited to clarify this (Section 4.4.2.2). The EIS indicates that the benefits derived from the sharing of resource knowledge and the establishment of enhanced collaborative research relationships would be the most valuable component of a benefits-sharing package (EIS Section 4.4.1.1). The benefits-sharing agreement would establish this relationship and outline expected non-monetary benefits. The annual report to Congress and the public would provide details about the actual non-monetary benefits received by the NPS.

Public Comment:	Commenter:	Affiliation:
7463	National Parks and Conservation Association	Organization
7492	Public Employees for Environmental Responsibility (PEER)	Organization

***Should the monetary terms and conditions of benefits-sharing agreements be disclosed?***

**Comment #6:** I prefer alternative B3 [never disclose financial terms of agreements], which both benefits NPS and gives some flexibility in negotiation with researchers regarding financial matters.

**Comment #85:** Many private corporations are highly secretive about their financial arrangements, and will not establish a research collaboration if terms are made public. The NPS will best be served by not having a strict policy regarding the disclosure of financial terms of agreement. Mandatory transparency will significantly reduce the number of commercial parties willing to engage in benefits-sharing research, and these are precisely the parties that can provide the most benefits to the Parks. Another reason the NPS should be cautious about revealing financial terms is that once made public, these terms will become a de facto standard for parks and countries around the world.

**Comment #89:** I write in favor of Alternative B1, benefits-sharing with mandatory disclosure of all terms and conditions. I am not in favor of the preferred alternative with optional disclosure. These lands are our national heritage; I want to know exactly what is occurring on them, who is benefiting, and how.

**Comment #7444:** I ... do believe that mandatory disclosure of terms and conditions of any and all benefit sharing agreements must be a critical condition to avoid the appearance of impropriety and prevent benefit sharing agreements and bioprospecting from failing due to public perception of wrong doing.

**Response:** The Benefits-Sharing EIS contains three different options concerning release of information protected under confidentiality laws as described in Section 2.4.4. The title of Alternative B2 has been changed in the final EIS to emphasize that Alternative B2 would disclose all information not protected by unfair business practice and confidentiality laws. The potential impacts of these options are discussed in Section 4.4.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
6, 85, 89, 7444		Individuals

**5.3.10.2 Entering into benefits-sharing agreements**

***All of the reports and information generated under a benefits-sharing agreement should be disclosed, even when contrary to FOIA***

**Comment #7261:** Whatever the intentions of the NPS, the other parties to CRADAs may designate part of the CRADA as confidential business information. The public will have no effective means of accessing this information, not even the Freedom of Information Act.

**Comment #7463:** The public should have the right to view any agreement, including the agreement's financial terms and the underlying research permit.

However, we disagree with 2.3.4, “Protected CRADA Information” in the Model CRADA (Appendix A, p. 190), and we believe that language should be struck from the model CRADA. NPCA is specifically interested in the agreement’s financial terms, including royalty rates, up front payment rates, and the underlying metrics used to derive an agreed upon cash payment. It is also important to understand a detailed description of the biological materials, the discovery or development, process, function, anticipated use and market for the product ... Finally, all reports made by the company and all subsequent audits (as described in the Model CRADA, 4.4 “Records”, p. 193) conducted by NPS, or NPS agent, must also be made available for public review.

*Response:* Under the preferred alternative, the NPS would comply with confidentiality and unfair business practice laws which protect certain business or commercial information potentially received from benefits-sharing partners. All benefits-sharing agreements would be made available to the public in their entirety upon request unless one or more parties to an agreement objected to the release of any specific information for reasons satisfying one or more of the statutory disclosure exemptions provided under the federal Freedom of Information Act (FOIA). A summary of such information would be prepared and released to the public upon request (EIS Section 2.4.4.2). The research permit associated with each CRADA would be appended to the CRADA and provided to the public with the CRADA. (Research permits restrict the collection of biological or other materials to those specified in the permit by location, description and quantity.) In addition, the total non-monetary and monetary benefits generated by the benefits-sharing agreement would be reported to the public annually and also when requested.

Alternative B1 would implement benefits-sharing agreements with mandatory disclosure of the entire agreement, without exception, including its associated research permit. NPS expects that researchers would have two responses to this alternative. First, researchers could simply withhold information from NPS (e.g., market projections and other financial business information) that would have been useful to the NPS in negotiating favorable terms for agreements. Second, information collected by NIH indicates that many researchers would simply refrain from performing NPS-related research or not develop their discoveries for commercial applications to avoid entering into completely transparent negotiations.

If NPS were to implement Alternative B1 and release certain information contrary to a CRADA partner’s wishes, the NPS could find itself enjoined in a “reverse FOIA” or similar litigation, whereby the NPS would be sued by the CRADA partner to prevent disclosure of the information. The NPS could also be liable for any damages caused by release of a CRADA partner’s protected information (EIS section 4.4.2.2).

If Alternative B1 is selected, financial information contained in the CRADA would never be withheld, the parties to the agreement would be so advised, and “Protected CRADA Information” would not apply to the financial terms of the CRADA. Under all benefits-sharing alternatives, “Protected CRADA Information” would only be withheld for a period of five years after which it would be released to the public upon request (example [model] CRADA Article 10.3.2).

The example (model) CRADA assures that all information generated in the performance of the CRADA (“Subject Data”) can be used by the NPS for park management, whether or not it

has been disclosed to the public (example CRADA Article 10.1).

By their nature, audits of company records, while generally infrequent events, can be expected to examine proprietary information that is seldom if ever disclosed to the public in any other context. Therefore, the NPS would comply with confidentiality and unfair business practice laws when determining whether to disclose the results of any audit that might occur.

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7463	National Parks and Conservation Association	Organization

***Each specific benefits-sharing agreement should be subject to public review prior to finalizing***

*Comment #7241:* Delaying time to market typically results in loss of revenue through missed opportunity, salary/manufacturing/distribution overhead, delay of new product research, reduce stock value and can result in employee lay-offs. The steps from Discovery to Marketing, layed out on page 85, are not separate events, but overlap substantially to aid in reducing the time to market. Although a delay to market may be viewed as more “equitable” to the national parks, it can be devastating to a research company.

*Comment #7463:* The NPS process for negotiating and entering into benefits-sharing agreements must be transparent -- fully open and accessible to the public.

*Comment #7502:* The process for entering into benefits-sharing agreements must be open to the public and transparent. The public ought to be provided with an opportunity to comment on the agreement and the final agreement must be available to the public.

*Response:* Congress specified that NPS benefits-sharing procedures must be equitable and efficient.<sup>45</sup> In order to be “efficient,” the negotiation and completion of a benefits-sharing agreement must occur within a reasonable timeframe. As correspondent #7241 describes, researchers who commercialize research results face many obstacles on the way to marketing their product, and a typical 30- to 60-day public review period followed by revisions and further negotiations would be contrary to the “equitable, efficient benefits-sharing arrangements” required by the law.

An “equitable” negotiation must deal fairly and equally with both the NPS and the benefits-sharing partner. Exposing a company’s negotiating positions to the public can reasonably be expected to cause competitive harm to that company. Some commenters might be concerned that the NPS would fail to demand appropriate levels of benefits. However, making negotiations a matter of public record would more likely (1) limit payment equitability, (2)

create an artificial “rate ceiling,” (3) expose the NPS to litigation or other penalties, (4) discourage some research, and (5) discourage establishment of benefits-sharing agreements (EIS Section 4.4.2.2). Public negotiations would be more likely to result in lower levels of benefits for individual agreements and also lower levels of benefits over all.

Some commenters might have an underlying concern that a benefits-sharing agreement could give researchers special privileges in a park. The EIS explains that a benefits-sharing agreement would not regulate or authorize any researcher’s access to NPS resources (EIS Sections 1.2.1 and 2.4.5.1).

If benefits-sharing is implemented, publicly available annual reports to Congress would describe all non-monetary and monetary benefits received by the NPS from benefits-sharing agreements. Additionally, the benefits-sharing agreements and their underlying research permits would be made available to the public, providing an opportunity for public oversight of NPS benefits-sharing.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7241		Individual
7463	National Parks and Conservation Association	Organization
7502	Greater Yellowstone Coalition	Organization

***Each specific benefits-sharing agreement should be subject to NEPA review prior to entering into that agreement***

**Comment #7261:** [The DEIS] simply states ... that NEPA is applied at the permit issuance level. By this tactic, the NPS attempts to evade the “hard look” required by NEPA. Further, according to DEIS estimates, negotiating a new CRADA will require a high-end estimate of 0.18 FTE staff time, and the more CRADAs, the less time spent per agreement. This amount of staff time is clearly inadequate for scientifically credible NEPA compliance.

**Comment #7463:** All benefits sharing agreements/CRADAs must undergo full NEPA analysis, disclosure and appropriate public review in order for the NPS and the public to understand the potential environmental impacts of each agreement.

**Response:** If Alternative B (Implement Benefits-Sharing) is selected, an environmental (NEPA) review (Categorical Exclusion, Environmental Assessment, or Environmental Impact Analysis<sup>46</sup>) of specific benefits-sharing agreements that might be established by individual parks in the future can be tiered from this programmatic EIS. If an individual park proposed site-specific resource management projects using non-monetary or monetary benefits generated by a benefits-sharing program, such projects would receive a separate environmental review for potential project-specific impacts in compliance with NEPA.<sup>47</sup>

Benefits-sharing agreements would not authorize any research activities in parks that otherwise require a permit.<sup>48</sup> This means that any kind of research proposal that currently

requires a research permit would still require the same permit, including a NEPA review, if any benefits-sharing proposal in this EIS is implemented.

Correspondent #7261 may not recognize the distinction between the proposed benefits-sharing agreement and its underlying research permit. All research permit applications are evaluated under NEPA and the benefits-sharing proposal would not supersede or circumvent this policy. In addition, personnel who negotiate benefits-sharing agreements would not be involved in review, approval or denial of research permit applications. The time estimated for entering into a benefits-sharing agreement (0.18 FTE) was based on the experience of the Association of University Technology Managers (AUTM) annual survey respondents who enter into thousands of similar agreements each year. Because the AUTM FTE figure includes a variety of activities not included in the NPS’s benefits-sharing proposal, the 0.18 FTE is a generous estimate of the workload to execute a single new benefits-sharing agreement (see EIS Section 4.4.5).

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7463	National Parks and Conservation Association	Organization

***NPS Scientists should not be diverted to CRADA negotiations.***

**Comment #6733:** Furthermore, our national parks are understaffed as they are, and option C in the DEIS is the only option that would allow the park staff to continue on their mission on the public’s behalf. Other options would divert time away into negotiating Commercial Research and Development Agreements (CRADAs). Not only would the public lose its national park resources, it would also lose tax-funded working hours of national parks employees.

**Comment #7488:** The Sierra Club is concerned that the size of the National Park Service scientific staff is very limited at present and that this staff needs to focus its time on science in the public interest, not developing, negotiating and managing Commercial Research and Development Agreements (CRADAs).

**Response:** The NPS shared this concern and developed the benefits-sharing proposal in a way that would avoid undue impacts to park staff. With few exceptions, NPS scientists would not be diverted to negotiate agreements. Ordinary administrative functions would be performed by specialized administrative staff, not scientists. To the contrary, the proposal seeks to increase the quantity and quality of research and scientific knowledge available to manage parks.

The potential impacts of benefits-sharing to NPS staff workload were analyzed in the EIS using the best available data. No additional data or specific evidence was offered that demonstrated the analysis in the EIS was flawed.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
6733		Individual
7488	Sierra Club--National Parks and Monuments Committee	Organization

***5.3.10.3 The benefits generated by benefits-sharing agreements***

***What kind of benefits should be required?***

**Comment #79:** A wise private landowner would certainly require some sort of benefit-sharing agreement from the same persons if the private landowner allowed such research on their property. United States citizens who use and enjoy the national parks, as I do, should not be denied similar benefits. I consider the money received from benefit-sharing agreements a benefit to all US citizens, not just to the NPS, when it is used for the maintenance and continued preservation of the national parks.

**Comment #95:** A modification of the Preferred Alternative, in which scientific benefits and in-kind services would be shared with NPS by the researchers, but no royalty benefits paid, would be the ideal solution.

**Comment #7463:** NPCA is most interested in assuring that the non-monetary benefits are secured as a first priority, as we believe it is a critical tool to provide the public with new

scientific knowledge about park resources.

**Comment #7483:** The Washington Biotechnology Action Council ... has long opposed the NPS-Diversa sort of agreement, an an egregious example of the privatization of a public good. Corporate give-aways along these lines are inconsistent with the purposes of the National Parks, and should not be tolerated.

We could support a variant of Alternative B which included ... the proportion of direct monetary benefits is high and significant.

**Comment #7490:** One idea to examine during the benefit-sharing discussion is to require that most (if not all) of the benefits are non-monetary for commercial organizations as well. This approach might promote cooperation between those commercializing something derived from a biological resource collected in a National Park to work towards the desired non-monetary benefits that each park and commercial organization is uniquely suited to provide. For example, the commercial organization may be able to provide special services such as genetic work, or funding training opportunities (for Ph.D. and masters students, NPS personnel, academics). Focusing on non-monetary benefits might stimulate other novel and creative ideas and plans for how to enhance the education, research, and conservation efforts in the National Parks more than the approach of simply taking in monetary benefits. In addition, some organizations might be more willing to provide non-monetary than monetary-benefits for several reasons including: enhancing their public relations image or more willingness to provide special services that are less costly to give to the NPS than it would be for the NPS to obtain by using outside consulting services. This might be more favorable to the NPS as well, to more easily demonstrate the true scientific and conservation goals of the NPS to U.S. citizens, some of which may have a misperception that the NPS is "selling off" their natural resources.

**Response:** As stated in the EIS, the NPS expects that non-monetary benefits would be the primary benefit resulting from any benefits-sharing agreement.

Federal law (the National Parks Omnibus Management Act of 1998) requires any potential NPS benefits-sharing agreements to be "equitable." The NPS recognizes that companies will only accept agreement terms that allow the company to recoup its costs and realize some profit. Requiring a majority of income from a discovery to accrue to a park may not recognize the costs associated with research and development of the discovery. (See EIS Appendix C for more information about how potential monetary benefits were estimated.)

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
79, 95, 7490		Individuals
7463	National Parks and Conservation Association	Organization
7483	The Washington Biotechnology Action Council	Organization

***Where should benefits be distributed?***

**Comment #38:** The money should go into a national NPS pool and not to one park or area. Otherwise there is a very clear conflict of interest for individual park superintendents, especially in these times of tight budgets. There would be a much more objective review of proposals if parks knew they were not going to get all of the money generated ...

**Comment #76:** I would support these revenues returning directly to the NPS unit where the research originated.

**Response:** The distribution of monetary benefits from CRADAs would be accomplished pursuant to the requirements of the Federal Technology Transfer Act (FTTA). In accord with the FTTA, if monetary benefits result from commercialization of a patentable invention, the majority of any monetary benefits must be retained by the park that entered into the CRADA. The specific distribution of the remainder of any monetary benefits received from the commercialization of a patentable invention would be determined by the NPS Office of Natural Resource Stewardship and Science Associate Directorate in Washington, D.C.

If monetary benefits result from commercialization unrelated to a patentable invention, all monetary benefits must be retained by the park that entered into the CRADA for the conduct of specified research or development efforts which are consistent with the missions of the park.

Although the analysis in the EIS concludes that it is unlikely, if monetary benefits exceed 5% of the entire NPS budget, the FTTA specifies that most of that excess must be deposited in the U.S. Treasury.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
38, 76		Individuals

***How should benefits be used?***

**Comment Form Letter #167:** All scientific information resulting from any agreement must be shared with the park, and any compensation received should be used to benefit resource protection and research.

**Comment #7241:** I do not agree with potential research dollars being re-directed to conservation of our national parks when an option of directing funds to the Natural Resource Challenge exists. Alternative B would be more acceptable if dollars gained by NPS from benefits-sharing were applied to the NRC [Natural Resource Challenge].

**Comment #7463:** Monies that are received as a result of benefits sharing agreements should be employed to directly benefit resource protection, as opposed to other park needs or other general government budget items.

**Comment #7490:** The original researcher who collected the species could have a role in defining how the species from which the commercial use was derived can best be conserved.

Or if the species is abundant, the original researcher could recommend other species to which such monetary benefits could be directed.

**Comment #7492:** A means to ensure that park managers meet the highest professional standards in negotiating and approving BSAs is to direct all monetary benefits to a central account in the NPS Headquarters in Washington, D.C ... The central account should be devoted solely to the research needs of the national park system.

**Comment #7501:** We suggest that the Final EIS establish mechanisms to ensure proceeds are focused on protecting natural resources in the Parks ...

**Response:** The benefits-sharing proposal specifies that all benefits, both non-monetary and monetary, received by the NPS under a benefits-sharing agreement would be dedicated to the conservation of resources protected and managed by the NPS. In addition, article 5.1 of the example CRADA (Appendix A) specifies that all payments and non-monetary benefits received by the NPS may only be used for natural resource conservation purposes.<sup>49</sup> The example CRADA, once signed by all parties, is an enforceable contract and the NPS must use benefits for the stated purpose and in accordance with the FTTA.

Benefits could be used for the purposes and projects undertaken for the NPS Natural Resource Challenge, but this is not a requirement of the proposal. In general, CRADA benefits must be used for scientific purposes.

The NPS expects that the researcher who enters into a benefits-sharing agreement would be consulted regarding the specific benefits that researcher could offer to the park. The EIS indicates that non-monetary benefits derived from the sharing of resource knowledge and the establishment of enhanced collaborative research relationships would be the most valuable component of a benefits package (EIS section 4.4.1.1).

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
167 (form letter) and 7463	National Parks and Conservation Association	Organization
7241, 7490		Individuals
7492	Public Employees for Environmental Responsibility	Organization
7501	US Environmental Protection Agency	Government Agency

**5.3.10.4 The NPS should evaluate the use of benefits-sharing agreements other than CRADAs**

*Comment #7261:* Throughout the DEIS analysis, only one form of benefit sharing agreement is considered: the CRADA ... The NPS should have considered other forms of benefit sharing, including the use of fully transparent contracts made available for public view.

*Response:* The NPS proposed use of the standardized agreement provided in Appendix A because it best suits the overall needs of the NPS. Additionally, CRADAs are used by many other agencies throughout the federal government for technology transfer, and there is an existing legal foundation and framework surrounding their use. The General Provisions of a CRADA provide a well-used and well-accepted framework to allow sharing of scientific and monetary benefits resulting from improved cooperation between national parks and the research community. Since the enactment of the Federal Technology Transfer Act (FTTA), CRADAs have been used to strengthen cooperative research activities between federal agencies and private sector researchers, something the NPS finds highly desirable.

Objective 2 of the EIS is to “Strengthen conservation and protection of resources managed by the NPS by deepening understanding of biodiversity and physical and biological processes” (EIS Section 1.4.2). This objective is responsive to Congress’s mandate that the NPS must “assure that management of units of the National Park System is enhanced by the availability and utilization of a broad program of the highest quality science and information.”<sup>50</sup> CRADAs provide an established mechanism and model to accomplish that through enhanced collaborative relationships with researchers, even in the absence of monetary benefits or a major commercial discovery.

The NPS decided to use a well-established and well-accepted agreement instrument rather than attempting to use or create an entirely new and untested agreement format. The NPS did investigate and consider other forms of benefits-sharing while developing the alternatives, including cooperative agreements. No other form of contract available to the NPS by law allows monetary benefits, if any are generated, to be used by the NPS for purposes other than cost recovery. Other agreement and contract types all require that monetary benefits remaining after cost recovery be deposited in the U.S. General Treasury. Only CRADAs allow monetary benefits to be retained by the NPS for use in the parks. Since 1995, when the idea of NPS benefits-sharing was first discussed with the public, it has been clear that most researchers would be happy to comply with benefits-sharing on the condition that the benefits would be used to help protect the resources upon which the research was based. Researchers have explained to the NPS that they would not be encouraged to provide benefits to the U.S. General Treasury if there was no expectation that any such benefits would accrue to the NPS.

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

**5.3.10.5 The benefits-sharing program should be routinely evaluated**

*Comment #7490:* In summary, if it is possible that any benefit-sharing system may be more expensive than the value of the benefits brought in, then the NPS should evaluate critically the worth of applying benefit sharing to the National Parks.

*Comment #7502:* The NPS should review the benefits-sharing program every five years to assess lessons learned, evaluate opportunities to strengthen the program, ensure the research permitting process remains insulated from the benefits-sharing agreements, and demonstrate that any benefits accrued are not negatively affecting congressional spending on park programs.

*Response:* The NPS agrees that a program such as benefits-sharing should be evaluated periodically. If the NPS implements benefits-sharing, the timing and elements to include in such reviews will be determined at that time.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7490		Individual
7502	Greater Yellowstone Coalition	Organization

**5.3.10.6 Some park officials might be inclined to issue research permits based on an expectation that benefits-sharing might be likely**

*Comment #166:* Isn't this going to invite unwarranted and invasive research in the hopes that it will create "benefits"?

*Comment #7261:* This policy of benefit apportionment represents a built-in system for potential abuse of discretion in the issuance of permits, favoring commercial bioprospectors and opening the door for conflict of interest in permit issuance and environmental impact review.

*Comment #7418:* If two (or more) proposals would impact the same resource, the NPS may give priority to the activity that involves a benefits-sharing agreement over one that does not. The benefits-sharing agreements may also encourage the NPS to limit access to natural resources for academic study, because the prior discovery of valuable information in non-commercial research may undermine the value of benefits-sharing agreements. There is a very real incentive for the NPS to favor research involving benefits-sharing agreements over academic research.

*Comment #7429:* Any proposal to collect any sort of fees for commercial activity in the parks, other than those for limited traditional franchises such as lodges and gasoline stations, is entirely unacceptable. It creates a financial incentive to permit activities which are detrimental to the Park Service's mission to preserve the natural and historical features of the parks.

*Response:* NPS agrees that these are valid concerns and the EIS has addressed them. The major purpose of the mitigation measures included in the proposal is to prevent NPS

employees from creating a bias toward research projects associated with benefits-sharing agreements and making improperly influenced decisions.

Specific mitigation measures associated with the benefits-sharing proposal were explained in detail in EIS sections 2.4.6, 2.4.6.1, 2.4.6.2, 2.4.6.3, 2.4.6.4, 4.4.4.6, and 4.4.5.5.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
166, 7429		Individuals
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7418	The Ornithological Council	Organization

### **5.3.10.7 The CRADA fails to control specimens**

*Comment #7418:* The CRADA (Appendix A) does not specify that NPS retains ownership of the physical specimen or any part of the specimen that is the underlying basis for the agreement. The CRADA does not prohibit destruction or consumption of the specimen, or any part of it, nor does the CRADA require return of the specimen or any part of the specimen that is not consumed, destroyed, or altered in research or development. The CRADA, in fact, talks only of the intellectual property, ignoring the fact that without the transfer of a physical specimen there could be no CRADA.

*Response:* The example CRADA in the EIS (Appendix A) stipulates that the parties to the agreement are aware that the federal government retains ownership of the research specimen collected by a researcher pursuant to a research permit (Article 6.1 of the example CRADA). However, research specimens themselves are controlled by the research permit under which they were collected, not by the CRADA. The specific purpose of the CRADA is to address the handling of intellectual property and to clarify the rights and responsibilities of researchers and the NPS.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7418	The Ornithological Council	Organization

### **5.3.10.8 Researchers would or would not comply with benefits-sharing requirements**

*Comment #85:* CRADAs and MTAs are long-standing and proven procedures used widely by government and academic institutions both for commercializing their knowledge and intellectual properties and for ensuring that they capture a fair share of the profit streams that result from such commercialization.

*Comment #7492:* Researchers who develop commercial applications derived from NPS research permits have no incentive to seek out or enter into CRADA agreements with NPS. The cumbersome 30-page model CRADA with profit-sharing as well as detailed reporting requirements is something an entrepreneur would seek to avoid at all costs. Researchers are not required to enter into any contracts to implement a CRADA. Rather, the obligation to enter into a CRADA only arises when or if useful discoveries are developed. In the event that NPS was able to discover the discovery, it lacks any legal means to force the commercial researcher to negotiate a CRADA with it.

*Response:* Authorization to conduct research and collect research specimens in NPS units is granted only after an NPS research permit specific to that researcher is signed by both the park superintendent and the researcher. The research permit (see Appendix H) is a legally binding contract that obligates the researcher to negotiate a benefits-sharing agreement with NPS in the event the researcher wishes to commercialize their research results involving the study of a park research specimen.

The 30-page example (model) CRADA is based closely on the well-accepted CRADAs already used by over 5,000 researcher/government partnerships annually. In addition, the format of the CRADA is similar to the tens of thousands of commercial licenses in use by academic institutions annually. Although the example CRADA may be confusing to the layperson, the NPS expects that many researchers would have the assistance of technology transfer experts in their own institutions who would already be familiar with the CRADA format.

There are many important reasons researchers are likely to comply with benefits-sharing requirements. First, and most importantly, research and development (R&D) institutions need and expect legal clarity. R&D institutions increasingly anticipate that benefits-sharing will be required and are concerned about their related rights and obligations. R&D institutions also are increasingly being required to demonstrate that they have legal rights to use biological material in their possession. For example, some federal research grants require that biological materials be obtained in full compliance with all applicable benefits-sharing laws and regulations, as encouraged by the State Department (guidance dated November 5, 2003), and many institutions routinely use Material Transfer Agreements that include a requirement to obtain additional authorization before using research results for commercial purposes (e.g., NIH's Universal Biological Material Transfer Agreement in use since 1995).

Secondly, the Biotechnology Industry Organization (BIO) endorses benefits-sharing. BIO, the premier biotechnology trade group, has published voluntary "Guidelines for Bioprospecting" that encourage members to engage in benefits-sharing with the providers of their research specimens. These guidelines also encourage companies to acquire prior informed consent from the provider for specimen collection and third-party material transfers (see <http://www.bio.org/ip/international/200507guide.asp>).

Lastly, through the research permitting process, researchers acknowledge by signing their permit that if they fail to enter into a benefits-sharing agreement before using their research results for commercial purposes, "the permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled including but not limited

to injunctive relief against the permittee” (see Item 6 of the “Conditions Subject To All National Park Service Research Permits” in the “Scientific Research And Collecting Permit,” in Appendix H). Twenty percent of gross revenues would be an onerous amount compared to the royalty rate potentially negotiated through a CRADA with the NPS. Every NPS permitted researcher is legally bound to the conditions of the servicewide NPS research permit, as it constitutes a legally enforceable contract.

Public Comment:	Commenter:	Affiliation:
85		Individual
7492	Public Employees for Environmental Responsibility	Organization

### **5.3.10.9 Questions and suggestions for implementation of benefits-sharing**

**Comment #7241:** Parks may elect not to enter into the agreement if negotiation reveals that royalty payments, which would otherwise be reinvested back into research, will only cover park administration costs.

To fully accept Alternative B, I would need to see more detail on what factors would be considered during a benefits-sharing negotiation?

The developed service-wide institutional record of benefits-sharing agreements must be easily assessable to the researchers and their companies for the same reason these would be beneficial to the parks to enhance institutional expertise and efficiency.

Would monetary benefits be paid to the park before or after taxes?

**Comment #7418:** It is not entirely clear if the DEIS and the benefits-sharing agreements contemplated by the National Park Service (NPS) pertain to the noncommercial, academic research conducted by the members of the organizations we represent.

The DEIS implies that a CRADA (which we use here to refer to all benefits-sharing agreements, whether arising under the FTTA or otherwise) may or will be required for every collection of resources, for all purposes, including the development of noncommercial (i. e., traditional, academic) scientific knowledge.

**Comment #7461:** Would biomechanical inventions—such as a clamp which was designed after watching the use of a spider’s mouth—be covered? Would the development of a cancer fighting drug from a plant in Canada which was studied because it was related to a plant in an American National Park be covered, even if the American plant did not provide the ultimately useful product but was part of the discovery process?

**Comment #7463:** NPCA requests that this provision [the audit] be conducted by an agency or organization acting in the public interest.

Please conduct and disclose appropriate analysis to understand which NPS units may have enabling legislation that contains guidance that would prevail over this service-wide [benefits-sharing] policy.

*Response:* Correspondent #7418 asked whether a benefits-sharing agreement would be required for the development of “noncommercial scientific knowledge” associated with an NPS research permit. Data presented in the EIS indicates that less than 1% of permitted researchers were declared bioprospectors (EIS section 3.4.3.2), so requiring the rest of the nearly 4,500 researchers annually to complete benefits-sharing agreements where no commercially valuable research results were anticipated would not be an effective use of NPS personnel or resources. Under Alternative B, the NPS would expect to enter into the majority of benefits-sharing agreements only with declared bioprospectors.

Correspondent # 7418 suggested that a benefits-sharing agreement would be required before a researcher could collect specimens. Benefits-sharing agreements do not authorize collections or research. Additionally, research permits would not be issued at the same time a benefits-sharing agreement was negotiated. As noted in the EIS, this would compromise the separation necessary to keep these processes independent of each other. Research permits, including those authorizing specimen collection, would be issued or permit applications denied without regard to whether the permit applicant was or might become a party to a benefits-sharing agreement. Negotiation and establishment of a benefits-sharing agreement would not change or affect the existing procedures relating to the issuance of permits for research activities. Issuance of a research permit would not be conditioned on negotiation of a benefits-sharing agreement (see EIS Section 2.4.6.3).

In some instances, a benefits-sharing agreement could be established before a researcher had a commercially valuable discovery. However, it would be up to the researcher to begin the process of entering into a benefits-sharing agreement by identifying or acknowledging to the NPS that their research results could have potential, reasonably foreseeable commercial uses. In most cases, benefits-sharing agreements would be requested by researchers at an appropriate time during the research and development process.

Some correspondents asked very specific questions or offered specific recommendations on how the NPS might implement benefits-sharing and negotiate terms in individual agreements. While the NPS will consider these comments if benefits-sharing is implemented, some issues may lack the necessary detail an actual situation would provide or are otherwise unripe for consideration before the decision of whether or not to benefits-share is made.

Correspondent #7461 asked whether certain types of discoveries would be subject to benefits-sharing. Generally speaking, the types of discoveries mentioned by the correspondent could be the subject of benefits-sharing agreements. However, additional information such as the monetary value of the discovery and the role a park specimen played in the development of a discovery could also be significant in determining whether a benefits-sharing agreement would be required.

Correspondent #7463 proposed procedures for conducting audits. Audits of company records are generally expected to be infrequent events and could involve the examination of proprietary information that is seldom if ever disclosed to the public in any other context. In considering who might participate in an audit, the NPS would need to consider a number of things, such as existing NPS audit procedures and compliance with confidentiality and unfair business practice laws regarding disclosure of audit results.

Correspondent #7463 requested a review and analysis of park enabling legislations for directives that would prevail over servicewide benefits-sharing policy. This comment likely responds to a sentence in EIS section 1.7.1 indicating that parks should conduct such a review. This sentence was included as a general statement to indicate that a park’s enabling legislation would take precedence in the event there was a park with explicit language contrary to servicewide benefits-sharing policy. The NPS is unaware of any such parks. The data in the EIS for nearly 400 NPS units indicates, with the exception of Yellowstone, there is a low probability of any one park entering into a benefits-sharing agreement in any given year. Thus, specific reviews of park enabling legislation will be done if benefits-sharing is implemented and at the time a benefits-sharing agreement is under consideration at that specific park unit.

Public Comment:	Commenter:	Affiliation:
7241, 7461		Individuals
7418	The Ornithological Council	Organization
7463	The National Parks and Conservation Association	Organization

### 5.3.11 Correspondents Discuss the EIS Impact Analysis

#### 5.3.11.1 *The EIS should have analyzed the potential impacts of research specimen collection*

*Comment #7261:* The subjects of the commercial bioprospecting program are biological in nature and involve living park resources, with bioprospectors potentially searching over large geographic areas. The issues are physical and environmental and are directly related to the exploitation of natural resources.

*Comment #7418:* The analysis of impacts is inadequate because it never addresses the impact of the permanent removal of natural resources from the parks ...

We wish to make clear that we do not of course object to the removal of natural resources from the National Parks, whether under benefits-sharing agreements or for academic research.

*Comment #7492:* Each proposed specimen collection, or other intrusive research, whether subject to a benefits-sharing agreement, requires NEPA review. It is impossible for a programmatic NEPA document to anticipate, much less assess, the impacts of benefits-sharing agreements throughout the national park system.

*Response:* Implementation of benefits-sharing as proposed in Alternative B would not change the criteria by which all scientific research permit applications are evaluated. No benefits-sharing agreement would authorize the collection or extraction of natural resources from park units.

This EIS was developed to identify potential impacts from alternative ways to clarify the rights and responsibilities of researchers and National Park Service (NPS) managers in connection with the use of valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks. (See Section 5.3.6 for more information about the subject of the Benefits-Sharing EIS.)

Authorization to conduct scientific research in national parks is subject both to well-established NPS policies and regulations and to separate environmental review (NEPA) procedures. Actions analyzed in this EIS would not change the environmental review procedures under which research activities could be conducted. Therefore, the EIS does not discuss or analyze the impact of the alternatives on specific research activities in the National Park System.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7418	The Ornithological Council	Organization
7492	Public Employees for Environmental Responsibility (PEER)	Organization

### **5.3.11.2 The EIS should have analyzed potential impacts of benefits-sharing on the existence value of parks**

*Comment #1401:* The creation of new scientific knowledge in national parks is a significant benefit which is compatible with the conservation of the resource and undiminished public appreciation under this alternative.

*Comment #7261:* In this DEIS, the NPS has failed to discuss or analyze the impact of its proposed benefit sharing policies on the American people's perception of and regard for the National Park System, as well as on their aesthetic and recreational interests. Rather, the NPS on page 82 characterizes the social environment of potential impact as containing researchers and NPS personnel only, with no recognition of their plan's impact on the American public. In fact, the District Court provided the NPS with an opportunity to comprehend the significance of NPS's "dramatic shift in park management policy" and the impact it would have on the public users and owners of the National

Park System when the Court wrote, "This ignores the reality that the commercial nature of an activity can and does affect its impact on the subject environment and particularly on people's aesthetic and recreational interests in the Park. Although parkgoers may be willing to forgive the trespass of their national parkland when the goals of that trespass are scientific and educational, commercial exploitation of that same parkland may reasonably be perceived as injurious. This commonsense notion has not even been challenged in other contexts." The Court went on to say, "There is an undeniable reality that commercial activity is qualitatively different than scientific and educational activity of a similar nature, due to the very different forces and motivations that drive them."

The NPS has had a long time to consider the impact to the public perception of and regard for the NPS and the quality of its stewardship. The failure to assess the national precedent the commercial bioprospecting program would set is particularly egregious since, as the Court noted in its ruling, documents obtained through the Freedom of Information Act show that Park Service officials knew as early as 1996, ten years ago, that commercial bioprospecting would apply systemwide. Moreover, one memorandum stated "any precedent set will affect all parks, and may influence profitable resource access by other industries besides biotech/microbiology."

The importance of the impact of commercial bioprospecting - "profitable resource access" - on public perceptions of the meaning (and public nature) of the parks cannot be underestimated.

*Response:* The concept of existence value is recognized by the NPS. However, and more importantly, the NPS supports the right of visitors to hold their own individual points of view about the meaning of national parks.<sup>51</sup> NPS employees are instructed to present the facts and let visitors form their own intellectual, emotional, and physical connections to the meanings and values found in the parks. The NPS Interpretive Development Program makes it clear that visitors' conflicting opinions about the meaning of parks should be respected. Visitors have the right to ascribe whatever meanings they wish to the resources; the NPS must provide for the resources themselves to be protected. Therefore, the EIS does not discuss or analyze the impact of the alternatives on the American people's perception of and regard for the National Park System.

Correspondent #7261 quotes the District Court's March 1999 decision without reference to the clarifications given by the same court in April 2000 (the text of both court decisions

may be found in Appendix I).<sup>52</sup> The District Court provided its opinion on the significance of benefits-sharing when it made its April 2000 decision. In 2000, the court explained that the NPS had “determined that the potential scientific and economic benefits resulting from collaboration with private industry would support and strengthen the Park Service’s primary mission of resource conservation.”<sup>53</sup>

The memorandum quoted in Correspondent #7261 was the unsubstantiated opinion of a single employee without the authority to speak finally and officially for the agency and did not represent agency policy or decision-making. The phrase quoted by this correspondent, “profitable resource access,” is taken out of context and does not refer to any harvest or sales whatsoever of park resources for commercial uses. The memo, written in 1996, lacks the benefit of an informed perspective about the potential for research to lead to results with commercial application, which the NPS has gained in the intervening decade. After the analysis conducted for this EIS, the NPS has determined that such potential uses for research results are rare at best.

The proposal in Alternative B is not a “commercial bioprospecting” proposal, as Correspondent #7261 suggests. See Section 5.3.7.2 addressing the concern that benefits-sharing agreements might allow parks to approve research with purely commercial purposes.

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
1401		Individual

### **5.3.11.3 The EIS should have analyzed the potential impact of the alternatives on park values**

*Comment #102:* You have defined the scope of the investigation as extending beyond just the physical environment to a social one. Therefore you need to consider the ethical impact of your proposals on how the NPS carries out its mission, and the impact on the culture at large. On page 106 you describe the purpose of the NPS as conservation not only of park resources, but also of “park values.” What are these?

*Response:* The EIS “succinctly describe[s] the environment of the area(s) to be affected or created by alternatives under consideration” in compliance with regulations promulgated by the Council on Environmental Quality (CEQ).<sup>54</sup> CEQ regulations require the inclusion of social effects in an environmental analysis and as a result, visitor experience and enjoyment and the research community were included as topics for analysis. Neither CEQ nor NPS NEPA guidance include “ethical impacts” as a required analysis topic.

The NPS supports the right of visitors to hold their own conflicting opinions about the meaning of national parks. Visitors have the right to ascribe whatever meanings they wish to the resources: the NPS must provide for the resources themselves to be protected.<sup>55</sup>

The resources and values that NPS must protect are defined in the NPS Management Policies as follows:

- The park’s scenery, natural and historic objects, and wildlife, and the processes and conditions that sustain them, including, to the extent present in the park: the ecological, biological, and physical processes that created the park and continue to act upon it; scenic features; natural visibility, both in daytime and at night; natural landscapes; natural soundscapes and smells; water and air resources; soils; geological resources; paleontological resources; archeological resources; cultural landscapes; ethnographic resources; historic and prehistoric sites, structures, and objects; museum collections; and native plants and animals;
- Appropriate opportunities to experience enjoyment of the above resources, to the extent that can be done without impairing them;
- The park’s role in contributing to the national dignity, the high public value and integrity, and the superlative environmental quality of the national park system, and the benefit and inspiration provided to the American people by the national park system; and
- Any additional attributes encompassed by the specific values and purposes for which the park was established.<sup>56</sup>

Public Comment:	Commenter:	Affiliation:
102		Individual

**5.3.11.4 The EIS analysis of the potential impact of the alternatives on the quantity of scientific research in parks was incomplete**

*Comment #7261:* The DEIS contains allegations apparently meant to steer people away from Alternative C. Sometimes this involves making broad claims, without documentation or substantiation.

The DEIS states elsewhere that approximately 99.5% of research in the parks would be unaffected by Alternative C. On page 150 it states: “At the Servicewide level, Alternative C is likely to result in only a slight change in the availability of new scientific knowledge about park resources.” Further, on page 122 the DEIS states: “No significant difference in the number of research projects conducted in any context was detected between the pre-benefits-sharing and post-benefits-sharing time periods.”

There is also no analysis of the effect a “major commercial” find might have on the number of bioprospecting permits issued. A “bioprospecting gold mine” might encourage a rush of commercial bioprospectors.

*Comment #7490:* Alternative C appears certain to make basic scientific research in the National Parks more difficult, and as stated in the EIS, there is the potential that this inhibition

of research could be major. This “hands-off” or “no access” approach has several adverse impacts, some of which are immediately recognizable, others adverse impacts will become evident over time. Does the NPS want to take responsibility for trying to discern which species might lead to commercially valuable information and which do not? Where would NPS draw the line? Discerning these issues will most likely require more capacity to evaluate research proposals than the NPS currently has. Although the report states that less than 1% of all research activities would be prohibited under Alternative C, any species could, theoretically, contain bioactive compounds, enzymes, or interesting properties that might later lead to commercial benefit. ...

Does this mean, for example, if a botanist identifies a plant to have medicinal compounds, that this botanist can no longer study this plant species in the National Parks? Would this prohibit all other researchers from researching this species in the NPS as well? Excluding certain species from study in the NPS appears to counteract conservation measures for species. How can species be conserved if basic research on its systematics, ecology, and population biology cannot be conducted? In addition, Alternative C could create perverse incentives for people to collect target species illegally in National Parks. When such research is done without approval, it would be more likely to be done in environmentally harmful ways.

*Response:* During initial scoping, several commenters suggested that implementing benefits-sharing could affect the quantity of research activities in parks, either by attracting or discouraging scientific research activities undertaken by bioprospectors. In an effort to determine whether any alternative would have an indirect effect on research activities in parks, the EIS analyzed the potential of each alternative to impact the amount of independent research conducted in parks using the best available information, as directed by NEPA. Data and discussion for this analysis are presented in Appendix F of the DEIS.

The NPS found no evidence to substantiate concerns that a “major commercial” discovery could potentially cause a “rush” of new research permit applications. For example, even after the prodigious success of Taq polymerase (a highly lucrative DNA fingerprinting enzyme first isolated from a microbe collected from a Yellowstone National Park hot spring and then successfully synthesized in a lab), only a few researchers have expressed interest in discovering similar research reagents through the study of newly collected park specimens or research. As Correspondent #85 said, researchers know that “bioprospecting is an activity that is rarely successful. Most bioprospecting campaigns end in failure.”

The NPS has not proposed to create a new kind of research permit, and there would be no such thing as a “bioprospecting permit.” No change is proposed to NPS’s long-standing research permit procedures. The NPS does not treat declared or potential bioprospectors differently from other researchers. They are all subject to the same strict research permitting procedures.

Under Alternative C, the NPS would not have to determine which projects might lead to research results with commercial applications. Researchers could qualify for and receive NPS research permits until and unless they identified or acknowledged their proposed specimen collections as being associated with potential development of research results for commercial purposes. Researchers who unexpectedly discover a commercial application for their research results would be prohibited from developing such discoveries for commercial

purposes unless the NPS Director determined the development of that discovery to be in the public interest. In any case, such researchers would be prohibited from acquiring any more NPS research specimens. Correspondent #7490 provides both concrete and speculative examples of potential adverse impacts of Alternative C, including effects on the quantity as well as the quality of scientific research. These types of effects are summarized in EIS Sections 4.5.2 and 4.5.4.

Alternative C in the EIS has been edited to clarify that the criteria parks would use to determine whether or not to approve proposed research activities hinges on the potential for commercial application of research results, not simply on their potential for being “useful.”

Public Comment:	Commenter:	Affiliation:
7490		Individual
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

### **5.3.11.5 Other countries with benefits-sharing have discouraged research**

*Comment #7418:* The unfortunate outcome of the good intentions of those who have tried to protect the intellectual property derived from natural resources has been a serious barrier to noncommercial scientific research, as described at length in the attached New York Times article. Scientists ... are now experiencing difficulty obtaining permission to conduct scientific research in many countries due to concerns about benefits sharing. In particular, they are having tremendous difficulty obtaining permission to export scientific specimens even for entirely academic, noncommercial research. Some countries have come to be suspicious that scientists will “steal” the value of the intellectual property that is derived from the natural resources, or have become interested only in scientific research that has the potential to return benefits.

*Comment #7461:* The experiences from other countries trying to implement ownership based models of benefit sharing have all created large bureaucratic and procedural impediments to research and development, and few have seen any substantial flow of benefits to them. All have seen a decrease of research opportunities and a decrease in the many non-monetary benefits which flow from pro-research policies and procedures.

Is there a less heavy handed and much more precise process which could be developed?

*Response:* Correspondent #7418 suggests that implementing benefits-sharing would discourage academic researchers from applying for NPS research permits and references a *New York Times* article about the difficulty scientists are experiencing in other countries that have implemented “Access and Benefit Sharing” (ABS) programs. The NPS is aware of the critiques of ABS programs outlined in the *New York Times* article. The NPS benefits-sharing proposal seeks to solve the problems described in the article by deliberately separating the research permit application process (“access”) from benefits-sharing. The NPS proposal is

not an ABS program, and it makes no changes to the criteria used to evaluate NPS research permit applications. The NPS proposed benefits-sharing agreements would not authorize research activities or collections, and therefore no scientist would be prevented or delayed from studying park resources simply because a benefits-sharing agreement was not in place. Researchers would not be required to enter into benefits-sharing agreements until and unless they provide information to the NPS that their research results could have potential, reasonably foreseeable commercial uses. Unlike most or all of the ABS programs referenced by the comment, the NPS proposal would not change research permitting procedures or policies (EIS Section 2.4.6.3). The potential for benefits-sharing would not be a factor in park evaluations of research permit applications or require NPS employees to “suspect” researchers of bioprospecting. Mitigation measures identified in the EIS would help protect research permit issuance decisions from being influenced by benefits-sharing considerations (see EIS Section 2.4.6). The benefits-sharing process would be precisely targeted to those researchers who actually discover a commercial application for their research results and would not affect the majority of researchers.

Public Comment:	Commenter:	Affiliation:
7418	The Ornithological Council	Organization
7461		Individual

### **5.3.11.6 Benefits-sharing and Material Transfer Agreements would be difficult for all researchers**

*Comment #95:* In the first place, the parks are publicly owned and paid for the by the public, many times over, through Federal taxes, entrance and camping/backcountry fees, and boating registrations. It seems pure and simple greed on the part of the NPS to expect more financial gain from work that does not destroy the environment, yet could serve the furtherance of science. Second, entering into an agreement for financial gain by the NPS is just more red tape for researchers to deal with, not to mention the law suits that would inevitably follow this greed.

*Comment #1903:* Agreements should not be so one-sided as to discourage scientific research within the parks.

*Comment #7241:* It is unacceptable that there is no penalty or incentive for the park to negotiate an acceptable benefit-sharing agreement swiftly. This section allows for a park to purposely slow negotiation to force the researcher in to a compromising position to accept a less than reasonable agreement to assure timely market entrance. If a product launch is delayed due to poor negotiation the company can potentially suffer substantial economic set back, encouraging violation of the agreement (or yet to be agreement). There must be an incentive or penalty built into Alternative B in relation to the park, if one exists for the researcher).

*Comment #7461:* With the proposed MTA, NPS is ... setting up elaborate, expensive, anti-science systems of control and oversight. More important are the resulting restrictions ... to the future when the necessary specimens

which document the National Parks in this day and age are not widely available due to the difficult and onerous conditions which this policy forces the NPS to take.

*Response:* Benefits-sharing agreements would be required, by law, to be equitable and efficient.<sup>57</sup> Because the NPS proposal provides that terms of benefits-sharing agreements would be negotiated and mutually agreeable to both parties, it is reasonable to expect that the potential impacts of an agreement would not rise above negligible for researchers or their institutions. It is anticipated that most declared bioprospectors would be affiliated with organizations such as academic institutions or corporations with experienced technology transfer offices. These researchers could rely on the technology transfer expertise already present in their institutions, thus reducing any adverse workload impacts on the researchers (EIS section 4.4.4.1). The NPS based its example CRADA and MTA on established models in part to further reduce workload concerns.

Additionally, the NPS views benefits-sharing as a two-way street, as an opportunity to encourage and improve collaborative relationships between researchers and NPS scientists that could have beneficial impacts for researchers. For example, the inadvertent bioprospector described in EIS section 3.4.3.2 explained that his discovery was based in part on a conversation with a park employee.

The purpose of a Material Transfer Agreement (MTA) is to track the location of NPS specimens and material originating as an NPS specimen. A request for an MTA requires no more than a phone call from the researcher, who already has NPS authority to study such material and therefore has the specimen on hand. The MTA is established between the third-party researcher and the park with a simple form based on the well-accepted form used by the National Institutes of Health, variations of which are used routinely by many scientific institutions. Use of this tracking system is routine in many institutions and would not constitute a substantial burden to researchers.

Finally, the benefits-sharing proposal would not affect an estimated 99% of researchers with NPS research permits. Benefits-sharing obligations would be triggered only when and if researchers provide information to the NPS that their research results could have potential, reasonably foreseeable commercial uses.

Public Comment:	Commenter:	Affiliation:
95, 1903, 7241, 7461		Individuals

**5.3.11.7 How do you support the claim that Alternative C would reduce the amount of useful discoveries made from study of NPS resources?**

*Comment #7261:* For example, on page 58 the DEIS states: “Under Alternative C, researchers would be prohibited from conducting most research that could improve health, safety, and productivity.” ... These blanket statements are nowhere substantiated.

*Response:* By regulation, an EIS must include a description of designated criteria used to determine the environmentally preferred alternative. These include describing each

alternative’s potential to attain the widest range of beneficial uses of the environment without degradation, risk of health or safety, or other undesirable and unintended consequences.

EIS Section 2.5 indicates that “Under Alternative C, the NPS would prohibit research specimen collection for research involving any potential commercial applications in all units of the National Park System.” As explained in EIS Section 2.8, under Alternative C researchers would be prohibited from conducting most research for applications that could improve health, safety, and productivity because most such discoveries are distributed to the public through the marketplace as commercially available products or services. Researchers would also be prohibited from developing unexpected research results for commercial applications that could improve health, safety, and productivity. Therefore, Alternative C would not attain as wide a range of beneficial uses of the environment as the other alternatives. A clarification has been made to the EIS specifying that the discoveries that would be prevented are those with commercial applications.

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations

**5.3.11.8 The administrative burdens on NPS operations for Alternative B was understated in the EIS**

*Comment #7241:* Discussion of FTE for research permit applications is not a valid as any type of indicator for negotiation of a benefits-sharing agreement. As outlined in the DEIS, the two events are separate. As a researcher in industry I am well aware that negotiation for sharing of profit takes a great deal more time than 1.6 hours. Timeframes of negotiation range from 1 month to 2 years.

*Comment #7261:* Further, according to DEIS estimates, negotiating a new CRADA will require a high-end estimate of 0.18 FTE staff time, and the more CRADAs, the less time spent per agreement. This amount of staff time is clearly inadequate for scientifically credible NEPA compliance.

*Comment #7463:* NPCA is concerned about the additional costs to be borne by individual parks and the agency as a whole as a result of implementation of Alternative B1. Not only will significant existing staff time and resources be required to develop and administer agreements, but NPS may need additional staff expertise that it currently does not have to assure NPS negotiates the best possible benefits sharing agreement. All staff time and all other costs associated with the negotiation, development and administration of benefits sharing agreements should be reimbursed and included in the benefits sharing agreement ...

*Comment #7490:* Although the administrative and other costs are evaluated quantitatively and concluded to be “negligible,” this should be very carefully examined before committing to

a benefit-sharing program that is mandatory for both researchers and the NPS. If the NPS will need a team of lawyers and scientists to evaluate agreements, this may well have substantial costs. In summary, if it is possible that any benefit-sharing system may be more expensive than the value of the benefits brought in, then the NPS should evaluate critically the worth of applying benefit sharing to the National Parks.

*Response:* The EIS used the best available information to estimate the time required to enter into a benefits-sharing agreement, data reported by the Association of University Technology Managers (AUTM) in negotiating and entering into licenses regarding research and development of academic discoveries or inventions. Because the AUTM FTE figures included activities not included in the NPS benefits-sharing proposal, the 0.18 FTE is a generous estimate of the workload to execute a single new benefits-sharing agreement (see EIS Section 4.4.5).

As described in EIS Appendix G, the NPS recognizes that negotiation of benefits-sharing agreements would not happen all at once, but would be a process taking days and weeks over a period of months and sometimes years. The NPS estimated that 0.18 FTE (which is well over 300 hours) would be used during this drawn-out process.

Correspondent #7261 has probably not recognized the distinction between the proposed benefits-sharing agreement and its underlying research permit. As NPS proposed in the EIS, these are two very distinct and separate processes which the EIS indicates need to remain distinct and separate (EIS section 2.4.6.3). All research permit applications are evaluated under NEPA and the benefits-sharing proposal would not supersede or circumvent this policy.

NPS agrees with correspondent #7490 that the negotiated benefits should outweigh the expense of entering into and maintaining agreements.

<b>Public Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7241, 7490		Individuals
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7463	National Parks and Conservation Association	Organization

## 5.3.12 Miscellaneous Topics

### 5.3.12.1 Support research in parks

*Comment #7463:* Research in parks is among the most important means of demonstrating not only the value of preserving parks, but also of preserving other elements of our natural heritage. NPCA believes that the rigorous research permit review process currently used in Yellowstone, outlined on p. 144 of the dEIS, should be applied to the entire NPS system, with the addition of peer review of research proposals.

We request that research permits specify that no collection of duplicate samples, whose purpose is to collect more of the same material as previously collected, will be permitted.

*Comment #7488:* The Sierra Club is very supportive of scientific research occurring in our national parks and aware that on occasion biological resources will inevitably result in discoveries which may have economic, social or environmental values.

Scientific research that occurs in the national parks on occasion may end up being important in the development of pharmaceuticals and other commercial products.

The EIS should better describe that the benefits of permissible research.

*Comment #7490:* As implied in this EIS, the most important issues at hand are to insure that the NPS has measures in place to continue and to increase conservation of species and the "science for parks" in the NPS. The "science in parks" efforts will strengthen many fields of scientific research in the United States and improve the environmental management decisions made for the National Park System.

*Response:* NPS agrees that research is important in fulfilling the NPS mission. The fundamental purpose of parks includes deriving scientific knowledge from parks.<sup>58</sup> NPS encourages appropriately reviewed natural resource studies. These studies support the NPS mission by providing the NPS, the scientific community, and the public with an understanding of park resources, processes, values, and uses that will be cumulative and constantly refined. Natural resource studies provide a scientific and scholarly basis for park planning, development, operations, management, education, and interpretive activities.<sup>59</sup>

The NPS is pleased that these correspondents support research in national parks. However, the administration of park research is not the subject of this EIS. Authorization to conduct scientific research in national parks is subject both to well-established NPS regulations and to separate environmental review (NEPA) procedures. Actions analyzed in this EIS would not change the compliance procedures under which research activities could be conducted.

Public Comment:	Commenter:	Affiliation:
7463	National Parks and Conservation Association	Organization
7488	Sierra Club--National Parks and Monuments Committee	Organization
7490		Individual

### 5.3.13 New Alternative Suggestion

#### ***5.3.13.1 The EIS should have a “Science in the Public Interest” alternative to conduct bioprospecting, perform park research, and receive benefits***

##### ***The EIS should have examined alternative ways to increase park science***

**Comment #7261:** The NPS should have included a Science in the Public Interest Alternative. That alternative would have relied on federally and publicly funded researchers to make “beneficial” research discoveries ....

This approach would represent a clear and distinct alternative to reliance on commercial bioprospecting to fulfill the hoped-for research functions.

##### ***The EIS should have examined alternative ways to get benefits***

**Comment #7261:** Instead of including such an alternative, the DEIS narrowly cast the alternatives as a choice -- we would say a false choice -- between commercial bioprospecting with increased benefits to the Parks and society or no commercial bioprospecting and no increased benefits.

As posited in the DEIS, the central aim is to make additional research discoveries that will enhance NPS resource management and protection as well as enhance interpretive programs and signage for the increased enjoyment and understanding of the visiting public. But the DEIS does not consider all the options for achieving this.

##### ***The EIS should have examined alternative ways to conduct bioprospecting***

**Comment #7261:** The NPS does not present any information whatsoever to explain why it cannot hire its own microbiologists to conduct research and make discoveries that can improve health, safety, and productivity in the public interest.

**Comment #7497:** I am therefore surprised and dismayed to note in your DEIS that research, specimen collection and contractual arrangements for potential new commercial products derived from species found in the parks is “preferred” to be performed on a commercial basis.

**Response:** A reasonable alternative under NEPA must either solve or at least address the problem at hand. As stated in its first sentence, the central aim of the EIS is “clarification of the rights and responsibilities of researchers and National Park Service (NPS) managers in connection with the use of valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks.” In addition, the NPS developed three objectives, as stated in the EIS (section 1.4) “to help determine the reasonableness of each alternative, and to select the preferred alternative” and to aid in the selection of an “environmentally preferred alternative.” As stated in the EIS, the existing conditions that NPS wishes to address include and are characterized by the lack of clarity and confusion concerning “NPS’s interest in the financial and other benefits from the results of research involving park research specimens” and a desire to capture missed opportunities, as directed by NPOMA (16 U.S.C. Sec. 5931(4)) by encouraging use of national parks by researchers “for study to the benefit of park management as well as broader scientific value.”

The Council on Environmental Quality (CEQ, the agency of the President’s office considered as the “caretaker” of NEPA) defines reasonable alternatives as those that are technically and economically feasible (see CEQ’s “Forty Most Asked Questions Concerning NEPA Regulations”).<sup>60</sup> The alternative proposed in the comment would require NPS to begin a large and expensive program that is not necessary to meet the central aim or objectives of the EIS.

Additionally, the NPS has not proposed to begin or conduct bioprospecting. Commercially applicable research discoveries will inevitably result from park research, no matter what policy the NPS adopts regarding benefits-sharing. Under the proposal, any researcher could discover a commercial application for his or her research results; NPS has no preference regarding the affiliation of such researchers. The NPS has not proposed to rely on benefits-sharing as a major influence on “science for parks.”

Public Comment:	Commenter:	Affiliation:
7261	Edmonds Institute, Alliance for the Wild Rockies, Wilderness Watch, International Center for Technology Assessment, WildWest Institute	Organizations
7497		Individual

### 5.3.14 EPA Comments

*Comment #7501:* We suggest that the Final EIS establish mechanisms to ensure proceeds are focused on protecting natural resources in the Parks.

*Response:* The benefits-sharing proposal specifies that all benefits received by the NPS under any type of benefits-sharing agreement would be dedicated to the conservation of resources protected and managed by the NPS. In addition, article 5.1 of the example CRADA specifies that all payments and non-monetary benefits received by the NPS may only be used for natural resource conservation purposes.<sup>61</sup> The example CRADA, once signed by all parties, is an enforceable contract and the NPS must use benefits for the stated purpose.

*Comment #7501:* We suggest that the Final EIS develop adequate enforcement protocols to ensure the terms of permits are followed so that natural resources would not be significantly impacted.

*Response:* The impacts of research activities authorized by an NPS research permit are out of scope of this analysis. Actions analyzed in this EIS would not change the compliance or enforcement procedures under which research activities could be conducted. NPS regulations state that the violation of the terms and conditions of a permit is prohibited and may result in the suspension or revocation of the permit.<sup>62</sup> Furthermore, violation of the research permit term and condition is also subject to penalties including fines or imprisonment not exceeding 6 months or both. Permit conditions designed to insure resource protection are enforced in project-specific and site-specific ways and are beyond the scope of this EIS.

**Comment #7501:** In addition, EPA suggests that the Final EIS include information to clarify the range of research that has been permitted over the last 5-10 years. Lastly, we suggest including a sample permit in the Final EIS to clarify what types of information are required for issuing research permits.

**Response:** Additional information about research permits is provided in Appendix H.

<b>Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7501	Environmental Protection Agency	Agency

### 5.3.15 Government-to-Government Comments

#### 5.3.15.1 Comments concerning tribal intellectual property rights

**Comment #7467:** At risk are the Intellectual property rights of the Tribes from bioprospecting and benefits sharing. Plants, animals, minerals and landscape have and continue to be resources utilized for spiritual and subsistence to the Shoshone and Bannock people. Indian people have manipulated the landscape and environment through time to gain ecological benefits and in doing so have created an established ecological traditional knowledge base. This knowledge is considered “prior art” and its value is well known in the pharmaceutical industry as many medicines originated from “prior art” knowledge. ...

Simply stating in the DEIS that Intellectual Property Right Laws will be followed is not sufficient to assure the Tribes that our traditional knowledge is protected. ...

Section 2.2.3. Page 39 – Intellectual Property Rights will remain unaffected by commercialized knowledge created by research how will IP be monitored to ensure all IP laws are being met? It is documented the many of today’s medicines are derived from traditional knowledge held by Indian people. Also true is that future discoveries relating to human health may in fact be not a discoveries at all. Tribal people possess the knowledge but keep it within the traditional knowledge base this type of knowledge is known as prior art. ...

Section 2.6.1.7. Page 55 – Alternative A and B provide for tribal inclusion in benefits sharing, although the Alternatives are very different in how the tribes will participate. Not identified is how those tribes with treaty rights who do not participate in the research, and when the research utilizes the natural resources used by the tribes for subsistence or spiritual purposes will be mitigated. What mitigation measures provide for the loss of these cultural resources and intellectual property rights?

**Response:** The comments raise a serious concern. In some cases, these concerns relate more to the issuance of research permits than to actions proposed in this EIS. In the event that research activities involved the use of traditional knowledge or other valuable proprietary input from a Native American community or other source, it would be the responsibility of the park and the researcher to include such individuals or groups in any benefits-sharing arrangement (EIS Section 2.4.1.1).

As a programmatic document, this EIS has a broad scope and is general in nature. If the benefits-sharing proposal is implemented, more specific procedures would need to be developed after this EIS process. For example, existing tribal consultation processes could be used to assure that when a researcher identifies or acknowledges that traditional knowledge of the Shoshone-Bannock Tribes or other tribes provided input into the research process, the park and the researcher include the appropriate tribes in benefits-sharing.

Comment:	Commenter:	Affiliation:
7467	Shoshone-Bannock Tribes	Tribal

### 5.3.15.2 Tribal considerations about research activities

#### **Research activities could have impacts**

*Comment #7467:* As identified in the DEIS, Yellowstone National Park has the greatest amount of researchers applying and receiving permits to do research in the park. Shoshone and Bannock people living in Wyoming, Montana, and Idaho have used the natural and cultural resources in the Greater Yellowstone area from time immemorial according to the tribal history and the archaeological record. Accordingly, Tribes view the Greater Yellowstone Area as significant aboriginal land that continues to contribute and play an integral part in maintaining cultural beliefs and traditional practices. Tribal ethnography of this area is indicative of the significance of the Greater Yellowstone Area.

Research in the Yellowstone National Park concerns the Shoshone and Bannock Tribes. Yellowstone ethnographic study (2006) identifies tribes that have historically used the Greater Yellowstone area for the procurement of natural resources for sustenance. Shoshone and Bannock tribal members have resided on the Yellowstone Plateau and procured natural and cultural resources from the Greater Yellowstone Area like many generations before present. Additionally, the Fort Bridger Treaty provides the Shoshone and Bannock Tribes gathering and hunting access on unoccupied lands of the United States. Presently our tribal members continue to go to the Greater Yellowstone Area and exercise their cultural and traditional heritage. Moreover, research may impact a sacred area used for medicinal or spiritual purposes. For example, the hot springs are spiritually and culturally significant. As noted in the draft ethnography of Yellowstone National Park (Walker 2006) the concern is when a spiritual place overused by other uses may impact the spirits associated with the place and cause them to no longer reside there, therefore the place loses the ability to provide the cultural and spiritual needs of the Shoshone-Bannock Tribes. How will Tribes be assured resources that are important to them will be preserved for their needs? ...

Recommendations ... 3. Establish a monitoring plan to identify when and if a particular location for research activity is placing stress on or creating an ecological condition that results in the changing of ecological environment?

Recommendations ... 4. Shoshone and Bannock people have the right to self-determination and sovereignty over their own lands of natural and cultural resources., Indian people have ownership rights regarding traditional knowledge, biodiversity and genetic resources.

Consultation needs to occur regularly regarding the research at Yellowstone National Park. Project information sharing will facilitate tribal monitoring of natural resource use.

*Response:* While these comments relate specifically to Yellowstone National Park, the concerns expressed by the Shoshone and Bannock Tribes could well be concerns held by other American Indians, Alaska Natives and Native Hawaiians regarding resources in other national park units. The mission of the National Park Service is to preserve and protect natural and cultural resources. The National Park Service values the concern of the Shoshone and Bannock Tribes and will work to protect park resources and to consult with American Indians, Alaska Natives and Native Hawaiians as stated in section 1.11 of the NPS Management Policies: “the Service will pursue an open, collaborative relationship with American Indian tribes to help tribes maintain their cultural and spiritual practices and enhance the Park Service’s understanding of the history and significance of sites and resources in the parks.” If benefits-sharing is implemented, and research activities involved the use of traditional knowledge or other valuable proprietary input from a Native American community or other source, it would be the responsibility of the park and the researcher to include such individuals or groups in any benefits-sharing arrangement as appropriate. The comments regarding research in Yellowstone were referred to the Chief of the Yellowstone Center for Resources.

National parks are important places of special and complex biological diversity that offer unique opportunities to study natural systems and living things. Because of this special status, the NPS expects that researchers will continue to seek out opportunities to study natural resources in the national parks. Concerning the general preservation of resources that may be used by or are of importance to tribes that also may be the subject of research, the EIS benefits-sharing proposal does not seek any changes to the well-established procedures used for evaluating research in parks. Current National Park Service regulations and policy protect the ecological conditions at research locations in several ways. Parks are required to evaluate all research permit applications for environmental impacts under NEPA before deciding whether or not to issue a research permit. Federal regulations specify that research permits cannot be issued for any activity that would damage natural or cultural resources. Each park is responsible for evaluating the potential impacts of individual research permit applications using information specific to the actual area where the research would occur. For example, Section 4.4.5.5 of the EIS provides a description of the way Yellowstone National Park reviews research applications (see Figure 1). Each park is also responsible for assessing the effects any activities may have on park resources. As an example, Yellowstone National Park periodically assigns staff to accompany researchers in the field to monitor their activities.

### ***Tribes may want to conduct research in parks***

*Comment #7467:* Recommendations ... 2. Tribes may in the future want to participate, as environmental researchers. Are provisions in place to accommodate the native researcher similar to affirmative action procedures?

*Response:* Any qualified researcher can apply for an NPS research permit. NPS Management Policies (Section 4.2) specify that researchers and scholars associated with tribal colleges and organizations can qualify for research permits.

<b>Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7467	Shoshone-Bannock Tribes	Tribal

### **5.3.15.3 Bioprospecting and natural resources**

*Comment #7467:* Another concern not identified in the DEIS, where does the NPS identify in the researcher application process or benefit sharing agreement if no synthetic version can replicated, will the raw material from the national park be used? This might apply if research discoveries are of great value and is a significant contribution to the advancement of human health. Where is this addressed?

*Response:* The sale or commercial use of natural products obtained from units of the National Park System would continue to be prohibited pursuant to federal regulation (36 CFR 2.1). No element of any alternative would authorize any consumptive use of any park resources, or otherwise change the existing general prohibition against consumptive harvesting of park resources for any reason (EIS Section 2.2.1).

The development and natural resource collections related to the cancer drug Taxol offer an example by comparison which speaks to the commenter’s concerns. Research that led to the development and FDA approval of Taxol involved study and collection of large amounts of tree bark collected from lands outside the national park system. NPS regulations and policies would not allow the collection of these large amounts of tree bark or other natural resources. Raw material in parks cannot be used for production of products, not even new products that are still the subject of research. It’s interesting to note in this case that the company developing Taxol developed a semi-synthetic version of the new drug, pursuant to the requirements of a Cooperative Research and Development Agreement (CRADA), which was based on trees that could be grown on tree farms. The need for wild-collected bark was brief and quickly overcome.

<b>Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7467	Shoshone-Bannock Tribes	Tribal

#### **5.3.15.4 Distribution of Benefits**

##### ***Comment about benefits potentially due to tribal members or communities***

*Comment #7467:* Section 2.4.1.1 Page 42. – Any tribe, tribal community or tribal member who has traditional or cultural knowledge that is associated with the research can be a participant in benefit sharing. This is a general statement and does not begin to address the complex issue of Indian tribes and their traditional uses of the Greater Yellowstone Area. Also problematic is if individuals are recognized as beneficiaries of benefit-sharing agreements how will this affect the tribe as a whole and do tribes recognize individual actions as representing the tribes as a whole.

*Response:* As a programmatic document, this EIS has a broad scope and is general in nature, and therefore does not resolve such specific issues. If the benefits-sharing proposal is implemented and it becomes appropriate to include tribes as a beneficiary of a specific benefits-sharing agreement, issues such as those described would be addressed and resolved through consultation.

##### ***Would benefits be used for conservation of cultural resources?***

*Comment #7467:* Section 2.8. Pages 59 – explain how cultural and historic aspects will benefit from the monies generated by the benefit sharing and what specifically is targeted under cultural and historic aspects.

*Response:* Section 2.8 of the EIS identifies the “environmentally preferred alternative,” which is selected by applying the six criteria found in Section 101 of NEPA. This comment likely references the fourth criterion, “Preserve important historic, cultural, and natural aspects of our national heritage. . . .” While the use of all benefits-sharing agreements has been suspended servicewide pending completion of this EIS, if this process concluded with a decision to implement benefits-sharing, a benefits-sharing agreement could be developed in relation to cultural or historic research in which non-monetary or monetary benefits could target cultural and historic aspects and resources. Any such agreement and distribution of benefits would need to meet the requirements of the Federal Technology Transfer Act of 1986 (FTTA). For example, the NPS unit involved must qualify as a “federal laboratory” as described by the Act, and any benefits must be provided toward the conduct of research and development efforts which are consistent with the missions of the laboratory. Section 2.4.3 of the EIS states that all benefits received by the NPS would be dedicated to the conservation of resources protected and managed by the NPS. If such an agreement was prepared, Article 5.1 of the example CRADA (Appendix A) specifying that all payments and non-monetary benefits received by the NPS may only be used for natural resource conservation purposes would be amended.<sup>63</sup>

The EIS focuses on the management of natural resources since, based on available data, it is reasonably foreseeable that biologists would be the most likely participants in benefits-sharing.<sup>64</sup> Secondly, the direction provided by the court that ordered this EIS suggested that

the NPS focus on natural resources, as did the issues which arose in the court case (see EIS Section 1.7.6 and Appendix I).

<b>Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7467	Shoshone-Bannock Tribes	Tribal

### **5.3.15.5 Mitigation measures**

*Comment #7467:* Section 2.4.6. Page 47 – what are the mitigation measures? Include the measures in an appendix.

*Response:* Specific mitigation measures associated with the benefits-sharing proposal were explained in detail in EIS sections 2.4.6, 2.4.6.1, 2.4.6.2, 2.4.6.3, 2.4.6.4, 4.4.4.6, and 4.4.5.5.

<b>Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7467	Shoshone-Bannock Tribes	Tribal

### **5.3.15.6 Material Transfer Agreements (MTAs)**

*Comment #7467:* Section 3.4.2. Page 84 – states there is no process or protocol to track third party researchers and the specimens they may have acquired. For park managers to effectively manage the researchers and the natural resources of the park the third party researchers must be monitored and at the very least park manager must have knowledge of where the research specimen are located and who has possession of them. This lack of control provides for an opportunity for researchers to take advantage of the science and possible economic gain at the expense of the parks resources, Indian tribes and the public.

Recommendations ... 1. NPS [should] establish a monitoring plan for transfer of cultured samples to third party researchers and in the case of pirating of natural resource from poachers whom may have the ability to replicate research for commercial application.

*Response:* The NPS agrees and the EIS proposes use of Material Transfer Agreements to monitor transfers of material originating as NPS research specimens (see EIS Section 2.4 and Appendix B). Poaching is against the law and would be dealt with by NPS law enforcement officers.

<b>Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
7467	Shoshone-Bannock Tribes	Tribal

### **5.3.15.7 Do not destroy resources for commercial purposes**

*Comment #6717:* The Bridgeport Indian Colony does not agree with benefit-sharing with scientists. There are too many great lands across our great country being destroyed as we speak. Allowing more destruction to continue for research to benefit only those involved for monetary gain is unforgivable. How can one allow what god created to be used for commercial purpose - just to extract what is left of our natural resources. For centuries, as documented in history, Native Americans suffered at the hand of generations of political gain even to the point of extermination. Don't do this to our beautiful lands. National Park Service was created to protect and preserve the national parks not to tear it up.

*Response:* Thank you for this comment. The NPS agrees that protection of natural resources is of paramount importance and certainly the most important consideration when formulating or deciding among the alternatives in the EIS. The EIS does not propose sale of natural resources, "biomining," logging, or any kind of mining or extractive processes. Benefits-sharing agreements and research permits would not authorize any such resource extraction. No harvest of natural resources could occur under the guise of "research" because the strict resource protection provision of NPS regulations would not allow it, and NPS Management Policies reinforce this prohibition. The benefits-sharing proposal would not change this practice. NPS Management Policies require all research permit applications undergo an environmental review pursuant to NEPA to avoid, minimize or mitigate any potential adverse impacts to park resources. Benefits-sharing agreements would not circumvent or supersede any NPS planning process, permitting authority, or other regulatory procedure or policy in place to protect park lands and resources. For example, benefits-sharing agreements would not authorize any research activities in parks that otherwise require a permit. This means that any kind of research proposal that would have required a research permit before benefits-sharing was implemented would still require the same permit (including an environmental review under NEPA) after benefits-sharing was implemented. Benefits-sharing would only apply to research results and would not authorize harvest, use or sale of NPS natural resources for product production or any other commercial purpose.

<b>Comment:</b>	<b>Commenter:</b>	<b>Affiliation:</b>
6717	Bridgeport Indian Colony	Tribal

## **Notes**

### **Section 5.1 Introduction**

<sup>1</sup> 66 Fed. Reg. 33712, 33713.

<sup>2</sup> 67 Fed. Reg. 18034, 18035.

<sup>3</sup> This amount does not account for duplicates, e.g., those correspondences that were sent both via the Internet and the U.S. Postal System or identical correspondences that were sent multiple times.

### **Section 5.2 Responses to Comments on the Draft Benefits-Sharing EIS**

<sup>4</sup> 40 CFR 1503.4[5][b].

<sup>5</sup> National Park Service. 2001. Director's Order 12 and Handbook: Conservation Planning, Environmental Impact Analysis, and Decision Making, Section 4.6.

<sup>6</sup> This amount does not account for duplicates, e.g., those correspondences that were sent both via the

Internet and the U.S. Postal System or identical correspondences that were sent multiple times.

<sup>7</sup> Some of the non-form letter correspondents did not express a preference that could be characterized for this table. Other correspondents expressed conflicting opinions indicating support for both Alternative B and Alternative C.

<sup>8</sup> 40 CFR 1503.4.

<sup>9</sup> The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I of this EIS.

### Section 5.3 Comment Summaries and Responses

<sup>10</sup> Federal regulation 36 CFR 2.5(b) states: “A specimen collection permit may be issued only [if such] collection is necessary to the stated scientific or resource management goals of the institution or agency.” *NPS Management Policies 2006*, 4.2.2 states “[Research] Projects will . . . conform to current standards of scholarship.”

<sup>11</sup> *NPS Management Policies 2006*, page ii.

<sup>12</sup> 16 USC 1.

<sup>13</sup> 16 USC 5932.

<sup>14</sup> 16 USC 5931.

<sup>15</sup> 36 CFR 2.5.

<sup>16</sup> The United States Geological Survey (USGS) Organic Act of March 3, 1879 (ch. 182, section 1, 20 Stat. 394) codified at 20 USC 59.

<sup>17</sup> 16 USC 18f-2(a).

<sup>18</sup> NPS Outgoing Loan General Condition 3 and NPS Museum Handbook Part II (2000), Chapter 5.

<sup>19</sup> “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources within the meaning of [36 CFR 2.1]. . . . [T]he Park Service determined that there was a critical distinction between researchers profiting from the sale of the actual specimens themselves, which is prohibited by [36 CFR 2.1], and profiting from a future development based on scientific discoveries resulting from research on those resources, which is permitted. . . . The CRADA, in turn, accords with the regulations because any ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.” *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000) The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.

<sup>20</sup> 36 CFR Part 13.

<sup>21</sup> 36 CFR 2.2.

<sup>22</sup> 36 CFR 2.1.

<sup>23</sup> 16 USC 5931-5937 and 36 CFR 2.5.

<sup>24</sup> 16 USC 18f, 18f-2 and 18f-3.

<sup>25</sup> “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources within the meaning of [36 CFR 2.1]. . . . [T]he Park Service determined that there was a critical distinction between researchers profiting from the sale of the actual specimens themselves, which is prohibited by [36 CFR 2.1], and profiting from a future development based on scientific discoveries resulting from research on those resources, which is permitted. . . . The CRADA, in turn, accords with the regulations because any ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.” *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000). The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.

<sup>26</sup> *NPS Management Policies 2006*, 6.3.6.

<sup>27</sup> *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 68-69 (DDC 2000). The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.

<sup>28</sup> *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000). The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.

<sup>29</sup> S. Rep. No. 283, 99<sup>th</sup> Cong. Sess. 1, 11(1986).

<sup>30</sup> 40 CFR 1508.9.

<sup>31</sup> In April 2000, the federal court ruled on the assertion that the Yellowstone-Diversa CRADA was alleged to be a commercial use of Yellowstone resources. “The court finds that the Park Service reasonably

- determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources within the meaning of [36 CFR 2.1]. . . . [T]he Park Service determined that there was a critical distinction between researchers profiting from the sale of the actual specimens themselves, which is prohibited by [36 CFR 2.1], and profiting from a future development based on scientific discoveries resulting from research on those resources, which is permitted. . . . The CRADA, in turn, accords with the regulations because any ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.” *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000). The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.
- <sup>32</sup> *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000). The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.
- <sup>33</sup> *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999).
- <sup>34</sup> Federal regulation 36 CFR 2.5(b) states: “A specimen collection permit may be issued only [if such] collection is necessary to the stated scientific or resource management goals of the institution or agency.” *NPS Management Policies 2006*, 4.2.2 states “[Research] Projects will . . . conform to current standards of scholarship.”
- <sup>35</sup> In April 2000, the federal court ruled on the assertion that the Yellowstone–Diversa CRADA was alleged to be a commercial use of Yellowstone resources. “The court finds that the Park Service reasonably determined that the Yellowstone–Diversa CRADA does not involve the ‘sale or commercial use’ of park resources within the meaning of [36 CFR 2.1]. . . . [T]he Park Service determined that there was a critical distinction between researchers profiting from the sale of the actual specimens themselves, which is prohibited by [36 CFR 2.1], and profiting from a future development based on scientific discoveries resulting from research on those resources, which is permitted . . . The CRADA, in turn, accords with the regulations because any ‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.” *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000). The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.
- <sup>36</sup> 16 USC 3.
- <sup>37</sup> 36 CFR 2.5.
- <sup>38</sup> *NPS Management Policies 2006*, 4.2.
- <sup>39</sup> See Article 11 of the example CRADA in EIS Appendix A.
- <sup>40</sup> NPS Investigator’s Annual Reports are posted at <http://rprs.nps.gov/research/>
- <sup>41</sup> See, for example, <http://www.usgs.gov/usgs-manual/500/500-20.html>.
- <sup>42</sup> See <http://www.cdc.gov/od/science/techTran/> last accessed 4/6/07.
- <sup>43</sup> More information about patents can be found at the US Patent and Trademark Office website. <http://www.uspto.gov/web/offices/pac/doc/general/index.html#whatpat>
- <sup>44</sup> *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000). The full texts of the decisions in *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000) and *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) are provided in Appendix I.
- <sup>45</sup> National Parks Omnibus Management Act (NPOMA) 16 USC Sec 5935, “The Secretary may enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements.”
- <sup>46</sup> Department of the Interior Manual Part 516: National Environmental Policy Act of 1969.
- <sup>47</sup> EIS Section 3.1.
- <sup>48</sup> EIS Section 2.4.6.3.
- <sup>49</sup> Article 5.1 of the example CRADA is “Collaborator hereby agrees to make the payments and other contributions set forth in Appendix B, which shall be used by [name of collaborating unit of the National Park System] for natural resource conservation purposes only.”
- <sup>50</sup> National Parks Omnibus Management Act of 1998, Section 5932.
- <sup>51</sup> *NPS Management Policies 2006*, 7.1.
- <sup>52</sup> *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999) and *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000). (See Appendix I).
- <sup>53</sup> *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, 71–72 (DDC 2000). (See Appendix I).
- <sup>54</sup> 1502.15 CEQ regulations.
- <sup>55</sup> NPS employees are instructed to present the facts and let visitors form their own intellectual, emotional, and physical connections to the meanings and values found in the parks.
- <sup>56</sup> Park resources and values are defined in *NPS Management Policies 2006*, 1.4.6.
- <sup>57</sup> The National Parks Omnibus Management Act (NPOMA), codified at 16 U.S.C. Sec. 5935 requires NPS benefits-sharing agreements to be equitable and efficient.

<sup>58</sup> *NPS Management Policies 2006*, 1.4.3.

<sup>59</sup> *NPS Management Policies 2006*, 4.2.

<sup>60</sup> Available at the following weblink: <http://ceq.eh.doe.gov/nepa/regs/40/40p3.htm>

<sup>61</sup> Article 5.1 of the example CRADA is “Collaborator hereby agrees to make the payments and other contributions set forth in Appendix B, which shall be used by [name of collaborating unit of the National Park System] for natural resource conservation purposes only.”

<sup>62</sup> 36 CFR 2.5 (h).

<sup>63</sup> Article 5.1 of the example CRADA states “Collaborator hereby agrees to make the payments and other contributions set forth in Appendix B, which shall be used by [name of collaborating unit of the National Park System] for natural resource conservation purposes only.”

<sup>64</sup> Every research project identified by the NPS that involved study of NPS research specimens and has or could have commercial applications for research results has been in the field of biology (see EIS Section 3.4.3.1).

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# **Representative Comments**

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# Form Letters

12515-96	Parks Not For Sale
12515-167	National Parks and Conservation Association
12515-152	Letter modeled after Parks Not For Sale website

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12515-96  
page 1 of 1

BenefitSEIS  
National Park Service

I oppose commercial bioprospecting in our National Parks. Corporations should not be allowed to mine, exploit and profit from living organisms that we, the people, are supposed to be stewarding.

Therefore, I support Alternative C in the National Park Services Draft Environmental Impact Statement (DEIS) entitled Benefits-Sharing.

I do support the public interest research that takes place in the parks, but I am opposed to the National Park Services plans to enter Benefits-Sharing agreements with private corporations seeking to commercialize their research.

I believe that allowing commercial bioprospecting runs counter to the mission of our National Parks. The natural resources on our public lands must be preserved, protected and most importantly remain public for the public's benefit. That is why I oppose alternatives A and B in the DEIS. Alternative C, as its title implies, is the only option that Prohibits Research Specimen Collection for Any Commercially Related Research Purpose.

Sincerely,

Dee Warenaicia



12515-167  
page 1 of 1

Received January 12, 2007 via NPS's Planning, Environment and Public Comment (PEPC) website

Dear PEPC Benefits-Sharing,

Please select Alternative B1 in the final NPS Benefits Sharing Plan. Alternative B1 best protects park resource and visitor experience, while assuring the public the right to review any agreement between NPS and a private researcher or company.

In addition, the following points are critical to include in any final Benefits Sharing plan:

- Park resources and visitor experience must not be directly or indirectly adversely affected.
- The public should have a right to view the entirety of any agreement.
- All scientific information resulting from any agreement must be shared with the park, and any compensation received should be used to benefit resource protection and research.
- No benefits sharing agreement should be developed that results in resources being used for commercial purposes. Any research contemplated under Benefits Sharing agreements cannot result in the direct commercial use of those samples removed from parks.

I urge you to select Alternative B1 to implement the Benefits Sharing Plan. Thank you for considering my views.

Sincerely,

Sandy Sobanski

*Received December 31, 2006 via  
NPS's Planning, Environment and Public Comment (PEPC) website*

To Whom It May Concern:

I strongly oppose commercial bioprospecting in our National Parks. Corporations should not be allowed to mine, exploit, profit and even patent from living organisms that we, the people, are supposed to be stewarding. Life, biological organisms, proteins, DNA, RNA, or anything else that is produced by nature should not be allowed to be patented for private profit.

Therefore, I support "Alternative C" in the National Park Service's Draft Environmental Impact Statement (DEIS) entitled "Benefits-Sharing." Alternative C allows scientific research in the Parks, but will NOT permit research that is purely commercial in its purpose. Alternative C will ensure that wildlife and biological resources of the Parks not be exploited for commercial purposes. Yellowstone and the other national parks were designated as parks to protect them from exploitation and to ensure they "remain unimpaired for the enjoyment of future generations." Alternative C also let's Park scientific staff devote all their time to science in the public interest. They won't have to spend the time, effort, and budget necessary to negotiate Commercial Research and Development Agreements (CRADAs).

I strongly oppose all the versions of Alternative B, including the NPS favorite, Alternative B2. Alternative B would allow commercial bioprospecting and encourage deal-making with commercial enterprises, allowing them to remove biological organisms from the Parks for purely commercial purposes. This undermines the basic mission of the Parks and is a direct threat to the public commons. Alternative B2 does not guarantee transparency in the deal making. CRADAs, the kind of deals NPS is proposing, allow either side to designate part of the deal as confidential business information -- outside the public view. By law, NPS would be forced to keep details such as royalty amounts and other financial information from the public. We wouldn't even be able to judge whether NPS was making good deals or not.

Alternative B also would require NPS research staff to devote part of their time to negotiating and managing CRADAs made for commercial purposes. This would take time away from research in the public interest. This would force NPS officials and outside contractors to travel and devote time and money to make CRADAs.

Finally, Alternative B sets a bad precedent that will open the door to more extractive

activities for commercial purposes. Alternative B would apply to all 84.4 million acres of the National Park System, including millions of acres now designated as Wilderness Areas.

I do support the public interest research that takes place in the parks, but I am opposed to the National Park Service's plans to enter "Benefits-Sharing" agreements with private corporations seeking to commercialize their research.

I believe that allowing commercial bioprospecting runs counter to the mission of our National Parks. The natural resources on our public lands must be preserved, protected and -- most importantly -- remain public for the public's benefit. That is why I oppose alternatives "A" and "B" in the DEIS. Alternative C, as its title implies, is the only option that "Prohibits Research Specimen Collection for Any Commercially Related Research Purpose."

Thank you for your consideration of my comments.

Christopher Lish

# **Representative Comments from Organizations**

- 12515-6711 Montana State University,  
Thermal Biology Institute
- 12515-7261 Edmonds Institute
- 12515-7418 The Ornithological Council
- 12515-7424 University of Alaska,  
Museum of the North
- 12515-7459 American Society of Mammalogists,  
President
- 12515-7463 National Parks Conservation Association
- 12515-7464 American Society of Mammalogists,  
Systematic Collections
- 12515-7483 The Washington Biotechnical Action Council
- 12515-7488 The Sierra Club, National Parks  
and Monuments Committee
- 12515-7492 Public Employees for  
Environmental Responsibility
- 12515-7502 Greater Yellowstone Coalition

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November 30, 2006

Recently, the National Park Service released the Benefits-Sharing Draft Environmental Impact Statement for public comment. As members of the research community, the Thermal Biology Institute (TBI) of Montana State University (MSU) strongly supports the mission of the National Park Service in the protection of this valuable natural resource and feels that we have a responsibility to provide our input to the public review process on this important issue.

Yellowstone National Park (YNP) offers unparalleled research opportunities for faculty and students in Montana and across the U.S. These research opportunities are largely the result of over 130 years of protection for the natural biological and geological resources, many of which are found only at YNP. TBI conducts and promotes research and education focused on the biology and interrelated physical and chemical processes of geothermal environments in the Greater Yellowstone Ecosystem. Our scientific research has been encouraged by the NPS.

The preservation and vitality of YNP is critical to successful long-term scientific research. Likewise, ongoing research activity, such as that conducted by the TBI, generates data that is foundational to efforts by YNP personnel to manage and track park resources. **To continue this mutually beneficial research activity, TBI strongly supports the NPS Preferred Alternative, which would allow the implementation of benefits-sharing program with optional disclosure of all terms and conditions related to commercial development.** We feel that a "no action" alternative is not in the public's best long-term interest in that some recovery of commercial profits should be used to benefit the public and provide improved NPS stewardship of the public's resources. Further, we do not support the alternative that prohibits research specimen collection for commercially related research purposes for the following reasons:

1) Many commercial applications begin from fundamental scientific discoveries. Prohibiting specimen collection by researchers that might have commercial application would significantly limit scientific progress. Further, we agree with the DEIS where it specifically states that "Some of the independent research involving study of NPS research specimens will inevitably discover useful applications for research results that could have commercial applications."

**Thermal Biology Institute**

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Mountains & Minds



2) Prohibiting specimen collection by known commercial interests eliminates the possibility of revenue streams to the NPS that would help accomplish its preservation and protection mission.

To be clear, TBI does not support or condone any specimen collection or scientific research that results, directly or indirectly, in any damage whatsoever to non-renewable NPS resources. In fact, TBI has developed educational materials for researchers that visit YNP to help insure that research activities cause no harm to the park.

TBI strongly supports NPS efforts to manage research activities conducted by any scientist who qualifies for an NPS research permit without regard to whether that scientist is affiliated with or funded by public or private sources.

Dr. John W. Peters  
Director, Thermal Biology Institute  
Montana State University

Dr. Brent M. Peyton  
Associate Director, Thermal Biology Institute  
Montana State University

**Thermal Biology Institute**

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Mountains & Minds

**Comments on  
National Park Service  
Benefits-Sharing Draft Environmental Impact Statement (Service-wide)**

**Submitted by:**

- (1) Beth Burrows, President/Director  
on behalf of:  
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on behalf of:  
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- (4) Joseph Mendelson, Legal Director  
on behalf of:  
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- (5) Jeff Juel, Ecosystem Defense Director  
on behalf of:  
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Missoula, Montana 59807  
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**I. Introduction and Summary**

We respectfully submit the following comments concerning the National Park Service **Benefits Sharing Draft Environmental Impact Statement**, [1] hereafter referred to as the DEIS. We request that our comments be included in the official public record, carefully considered, and incorporated into the planning process, any further drafts, and the Final EIS/Plan and Record of Decision.

**These comments are submitted on behalf of** the following organizations:

- **Edmonds Institute**, a public interest, non-profit, 501(c)(3) organization committed to the health and sustainability of ecosystems and their inhabitants and focused on understanding and sharing information about environmental, social, legal, and economic impacts of technology;
- **Alliance for Wild Rockies**, a non-profit organization whose mission is to secure the ecological integrity of the Wild Rockies Bioregion through citizen empowerment, and the application of conservation biology, sustainable economic models and environmental laws;
- **Wilderness Watch**, a non-profit 501(c)(3) organization and the only national organization entirely dedicated to assuring that our great national heritage of Wilderness remains for future generations to know and enjoy;
- **International Center for Technology Assessment**, a non-profit 501(c)(3) organization devoted to exploring the economic, ethical, social, environmental, and political impacts that can result from the applications of technology or technological systems;
- **WildWest Institute**, an organization formed through the merger of the Native Forest Network and Ecology Center and designed to protect and restore forests, wildlands, watersheds, and wildlife in the Northern Rockies Bioregion.

The contact details for the above-named organizations and the names and titles of the persons submitting these comments on behalf of those organizations appear at the end of these comments, before the endnotes.

We believe the DEIS, as presented, is seriously flawed. It does not satisfy the District Court's Order in *Edmonds Institute et al. v. Babbitt, et al.*, nor does it meet the requirements of the National Environmental Policy Act (NEPA). Further, we consider that the DEIS makes proposals in violation of The Wilderness Act and National Park Service (NPS) regulations and we note that the DEIS has narrowly cast what should be a full range of alternatives into a false choice between commercial bioprospecting with increased benefits to the Parks and society, and no commercial bioprospecting with no increased benefits.

We believe it appropriate for the NPS to withdraw the DEIS, correct its deficiencies, and then issue a revised document for public review and comment as a Supplemental Draft EIS.

**We urge NPS to fully comply with NEPA by developing and fully analyzing a Science in the Public Interest Alternative.** We examine that alternative in some detail below.

parks.

#### A. 1872 Yellowstone Park Act

Yellowstone National Park was created by an act of Congress and signed into law by President Ulysses S. Grant on March 1, 1872. [2] The Act clearly spelled out a preservation mandate for Yellowstone National Park, stating: *"Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled*, That the tract of land in the Territories of Montana and Wyoming is hereby reserved and withdrawn from settlement, occupancy, or sale under the laws of the United States, and dedicated and set apart as a public park or pleasuring-ground for the benefit and enjoyment of the people."

Section 2 of the Act instructs the Secretary of Interior to develop regulations for the protection and management of the park, stating: "Such regulations shall provide for the *preservation, from injury or spoliation, of all timber, mineral deposits, natural curiosities, or wonders within said park, and their retention in their natural condition.*" (emphasis added) It also states: "He shall provide against the wanton destruction of the fish and game found within said park, and *against their capture or destruction for the purposes of merchandise and profit.*" (emphasis added)

#### B. The Antiquities Act of 1906

The Antiquities Act pertains to national monuments and archeological sites, and the legal authority for the President of the United States to establish such monuments. [3] This Act allows for the collection of artifacts within National Monuments, but explicitly states, "That the examinations, excavations, and gatherings are undertaken for the benefit of reputable museums, universities, colleges, or other recognized scientific or educational institutions, with a view to increasing the knowledge of such objects, and that *the gatherings shall be made for permanent preservation in public museums.*" (emphasis added)

#### C. National Park Service Act of 1916

The National Park Service Act states that the Park Service "shall promote and regulate the use of the Federal areas known as national parks, monuments, and reservations hereinafter specified by such means and measures as to conform to the fundamental purpose of the said parks, monuments, and reservations, which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations." [4]

In Section 3 of the Act it states that: "no natural curiosities, wonders, or objects of interest shall be leased, rented, or granted to anyone on such terms as to interfere with free access to them by

Among the alternatives presented by NPS, we find Alternative C the most reasonable. Only Alternative C removes commercial bioprospecting from the National Park Service palette of permissible activities in the parks. **We offer conditional support for Alternative C. We specifically oppose the other listed alternatives, particularly Alternatives B1, B2 and B3. We are opposed to ANY commercial bioprospecting in the U. S. National Park System.** While we strongly support scientific research in the parks, we believe there should be no research within the park system that is expressly commercial except that which is deemed, through a process of public deliberation, publication, and comment, as research clearly beneficial to the public interest.

Commercial bioprospecting in general undermines the basic mission, purpose and spirit of the National Parks. Were commercial bioprospecting to be disallowed, as NPS itself points out in the DEIS, the amount of research likely to be foregone is less than one half of one percent of all research in the National Park System. Further, commercial bioprospecting and the use of Cooperative Research and Development Agreements (CRADAs) in relation to such bioprospecting open up the possibility that aspects of such endeavors may be sealed from public view and oversight. Whatever the intention of NPS, it will always be the right of the other parties to CRADAs to request that particular proprietary information be kept secret. Once secret, the only means for the public to access such information would be through Freedom of Information Act (FOIA) requests and, under FOIA, "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential" may be exempted from public disclosure. Because the benefit sharing under consideration concerns public lands, lands that belong to the people of the United States, it is of paramount importance that deal-making about these places be completely and totally transparent. None of the B alternatives can effectively make the necessary guarantee of transparency. **We cannot support any NPS management plan that allows agreements that are not totally and completely transparent.** In this regard, please note that our above-stated support for Alternative C is conditioned on the premise that the NPS Director makes any proposed exemptions the subject of extensive public notice and comment.

Finally, we note that seven years after the court decision that gave rise to the DEIS in question, NPS only gave the public 90 days to comment on a very lengthy document. We recommend that in the future, the comment period be extended.

## II. Historical Background

To understand why commercial bioprospecting may be considered inimical to the basic mission, purpose and spirit of the National Parks, and why commercial bioprospecting will be harmful to the regard in which members of the public holds the parks (and thereby detrimental to what may be termed the "existence value" of the parks), it is useful to review some of the history of the

the public".

**D. General Authorities Act of 1970**

The General Authorities Act, which supplemented and clarified the provisions of National Park Service Act, [5] includes this statement: "The authorization of activities shall be construed and protection, management, and administration of these areas shall be conducted in light of the high public value and integrity of the National Park System and shall not be exercised in derogation of the values and purposes for which these various areas have been established, except as may have been or shall be directly and specifically provided by Congress."

**E. National Parks Omnibus Management Act**

The National Parks Omnibus Management Act of 1998, NPOMA, [6] established scientific research as a fundamental purpose of the parks and instructed the NPS to engage in cooperative research studies with other federal agencies and public institutions including universities. In § 5935(d) the Act states, "The Secretary may enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements."

Pursuant to NPOMA, the NPS has implemented the Natural Resource Challenge, including the creation of Cooperative Ecosystems Studies Units (CESUs).

**F. Bioprospecting & Litigation**

In the mid-90's officials in Yellowstone National Park entered into a first of its kind CRADA with the Diversa Corporation of San Diego. [7] The CRADA allowed money to flow back to Yellowstone from commercial bioprospecting in the various ecosystems of Yellowstone. The CRADA allowed Diversa to remove biological samples including microbes, soils, fungi, trees, plants, rocks and other natural features.

The Edmonds Institute, joined by the International Center for Technology Assessment and Alliance for the Wild Rockies, sued the NPS in Federal District Court, challenging the CRADA. [8]

A decision and order was issued by District Judge Royce Lamberth, [9] dismissing several claims brought by the plaintiffs, but upholding the NEPA claim, thereby suspending the Diversa/Yellowstone CRADA until completion of a fully compliant NEPA analysis.

**III. General Policy Arguments**

**Research for Purely Commercial Purposes is Inconsistent With the Original Purposes of the Park System and Individual Park Creation Acts**

NPS activities are legal to the extent they are consistent not only with NPS rules and regulations, but also with the original organic act of each park or monument. As the DEIS states on page 20, "Each unit of the National Park System is governed by its own enabling legislation, which provides specific legal authorities and direction for each park. Parks must review their park's enabling legislation to determine if it contains explicit guidance that would prevail over service-wide policy."

As noted above, the specific language in the creation acts for Yellowstone and the National Park Service clearly prohibits the removal of park resources for profit. For example, the Yellowstone Park Act of 1872 instructs the Secretary of the Interior to develop regulations for Yellowstone that "shall provide against the wanton destruction of the fish and game found within said park, and against their capture or destruction for the purposes of merchandise and profit." (emphasis added) As small as biological organisms, or portions of organisms, may sometimes be, whether they are microorganisms or macroorganisms, they are part of the Park's wildlife and biological diversity, and there can be no question that "capturing" their DNA - whether thermophile, grizzly bear, or elk DNA - within a test tube for the "purposes of profit" is a direct violation of the Yellowstone Park Act. The point is that in commercial bioprospecting, something essentially has been "captured for profit." For example, were a grizzly bear to be trapped and subsequently tranquilized against its will, it is easy to see that it would have been "captured" and the results of that capture could not be allowed to lead to profit. Presumably, the same standard applies to all the wildlife, whatever the size, in the Park.

Similarly, the Antiquities Act, pertaining chiefly to archaeological sites and ruins, nonetheless states that any "gatherings shall be made for permanent preservation in public museums." The Act contains no provision that would allow commercial gathering, i.e., commercial bioprospecting for private profit.

As the District Court noted, the Park Service could find no statutory authority for commercial bioprospecting and, struggling to find a shoe that might fit, began to creatively stretch the language and the imagination in order to allow it by claiming that Yellowstone and other national parks are "federal laboratories" under the meaning of the Federal Technology Transfer Act (FTTA) of 1986. [10] While the Court ultimately accepted this interpretation, in the minds of the public, such an interpretation was at odds with basic logic and commonsense. [11] Moreover, the legislative history of the FTTA would indicate that Congress enacted the law for the named "national laboratories", such as Los Alamos National Laboratory, Oak Ridge National Laboratory, National Institutes of Health, etc. Nowhere does FTTA history suggest that the law

was enacted for the purpose of declaring the units of the National Park System as national laboratories under the definitions of the FTTA.

While NPS claims commercial bioprospecting is consistent with the original mission and purpose of the Parks, the District Court recognized that NPS has engaged in "a dramatic shift in park management policy." [12] In this regard, the Judge rejected the Park Service position that bioprospecting is no different than other research conducted in the parks, writing: "This ignores the reality that the commercial nature of an activity can and does affect its impact on the subject environment and particularly on people's aesthetic and recreational interests in the Park. Although parkgoers may be willing to forgive the trespass of their national parkland when the goals of that trespass are scientific and educational, commercial exploitation of that same parkland may reasonably be perceived as injurious. This commonsense notion has not even been challenged in other contexts." The judge went on to point out that, "There is an undeniable reality that commercial activity is qualitatively different than scientific and educational activity of a similar nature, due to the very different forces and motivations that drive them."

While the District Court dismissed several claims in the litigation, it expressed its concern over this "dramatic shift in park management policy," and did not predetermine an outcome. Nor did the Court grant the NPS *carte blanche* to proceed as it wished. Rather, the Court ordered the agency to conduct a fully compliant NEPA analysis in order to make a rational decision, based upon the facts established in the analysis and the administrative record, as to *what* it should do and *how* it should do it.

In advancing as its preferred alternative an alternative that allows commercial bioprospecting, the NPS has failed to include an alternative providing for research in the public interest and failed to recognize an important distinction between commercial research and research in the public interest, notably the difference in transparency and public access to the science that is done. For example, researchers pursuing advanced degrees, or those affiliated with public research facilities not only report in annual summaries to the NPS, but their research is generally intended to result in scientific papers submitted to peer-reviewed journals for publication or for (publicly available) M.S. or Ph.D. theses. The methods and results of such research are therefore widely available to the public and other researchers, allowing them all to benefit from advances in research methods and techniques, the free exchange of ideas and knowledge, and the broadened base of scientific literature. However, researchers employed by commercial bioprospecting companies do not as a rule submit their research for peer review and publication. To the contrary, the fruits of their research are most often intended to be "trade secrets", not to be shared with others unless permitted by the relevant companies. The information is not easily, if at all, available to the public and other researchers do not gain from advances in methods and free exchange of ideas as they do in research in the public interest. Indeed, under the NPS preferred alternative, commercial bioprospectors with CRADAs may keep sealed from public view any information they consider to be proprietary, potentially meaning any or all important elements of any CRADA. This

amounts to using the public commons (the parks) to generate private knowledge. All that the CRADA guarantees to the public is access to a commercially (derived) product and a portion of the profits from that product. There is no guarantee -- nor reasonable expectation -- of transparency and complete access to the knowledge that flowed from access to public resources in the first place.

Such potential limitation on science done in the Parks and on the knowledge gained from research in the Parks is not acceptable and amounts to an injury to the Parks' mission. Were such injury to be allowed to persist, it can be expected to result in a lessening of public harmony with the parks mission, a lessening of the public's enjoyment of the parks, and eventually, a lessening of the public's willingness to support the parks and to direct their representatives to support the park system.

#### IV. Specific Issues

##### A. The DEIS Does Not Satisfy NEPA Requirements or the Court's Order

The NPS, while presenting a lengthy rhetorical analysis, has not presented a sufficiently substantive analysis. The NPS has chosen to take a bureaucratic approach by concluding that the major affected environment of its benefit sharing policies will be itself and its own administration. This profoundly narrow view fails to reveal or analyze significant aspects of the potential impacts, particularly those that relate to natural resources, wildlife habitats, and aesthetic environments.

There are a host of issues which the DEIS has failed to analyze, or in many cases, even to mention. **It is our position that the DEIS does not fulfill or comply with the instructions contained in the District Court's Order. It fails to take the "hard look" which numerous courts have found the National Environmental Policy Act (NEPA) requires.**

NEPA requires federal agencies to prepare an environmental impact statement in connection with all "major federal actions significantly affecting the quality of the human environment." [13] The Council on Environmental Quality (CEQ), created by NEPA, has established extensive regulations describing the requirements of an EIS. [14] It is our position, described in detail below, that the DEIS has failed to comply with numerous sections of the NEPA regulations.

##### B. The Analysis is Biased in Favor of Commercial Bioprospecting

The tone of the DEIS is clear. NPS portrays commercial bioprospecting as the only means available to obtain information necessary for proper resource management. Pursuing this direction, the DEIS contains allegations apparently meant to steer people away from Alternative

Once having made the decision to produce an EIS, constituting major federal action, the NPS committed itself to the more rigorous and comprehensive standard of analysis, particularly given that that the ambit of the EIS is Service-wide, applying to 84.4 million acres.

The DEIS makes a major error in portraying the affected environment of the document as purely administrative and related to paper shuffling. On pages 106-107, under the subsection 4.2.5 titled Impairment, the DEIS makes these incredible statements: "Impairment analyses only apply to natural and cultural resource topics, and do not apply to topics involving visitor use, social resources, or park operations. Therefore, because this document does not carry forward natural or cultural resource topics, impairment will not be analyzed further in this DEIS."

These statements are erroneous as the research entailed is not a paper-oriented literature review. The subjects of the commercial bioprospecting program are biological in nature and involve living park resources, with bioprospectors potentially searching over large geographic areas. The issues are physical and environmental and are directly related to the exploitation of natural resources. The DEIS states on page 5 that commercial bioprospecting isn't limited to thermal pools: "Studies of park resources, including rare bacteria and unique plants and animals, expand beneficial scientific knowledge, and research results occasionally generate substantial commercial profits." There are numerous issues with the potential for actual physical impacts which the DEIS fails to analyze.

The Court has already noted that the Yellowstone-Diversa CRADA covered a wide array of park ecosystems and included trees, plants, soils, rocks and other park wildlife. [15] Yet the scant discussion of Servicewide Impacts on pages 124-126 of the DEIS contains no discussion of environmental impacts to natural resources and instead erroneously concludes that all impacts are informational and monetary, and can be described as beneficial.

By the NPS's own admission, the source areas for bioprospecting contain an untold number of unknown organisms and less than 1% are catalogued. [16] Given that admission, bioprospecting activities, using the language of NEPA, "involve unique or unknown environmental risks" with "highly uncertain effects." All organisms have population dynamics and habitat requirements, yet little if anything is known about these dynamics and requirements of the likely candidates for bioprospecting. Nevertheless, there are "reasonably foreseeable" potential impacts that must be revealed in the DEIS.

NEPA §1502.22(a) states that "agencies shall insure the professional integrity, including scientific integrity, of the discussions and analyses in environmental impact statements." The regulations mandate that when "there is incomplete or unavailable information" concerning "reasonably foreseeable significant impacts on the human environment," an agency must either: (1) if the information "is essential to a reasoned choice among alternatives" and the overall costs of obtaining it are not exorbitant, obtain and include the information in its analysis or (2) if the

C. Sometimes this involves making broad claims, without documentation or substantiation. For example, on page 58 the DEIS states: "Under Alternative C, researchers would be prohibited from conducting most research that could improve health, safety, and productivity." And on page 59, the DEIS states: "Alternative C fails to meet this criterion because research that could be expected to lead to discoveries in health care, nutrition, agriculture, environmental management, or industrial fields would be prohibited. Accordingly, Alternative C would not attain the widest range of beneficial uses of the environment." These blanket statements are nowhere substantiated. Indeed, the DEIS states elsewhere that approximately 99.5% of research in the parks would be unaffected by Alternative C. On page 150 it states: "At the Servicewide level, Alternative C is likely to result in only a slight change in the availability of new scientific knowledge about park resources." Further, on page 122 the DEIS states: "No significant difference in the number of research projects conducted in any context was detected between the pre-benefits-sharing and post-benefits-sharing time periods."

In pursuing a policy favorable to commercial bioprospecting, the NPS years ago offered the debatable contention that parks such as Yellowstone are "federal laboratories". Now, the NPS has turned around and stated that these laboratories have no scientists or research equipment, and therefore it is necessary to bring in commercial enterprises to provide the expertise for them.

In further evidence of its bias towards the private sector, NPS tells us in the DEIS statement on page 77: "In a specific example of the contribution that independent researchers make to the NPS, the majority of new species currently being added to park biodiversity rosters are microbes, but the NPS does not employ permanent, full-time microbiologists to conduct microbial research and funds little research on microbes." Not only does the NPS not explain why it does not hire its own microbiological researchers or fund microbial research, but by not pressing for its own researchers, the NPS undermines its own position as to how crucial the microbial research information really is. If such research constitutes a central and vital purpose of the Parks, and if the benefits to the public are so potentially large, why has NPS not hired a single full-time microbiological researcher to conduct research for the NPS? The Service seems to be indicating that it is sitting on top of a virtual gold mine of biological diversity in Yellowstone and other parks and yet the Service has not seen fit to hire (or borrow from another agency) a single permanent full-time microbiological researcher.

In this regard the NPS has abdicated its responsibilities and come up with the weak claim that it must allow commercial enterprises to commercially exploit park resources in the name of filling a void that the NPS itself has apparently created.

**C. Specific NEPA Violations**

**1. Affected Environment & Lack of Impact Analysis**

information "cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known," include in the EIS a statement making clear the unavailability of the information, use "existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment," and "evaluate impacts based upon theoretical approaches or research methods generally accepted in the scientific community." The courts have found this mandate to be binding. In *Fritti/son v. Alexander*, the Court noted, "NEPA requires that an agency candidly disclose in its EIS the risks of its proposed action." [17] The NEPA regulations in § 1502.22 state that an agency must make clear in an EIS that there is incomplete or unavailable information.

Yet, in this case, the DEIS contains neither a discussion of environmental and human impacts or a statement that there is unknown or unavailable information. It simply states there are no impacts and that NEPA is applied at the permit issuance level. By this tactic, the NPS attempts to evade the "hard look" required by NEPA. Further, according to DEIS estimates, negotiating a new CRADA will require a high-end estimate of 0.18 FTE staff time, and the more CRADAs, the less time spent per agreement. This amount of staff time is clearly inadequate for scientifically credible NEPA compliance.

If the NPS does not take the required "hard look" at the programmatic, service-wide level, then it will be forced to perform this extensive analysis at the individual CRADA level, requiring far more resources in time, staff, and money than the Service has revealed in the DEIS.

While the District Court declined to specify exactly what to study, the Court clearly instructed NPS to fully comply with the NEPA in preparing an environmental statement for public review and comment and also provided several pointed examples of the potential environmental impact and injury that commercial bioprospecting potentially represents. For example, the Court wrote: "...the introduction of commercial bioprospecting into the nation's parks represents a dramatic change in Park Service policy both in Yellowstone and more generally. With regard specifically to Yellowstone, the defendants have offered no persuasive counter to plaintiffs' assertion that the CRADA, on its face, allows for a tremendously broad range of activities spanning a broad range of ecosystems." The NPS has done little to address - and therefore much to exacerbate - the original concerns for the impacts from a potentially "broad range of activities spanning a broad range of ecosystems".

## 2. Cumulative Impacts & Effects

NEPA § 1508.25(c) requires a complete disclosure and analysis of cumulative effects. However, the discussion of Cumulative Impacts on page 112 of the DEIS, so central to NEPA compliance, contains no information to the cumulative impact of commercial bioprospecting on park natural resources even though the NPS knows that commercial bioprospecting will apply to "soils, trees, plants, animals...and may influence profitable resource access by other industries besides those

concerned with biotech/microbiology." Moreover, there is no discussion of the cumulative impact of perhaps several dozen simultaneous bioprospecting operations covering vast areas of national park system lands. There is also no analysis of the effect a "major commercial" find might have on the number of bioprospecting permits issued. A "bioprospecting gold mine" might encourage a rush of commercial bioprospectors. Inexplicably, the DEIS only describes cumulative impact relative to interpretive services provided by the NPS to park visitors.

With respect to cumulative actions, the courts have noted that CEQ regulations require connected, cumulative, and similar actions to be considered together in the same EIS. When proposals up for decision are functionally or economically related, those proposals must be considered in one EIS. The analysis must not only include impacts from actions that are merely being contemplated at this time, but also those that are "reasonably foreseeable." [18]

In respect to this DEIS, future commercial bioprospecting CRADAs are reasonably foreseeable and even likely. However, NPS states that NEPA analysis will be applied at the individual permit level, thereby ignoring the cumulative effects analysis of reasonably foreseeable actions the program is likely to precipitate service-wide.

The courts have also found that, "To consider cumulative effects, some quantified or detailed information is required. Without such information, neither the courts nor the public, in reviewing the Forest Service's decisions, can be assured that the Forest Service provided the hard look that it is required to provide." [19] Without such quantified and detailed information in this case, we are forced to come to a similar conclusion.

## 3. Irreversible and Irrecoverable Commitments of Resources

On page 146, the DEIS presents its analysis of irreversible and irretrievable commitments of resources in one sentence: "Alternative B would not result in the temporary or permanent loss of any resources." NEPA requires far more than simple declarative statements. There must be some analysis presented to support such a sweeping declaration. After all, living organisms are being removed from their habitats.

If one accepts the NPS rationale that "research results" obtained from biological specimens removed from the National Parks can be commercially developed, then there is also no question that this process represents an "irreversible and irretrievable commitment of resources" under the language and regulations of NEPA. At a minimum, the "research result" or "valuable discovery" would be lost to the public domain. The rights to this discovery, and the majority of the potentially enormous profits it could yield, would flow to private commercial enterprise. It is in this sense that there would be an irreversible and irretrievable commitment of NPS resources. We will not examine the obvious case where individual organisms may be lost to the park.

#### 4. Lack of Reasonable Alternatives

NEPA § 1502.14(a) requires that agencies must "rigorously explore and objectively evaluate all reasonable alternatives." A primary purpose of NEPA is to prevent an agency from presenting only its own viewpoint concerning environmental impacts. "Perhaps most substantively, the requirement of a detailed statement helps insure the integrity of the process of decision by precluding stubborn problems or serious criticism from being swept under the rug." [20] Thus NEPA requires the NPS to objectively disclose and evaluate views or evidence which contradict its proposed course of action or preferred alternative. Under NEPA, the agency must discuss any "responsible opposing view." [21]

Yet this DEIS does not contain a discussion of opposing views. It simply states they have been incorporated into one of the alternatives, without identifying the specific opposing views or how they have been addressed within the given alternatives.

Based upon the public comment the NPS received and the existing mandate of NPOMA to create and participate in CESUs, the NPS should have included a Science in the Public Interest Alternative. That alternative would have relied on federally and publicly funded researchers to make "beneficial" research discoveries the benefits of which would reside in the public domain. Instead of including such an alternative, the DEIS narrowly cast the alternatives as a choice -- we would say a false choice -- between commercial bioprospecting with increased benefits to the Parks and society or no commercial bioprospecting and no increased benefits.

NEPA specifically requires an agency to consider a reasonable alternative: "Although there is no need to consider alternatives of speculative feasibility or alternatives which could be changed only after significant changes in governmental policy or legislation, the EIS must still consider such alternatives to the proposed action as may partially or completely meet the proposal's goal and it must evaluate their comparative merits." [22]

As posited in the DEIS, the central aim is to make additional research discoveries that will enhance NPS resource management and protection as well as enhance interpretive programs and signage for the increased enjoyment and understanding of the visiting public. But the DEIS does not consider all the options for achieving this. In particular, the DEIS is deficient in its omission of an alternative in which microbiological and other research in the public interest is conducted by park staff or staff from other public agencies. Even were we to grant the argument about the Parks being "laboratories," the NPS does not present any information whatsoever to explain why it cannot hire its own microbiologists to conduct research and make discoveries that can improve health, safety, and productivity in the public interest. NPS never even considers the public research possibility (or how that possibility might be realized). Perhaps it was this lack of considering this possibility that allowed the NPS to make the unsubstantiated claim in the DEIS that only through huge personal gain will researchers have the motivation and means to make

such discoveries. The NPS supposition about motivation and means completely ignores the motivation and accomplishments of many federal laboratories and research centers. It ignores the example of such agencies as the Centers for Disease Control, where public service scientists search for vaccines against such threats to public health and safety as the avian flu, and conduct extensive research in the public interest.

If, as the NPS claims, the National Park Service does not possess the required expertise, there is nothing to prevent the NPS from entering into cooperative research agreements with other federal agencies, and to receive, on loan, staff from other federal agencies with the desired skills and expertise. In fact, on pages 109-110 the DEIS describes how the NPS, acting through the NPS Natural Resource Challenge, participates in 17 Cooperative Ecosystems Studies Units (CESUs) to conduct research on NPS resources: "CESUs are yet another program supported by the Natural Resource Challenge and required by NPOMA which provides research, educational opportunities, and technical assistance in the biological, physical, social, and cultural sciences necessary to manage NPS natural and cultural resources. As of August 2005, there were 13 federal agencies, 160 universities, and 39 other partners involved in CESUs." Surely this array of public research assets and technical assistance would allow NPS to conduct its own scientific research in the public interest. And surely this approach would represent a clear and distinct alternative to reliance on commercial bioprospecting to fulfill the hoped-for research functions.

For the cost that the NPS projected for administration, including negotiation and management of CRADAs, the NPS instead could have (a) hired its own research grade biologists to conduct research in the public interest or (b) taken the option of working with the Cooperative Ecosystems Studies Units (CESUs) to obtain the necessary expertise while fulfilling its obligations under NPOMA. These approaches would have yielded the same benefits claimed under the B alternatives, but with all the benefits going to the public. Unfortunately, this Science in the Public Interest Alternative was not included in the DEIS, apparently because the NPS had a pre-decisional bias in favor of commercial bioprospecting.

A Science in the Public Interest Alternative could reap critically important benefits. It could: 1) protect the parks from commercial natural resource exploitation, 2) encourage scientific research in the public interest and domain, and 3) establish baseline data on thermophiles and other resources. The Science in the Public Interest Alternative would take the best of the projected benefits from Alternatives C & B, without at the same time adopting B's potential for keeping information from the public.

#### 5. Impacts on the Human Social Environment -National Precedent

Numerous courts have found that NEPA requires federal agencies to include meaningful consideration of fundamental factors within environmental impact analysis. [23] Under the Administrative Procedure Act, [24] an agency can be found to be "arbitrary and capricious" in its

NEPA analysis. In *Motor Vehicles Manufacturers Association v. State Farm Mutual*, the Court ruled that, "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, *entirely failed to consider an important aspect of the problem*, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." [25] (emphasis added)

In this DEIS, the NPS has failed to discuss or analyze the impact of its proposed benefit sharing policies on the American people's perception of and regard for the National Park System, as well as on their aesthetic and recreational interests. Rather, the NPS on page 82 characterizes the social environment of potential impact as containing researchers and NPS personnel only, with no recognition of their plan's impact on the American public. In fact, the District Court provided the NPS with an opportunity to comprehend the significance of NPS's "dramatic shift in park management policy" and the impact it would have on the public users and owners of the National Park System when the Court wrote, "This ignores the reality that the commercial nature of an activity can and does affect its impact on the subject environment and particularly on people's aesthetic and recreational interests in the Park. Although parkgoers may be willing to forgive the trespass of their national parkland when the goals of that trespass are scientific and educational, commercial exploitation of that same parkland may reasonably be perceived as injurious. This commonsense notion has not even been challenged in other contexts." The Court went on to say, "There is an undeniable reality that commercial activity is qualitatively different than scientific and educational activity of a similar nature, due to the very different forces and motivations that drive them."

The NPS has had a long time to consider the impact to the public perception of and regard for the NPS and the quality of its stewardship. The failure to assess the national precedent the commercial bioprospecting program would set is particularly egregious since, as the Court noted in its ruling, documents obtained through the Freedom of Information Act show that Park Service officials knew as early as 1996, ten years ago, that commercial bioprospecting would apply systemwide. [26] Moreover, one memorandum stated "any precedent set will affect all parks, and may influence profitable resource access by other industries besides biotech/microbiology." [27]

The importance of the impact of commercial bioprospecting - "profitable resource access" - on public perceptions of the meaning (and public nature) of the parks cannot be underestimated. Proposed commercial bioprospecting has been the subject of at least two law review articles, including *Are National Park Resources for Sale?* and a lengthy piece in *Ecology Law Quarterly*. [28] Numerous major media articles have also been published.

The NPS could easily have obtained the services of an unbiased party to develop a survey to be presented to park visitors and other interested members of the public to help sample and

characterize this impact. Certainly, there are methods available that would have uncovered the information.

The Parks have meaning to the public and the effects of all the alternative policies on that meaning must be acknowledged and assessed.

#### 6. Impacts on Congressional Appropriations

The DEIS claims that the document is not about appropriations. Yet the public comment record shows that many who commented were concerned that commercial bioprospecting might result in lower congressional appropriations and more pressure to commercialize park resources in order to obtain management and operating budgets. The NPS concludes that this issue is beyond the scope of the present analysis, conveniently forgetting that funding was one of the reasons for pursuing bioprospecting in the first place.

Further, should NPS proposals have adverse effect on public sentiment about the Parks, lowered levels of public commitment may lead, directly or indirectly, to lowered Congressional appropriations for the Parks.

#### 7. Inadequate Mitigation Measures to Prevent Conflict of Interest

NEPA § 1502.14 (f) directs agencies to "Include appropriate mitigation measures not already included in the proposed action or alternatives." In this DEIS, however, NPS provides only an inadequate mention of mitigation measures, simply stating that they will be developed. Further, this section of the DEIS does not outline several areas of potential conflict of interest. For example, there are potential revolving-door issues in situations where an NPS employee working on a CRADA project may decide to leave the NPS and go to work for the company involved in the CRADA.

Another serious problem, one which would affect the NPS Preferred Alternative, involves a statement on page 44 of the DEIS: "Individual park units that are identified as federal laboratories would receive and use the benefits resulting from a benefits-sharing agreement." This policy of benefit apportionment represents a built-in system for potential abuse of discretion in the issuance of permits, favoring commercial bioprospectors and opening the door for conflict of interest in permit issuance and environmental impact review. The policy raises the prospect that research staff within the parks may be - or may perceive themselves to be - subject to performance evaluations based upon the number of CRADAs they successfully negotiate, thus biasing the entire Park research program towards commercial bioprospecting. The policy also raises the specter of individual park units with similar biota competing with each other for perspective CRADA partners, with all the potential such competition might engender for a race to the bottom in Park benefits. The DEIS does not examine these issues and so does not explain

how they will be mitigated or resolved.

Unfortunately, the appropriate section of the DEIS neither outlines potential avenues for conflict of interest nor sets forth a procedure for developing the mitigation measures to come. With no vision of what needs to be mitigated, how mitigation measures will be arrived at, or how mitigation measures may play out differentially in the different alternatives presented, the NPS has made it difficult, if not impossible, to responsibly judge the impacts of each alternative.

**8. Cost/Benefit Analysis**

NEPA § 1502.23 requires cost-benefit analysis when such analyses are important to evaluating the differences among alternatives.

The narrow analysis provided in the DEIS does not measure the differences between different approaches, in part because not all potential alternatives have been presented. For example, given the alternatives the DEIS presents (and the absence of a Science in the Public Interest Alternative), the public cannot know:

- the cost difference between the cost of administering commercial CRADAs and the cost of funding research in the public interest, using NPS and other federal employees; or
- the difference in benefits (both monetary and non-monetary) between benefits derived from discoveries made in the public interest and residing in the public domain and those made for purely commercial goals and residing firmly in the private domain.

NEPA requires that cost-benefit analysis take into account non-monetary values. We have already noted the absence in the NPS analysis of any consideration of the impact of the proposals on the public's perception of and regard for the National Park System itself -- what some economists might term the "existence value" of the Parks to the people of the United States. [29] Here, we note the absence of any cost/benefit analysis of changes to that existence value occasioned by each of the presented alternatives, or by the absent Science in the Public Interest Alternative.

The absence of any consideration of the potential cost to the meaning of the parks for the people and legislators of the U. S. is inexplicable, given that the existence value is hardly a new concept and that this DEIS has taken a very long time to be published.

Finally, the DEIS cost-benefit analysis is sorely lacking in its consideration of the costs associated with negotiating and administering CRADAs. Important aspects of the analysis are not provided. For example, the DEIS does not indicate what level GS employees will be required to work on the CRADAs or assist individual park research staff. This makes cost/benefit

comparisons difficult. Further, NPS staff will have to come from the regional and national offices and so there may be extensive travel costs associated with their work. These costs are nowhere noted.

**B. Commercial Bioprospecting Violates the Wilderness Act and NPS Management Regulations for Designated and Recommended Wilderness**

The National Park System includes vast areas designated by acts of Congress as Federal Wilderness Areas. [30] Over 40 million acres of designated wilderness exists within the National Park System. Additionally, there are millions of additional acres that are eligible or "recommended for wilderness." The DEIS and its proposed policy fail to address the potential impacts to wilderness or even acknowledge that Wilderness exists within the national parks. This is a glaring oversight because the vast majority of national park lands are subject to wilderness laws and policies, which place these lands off-limits to commercial bioprospecting. As explained below, this prohibition applies to the more than 80 percent of national park lands that are designated as wilderness, recommended wilderness, and potential wilderness.

The Wilderness Act, § 4(c) states that, "Except as specifically provided for in the Act, and subject to existing private rights, there shall be no commercial enterprise within any wilderness area designated by this Act." [31] Exceptions for visitor services which support the recreational use of Wilderness apply primarily to guides for hiking, camping, fishing, hunting, climbing, and horseback riding. Commercial bioprospecting would clearly be a "commercial enterprise" that is prohibited within wilderness areas.

This prohibition applies even if the proposed activity might benefit non-commercial interests as well. The Court, in *Wilderness Society v. United States Fish and Wildlife Service*, [32] found that, "The language, purpose and structure of the Wilderness Act support the conclusion that Congress spoke clearly to preclude commercial enterprise in designated wilderness, regardless of the form of commercial activity, and regardless of whether it is aimed at assisting the economy with minimal intrusion on wilderness values."

In that same decision, the Court went on to note that the prohibition applies even if there was no impact from the commercial activity on the Wilderness or natural environment: "There is no exception given for commercial enterprise in wilderness when it has benign purpose and minimally intrusive impact." [33]

As already noted, National Park Service policies generally provide the same level of protection for and proscribe commercial enterprise on several categories of land, including eligible, study, proposed, recommended, potential and designated wilderness. [34] Combined, these categories of "wilderness" apply to more than 80 percent of the lands within the National Park System. In

Yellowstone National Park, for example, NPS policies would ban commercial bioprospecting on more than 90 percent of the park.

The DEIS needs to be modified to acknowledge the unlawful effects of the proposed action on wilderness lands within the parks. And, at a minimum, the proposed action and alternatives need to be modified to exclude from bioprospecting all designated wilderness lands, as well as all eligible, study, proposed, recommended and potential wilderness areas.

#### **IV. Additional Problems**

##### **A. Transparency**

Whatever the intentions of the NPS, the other parties to CRADAs may designate part of the CRADA as confidential business information. The public will have no effective means of accessing this information, not even the Freedom of Information Act.

The DEIS fails to contain a discussion regarding the likely lack of transparency associated with its proposals. For example, under the Freedom of Information Act, [35] there are several exemptions allowing agencies to withhold information from public view. Moreover, NPOMA § 207 states: "Information concerning the nature and specific location of a National Park System resource which is endangered, threatened, rare, or *commercially valuable*, may be withheld from the public in response to a request under section 552 of title 5, USC." (emphasis added) In this sense, and in the sense mentioned earlier in our comments, a CRADA will not be compliant with goals of complete transparency. Even the very geographic location of the activity may be made secret, and, under FOIA, kept secret. Thus, the public and independent scientists may have no way to objectively judge a project's impact on the environment. Potentially, the public may not even be able to know whether a project will take place within occupied endangered species habitat, or in designated or recommended wilderness, or whether the project will involve what is precluded in § 3 of the National Park Service Act, notably the lease, rental, or grant of natural curiosities, wonders, or objects of interest "on such terms as to interfere with free access to them by the public." The public will not be able to judge whether its own "free access" to certain areas will be precluded for unannounced commercial reasons. These are not trivial concerns and NEPA regulations require that they be disclosed in an EIS and their impacts analyzed.

It is doubtful that NPS has the authority, acting through a CRADA or any other vehicle, to override a commercial interest's desire to invoke FOIA and NPOMA exemptions. Thus any CRADA will effectively allow details to be withheld from the public at the discretion of a commercial party.

The DEIS should make clear that under any alternative that allows commercial bioprospecting,

the public will not have the right to view (or necessarily be able to access) all aspects of the CRADA and the subsequent scientific analysis, by-products and "research results", nor will NPS have the legal right to compel commercial bioprospectors to release such information against their will. Knowledge of this effect of allowing commercial bioprospecting and using of CRADAs is vital to the public's ability to objectively weigh the differing "benefit sharing" alternatives.

##### **B. Enforcement Provisions**

The DEIS does not outline crucial enforceability issues. It even states on page 41 that the burden of coming forth to negotiate a CRADA rests with the researcher. Such lack of assertive oversight could facilitate greater secrecy by researchers, particularly those with primarily commercial motives, than the law might allow. The DEIS must stipulate the methods for oversight and enforcement of CRADAs so that the public can judge whether any of the alternatives provided would feasibly operate in the public interest.

##### **C. Benefit Sharing Options Not Mentioned**

Throughout the DEIS analysis, only one form of benefit sharing agreement is considered: the CRADA. Given all the problems associated with this legal vehicle, particularly its lack of guarantee of transparency, and given the apparent NPS determination to proceed with commercial bioprospecting, the NPS should have considered other forms of benefit sharing, including the use of fully transparent contracts made available for public view. This is a particularly egregious omission.

##### **D. Costs of Preparation**

Since one of the costs of creating a "benefit sharing" policy at the NPS is the cost of designing the policy, including the cost of writing the DEIS, and since this DEIS is likely to be prelude to many other (larger and smaller) DEISs in relation to benefits-sharing, it would have been helpful for the public to know about the costs entailed in developing this policy and the cost entailed in writing this particular DEIS, including the costs for meetings, consultant fees, and transportation, and information about how all those costs were determined, distributed, and financed. Such considerations would help the public to decide whether all the hard work was worth it.

##### **V. Conclusion**

As written, the DEIS is deficient on numerous grounds and is in violation of numerous sections of the NEPA regulations. It is also in violation of The Wilderness Act and the Administrative Procedure Act. It is our view that this DEIS must be withdrawn, its deficiencies corrected, and the *improved* document circulated for public comment as a Supplemental Draft Environmental

Impact Statement. NEPA § 1502.9 provides for supplementing draft and final environmental impact statements. The test for deciding when to supplement is the same "significance" test used to decide whether to prepare an EIS. "In this respect the decision whether to prepare a supplemental EIS is similar to the decision whether to prepare an EIS in the first instance: If there remains 'major Federal action' to occur, and if the new information will affect the quality of the human environment in a significant manner or to a significant extent not already considered, a supplemental EIS must be prepared." [36] Here, both the new and missing information constitute a "major federal action significantly affecting the human environment" and a supplemental DEIS should be prepared.

Lastly, we note the omissions in our own comments. We have discussed our concerns about the DEIS at some length and everywhere we have focused on what NPS has presented and what we have found lacking or incorrect in that presentation. We have hardly acknowledged what was for some of us our most profound disappointment, notably, the appearance of a lengthy environmental impact statement, seven years in the making by an agency with a mission of stewardship, that barely touched on issues of preservation and conservation. [37]

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**VII. End Notes**

- 1. National Park Service U. S. Department of the Interior. Benefits-Sharing Draft Environmental Impact Statement, September 2006. Servicewide.
- 2. Yellowstone Park Act of 1872, 17 Stat. 32-33.
- 3. The Antiquities Act. 16 USC 431 et seq.
- 4. National Park Service Act. 16 USC 1.
- 5. General Authorities Act. 16 USC 1a-1.
- 6. National Parks Omnibus Management Act of 1998. 16 USC 5931.
- 7. Yellowstone-Diversa Cooperative Research & Development Agreement.
- 8. *Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).
- 9. *Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).
- 10. Federal Technology Transfer Act. 15 USC 3701
- 11. *Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).
- 12. *Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).
- 13. National Environmental Policy Act. 42 USC § 4332 (2)(C).
- 14. 40 CFR § 1502.1.
- 15. Yellowstone-Diversa CRADA.

16. *Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).
17. *Seattle Audubon v. Moseley*, 798 F. Supp. 1473, 1482 (W.D. Wash. 1992).
18. *Fritiofson v. Alexander*, 772 F.2d 1225 (5th Cir. 1985).
19. *Muckleshoot Indian Tribe v. U. S. Forest Service*, 177 F.3d 800, 809-10 (9th Cir. 1999)
20. *Silva v. Lynn*, 482 F.2d 1282, 1285 (1st Cir. 1973)
21. *Seattle Audubon Society v. Lyons*, 871 F. Supp. 1291, 1318, W.D. Wash. 1994.
22. *Natural Resources Defense Council v. Calloway*, 524 F.2d 79 (2d Cir. 1975).
23. *Foundation for North American Sheep v. U. S. Department of Agriculture*, 681 F.2d 1172, 1178 (9th Cir. 1982).
24. Administrative Procedure Act, 5 USC 701 et seq.
25. *Motor Vehicles Mfrs. Assn. v. State Farm Mut.*, 463 US 29, 43 (1983).
26. *Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).
27. *Edmonds Institute, et al. v. Babbitt, et al.* 93 F. Supp. 2d 63 (DDC 2000).
28. Michael D. Wood, 2000. Are National Park Resources for Sale?, *Public Land Law Review* 21, University of Montana School of Law, Missoula.
29. For those unfamiliar with "existence value" in economic analysis, see Frank Ackerman and Lisa Heinzerling. **Priceless: On Knowing the Price of Everything and the Value of Nothing.** The New Press: New York, 2004.
30. The Wilderness Act, 16 USC 1121 et seq.
31. 16 USC 1133(c).
32. *Wilderness Society v. United States Fish and Wildlife Serv.*, 353 F.3d 1051 (9th Cir. 2003)(en banc)(amended 360 F.3d 1374 (9th Cir. 2004)).
33. *Wilderness Society v. USFWS*. (9th Cir. 2003).
34. NPS Management Policies 6.3.1
35. Freedom of Information Act, 5 USC 552.
36. *Marsh v. Oregon Natural Resources Council*, 490 U. S. 360, 109 S. Ct. 1851 (1989) 361, 373, 374.
37. The expectation was that potential environmental and population impacts related to bioprospecting (including increased bioprospecting over time), e.g., changes over time in population dynamics and constituents, would be addressed in this DEIS. See, e.g., Robert Lindstrom, Robert F. Ramaley, and Richard L. Weiss Bizzoco, 2002, Invisible Invasion: Potential Contamination of Yellowstone Hot Springs by Human Activity, *Western North American Naturalist*: 62:1, 44 ff.



PROVIDING  
SCIENTIFIC  
INFORMATION  
ABOUT BIRDS

Comments on the Draft Environmental Impact Statement on Benefits-sharing

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The Ornithological Council submits these comments on the Benefits-sharing Draft Environmental Statement (DEIS). The Ornithological Council is a consortium of eleven scientific societies of ornithologists, seven of them in the United States. Among the members of these organizations are many scientists who conduct various kinds of specimen-based scientific inquiry, including taxonomic study, the documentation of biodiversity, and biochemical research. Some have worked or are working in the National Parks. The benefits-sharing policy may or may not apply directly to academic (noncommercial) research. We discuss this issue at length, below. However, even if it does not, the benefits-sharing policy will have impacts on the academic scientific community, as described below. For these reasons, we submit these comments on the DEIS and the benefits-sharing policy.

We have two concerns about the DEIS and the underlying benefits-sharing agreements: first, that the analysis of impacts is inadequate because it never addresses the impact of the permanent removal of natural resources from the parks; and second, that the analysis of impacts is inadequate because it does not recognize the possible impact on the NPS' ability to satisfy the Congressional mandate, under the 1998 National Parks Omnibus Management Act, 16 U.S.C. 1593-1956, that it encourage scientific research in the National Parks.

*The analysis of impacts is inadequate in failing to address the fundamental nature of the transaction, which involves permanent removal of natural resources from the National Parks.*

- American Ornithologists' Union
- Association of Field Ornithologists
- CIPAMEX (Sección Mexicana del Consejo Internacional para la Preservación de las Aves)
- Cooper Ornithological Society
- Neotropical Ornithological Society
- Pacific Seabird Group
- Raptor Research Foundation
- Society for the Conservation and Study of Caribbean Birds
- Society of Canadian Ornithologists/Société des Ornithologues du Canada
- Vauclaud Society
- Wilson Ornithological Society

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The impact analysis is based on a critical omission or faulty assumption about the exact nature of the transaction. The DEIS focuses only on the potential development of a commercially valuable product from the intellectual property derived from natural resources found in the parks, but overlooks the reality that the research and development can take place only if the NPS allows the removal of natural resources from the parks. The DEIS fails to explain to the public – who are the owners of these resources – that in many, if not most cases, the research and development process will result in the destruction of these resources and that it is unlikely that the resources will ever be returned to the parks from which they were taken.

Recent Supreme Court decisions make it clear that the NPS does not own wildlife found in the parks managed by the agency. “[I]t is pure fantasy to talk of ‘owning’ wild fish, birds, or animals. Neither the States nor the Federal Government... has title to these creatures until they are reduced to possession by skillful capture. *Douglas v. Seacoast Products, Inc.*, 431 U.S. 265, 284.” The opinion in *Edmonds I*, which ultimately led to the preparation of the DEIS, said the same: “In need of funds, and recognizing that potentially valuable natural resources were being removed from Yellowstone with no remuneration to the Park and its owners, the American people, see *Soukup Decl. ¶ 9; Edmonds Institute v. Babbitt*, 42 F. Supp. 2d 1, 4-9 (D.D.C. 1999). It should be noted that the declaration alluded to in this excerpt was a statement filed by NPS official Michael Soukup, Associate Director for Natural Resource Stewardship and Science.

The NPS has maintained, in discussions with the scientific community pertaining to the ownership of specimens taken from the parks under NPS-issued research permits, that it has, but cannot transfer ownership of specimens. That position is inconsistent with Supreme Court decisions, which are the law of the land. It is true that one cannot transfer what one does not have but the NPS’ position has been that it has ownership and is legally barred by the Organic Act and other statutory authorities from transferring ownership. The only formal expression of this NPS position is a condition imposed on permittees that reads: “Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property... Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization.” The scientific community has objected to this provision for nearly two decades but has not succeeded in persuading the NPS to eliminate it from the permit conditions. The NPS continues to insist that it has ownership and is legally prohibited from transferring ownership.

For the sake of argument, if the NPS is correct in alleging that it has ownership but is legally barred from transferring ownership (and we most say most emphatically that this assertion is not correct because the NPS does not, according to the Supreme Court, have ownership and because there are no laws barring transfer of ownership), then the benefits-sharing proposal must fail in its entirety. The fact is that the transaction that triggers benefit-sharing is the removal of natural resources from the parks; the transactions contemplated by the benefits-sharing proposal involve research and development, usually in a manner that consumes (destroys) the resource. Thus, the NPS is giving full dominion and control over the resource to the researcher. The CRADA (Appendix A) does not specify that the NPS retains ownership of the physical specimen or any part of the specimen that is the underlying basis for the agreement. The CRADA does not prohibit destruction or consumption of the specimen, or any part of it, nor does the CRADA require return of the specimen or any part of the specimen that is not consumed, destroyed, or altered in research or development. The CRADA, in fact, talks only of the intellectual property, ignoring the fact that without the transfer of a physical specimen, with all the rights of ownership, there could be no CRADA. In fact, they are part and parcel of one transaction; to

discuss the impacts of benefits-sharing without discussing the impacts of the underlying transaction is misleading.

The NPS benefits-sharing policy has to rest on the factually and legally implausible basis that giving personal property with full authority to make such use of that property as the recipient may wish, including destruction of the property, falls short of a transfer of ownership. Again, our position is that the Supreme Court has made it clear that the NPS does not own the property in the first place, so it does not matter if this transaction, in this manner, constitutes a transfer of ownership. We belabor the point only to demonstrate that under the NPS’s [mis]interpretation of the law, it cannot transfer ownership of park resources, and therefore, these transactions are legally prohibited and that furthermore, the DEIS is inadequate.

We recognize that the DEIS states that the benefits-sharing agreement does not modify existing regulation. That is true, but only because there is no regulation providing that the NPS has ownership, or retains ownership, of natural resources removed from the parks for research purposes. It is only through a permit condition – which we maintain is based on a faulty legal assertion of ownership – that the NPS imposes this requirement.

The DEIS is thus factually and legally inadequate in describing impacts in that it fails to make clear that natural resources will be removed from the parks, virtually always permanently and in a manner that constitutes a relinquishment of dominion and control so as to constitute a transfer of whatever ownership the NPS has or claims to have.

The CRADA, in fact, does not address the physical resources at all. Instead, it focuses on the value of the intellectual property or commercial value of the applications developed from the scientific study of the specimen. No commercial use may be made of the specimen itself, i.e., rocks or plants collected in the parks may not be sold. Nonetheless, the fact remains that in allowing the researcher to remove a specimen from the park, to study it with methods that may destroy or modify all or part of the specimen, and to retain the specimen permanently, the NPS has, in fact, transferred ownership of the specimen. That the DEIS fails to acknowledge this in its analysis of impacts or elsewhere in the document is a failing of the analysis itself. In fact, section 4.4.6 (at p.146) states, “Alternative B would not result in the temporary or permanent loss of any resources.” This is a physical impossibility in cases where the materials removed from the park are destroyed or altered in the course of the scientific research – which is likely to be the case in CRADA-related transfers.

We wish to make clear that we do not of course object to the removal of natural resources from the National Parks, whether under benefits-sharing agreements or for academic research. Such transfers must, of course, be consistent with NPS stewardship obligations under the Organic Act and other laws. It is our contention that the permanent and professional curation and storage, as well as professional scientific services that document the biodiversity of the parks – fully satisfies the stewardship obligation. The researchers we represent and the institutions with which they are affiliated provide these services to the NPS. If the removal and eventual destruction of park resources can be consistent with good stewardship, then surely the professional and permanent curation of the physical specimen and the scientific knowledge it yields is also consistent with good stewardship practices. However, an analysis of impacts that fails to acknowledge that the activity entails the permanent removal of natural resources from the National Parks and to assess the impacts of that activity is a faulty analysis.

*The impacts analysis is inadequate in failing to discuss the potential impacts of the benefits-sharing agreements on non-commercial scientific research in the National Parks*

In discussing the preferred alternative at ES.2.2 (page xiii), NPS states that the NPS has identified four types of non-monetary benefits that could occur under some or all benefits-sharing agreements. These are: knowledge and research relationships, training and education, research-related equipment, and special services, such as laboratory analyses. These are all benefits provided by the research community to the NPS as outcomes of the scientific collecting of research specimens. Researchers perform the specialized and costly analyses of specimens and through their professional curation, safeguard the specimens and preserve the knowledge derived from those specimens. Even the storage space provided for the millions of specimens collected in the parks – space that the NPS itself does not have – is a benefit provided to the NPS. The NPS pays for none of these services, except in very rare instances. Thus, in the case of research specimens that are not collected for commercial purposes, most of the benefits flow to the NPS. The NPS itself appears to recognize this fact in saying (at p.77) that “The NPS has statutory direction to inventory park biodiversity, and over the long term the contribution of personal services toward this effort by non-NPS scientists and experts has been significant. Much of the funding has come from non-NPS sources, as well.” The NPS also acknowledged that these scientists generally provide the largest single input of new knowledge parks receive. Regardless of the direction and balance of the flow of benefits, however, the point is that it appears that this DEIS may apply as much to the scientists we represent and to their research activities as it does to commercial interests such as bioprospectors.

There is good reason to be concerned that the benefits-sharing policy will discourage this academic, non-commercial research, and thus reduce the flow of benefits to the NPS. The sharing of benefits derived from intellectual property resulting from the scientific investigation of natural resources has been a focus of international policy at least since the Convention on Biological Diversity, which addresses the concerns of nations about the exploitation of their natural resources without compensation. While these concerns are valid and need to be addressed, the unfortunate outcome of the good intentions of those who have tried to protect the intellectual property derived from natural resources has been a serious barrier to noncommercial scientific research, as described at length in the attached New York Times article. It has been the experience of the scientists who are the members of the societies that comprise the Ornithological Council, and of other scientists, that they are now experiencing difficulty obtaining permission to conduct scientific research in many countries due to concerns about benefits sharing. In particular, they are having tremendous difficulty obtaining permission to export scientific specimens even for entirely academic, noncommercial research. Some countries have come to be suspicious that scientists will “steal” the value of the intellectual property that is derived from the natural resources, or have become interested only in scientific research that has the potential to return benefits.

Congress, by way of the 1998 National Parks Omnibus Management Act §§ 1593-1596 mandated that the NPS encourage scientific research in the National Parks. As we have stated publicly and to the NPS directly, the NPS has generally done an admirable job in meeting that mandate. The Natural Resource Challenge created many opportunities for scientists to work in the National Parks and has largely succeeded in establishing and implementing the “parks for science” principle.

It is plausible, if not likely, that the benefits-sharing agreements will have a detrimental effect on the efforts of academic (noncommercial) researchers to conduct research in the National Parks. First, they may be discouraged or daunted by the prospect of having to enter into a benefits-sharing agreement because the research may lead to commercial developments in the future. Second, the NPS itself, with its ever-diminishing funding and staffing, will have to divert resources and staff to managing the benefits-sharing system. They may give priority to the administration of research that involves a benefits-sharing agreement over research that does not. Third, and most significantly, the NPS must consider the environmental impact of all permitted activities. If two (or more) proposals would impact the same resource, the NPS may give priority to the activity that involves a benefits-sharing agreement over one that does not. Thus, creation and implementation of a benefits-sharing program may lead to the reduction of non-commercial scientific research in the National Parks – which surely contravenes Congressional directive and intent and that will undermine the NPS very laudable Natural Resource Agenda.

Furthermore, the potential impact of the benefits-sharing policy on noncommercial research may reduce the very substantial flow of benefits, described above and acknowledged by the NPS in the DEIS, to the National Parks. In order to perform the inventories mandated by the Omnibus Act, for instance, the NPS may have to contract with scientists to perform the services and provide the expertise that are currently provided at no cost to the NPS. The NPS may not have the necessary funds to do so, leaving inventories incomplete.

Of concern to the scientific research community and to the public is the potential loss of the value of the intellectual property derived from the natural resources in the parks. If noncommercial researchers are precluded or discouraged from working in the parks, these resources may never be studied. Valuable information that could benefit society in myriad ways may be left undiscovered. The benefits-sharing agreements may also encourage the NPS to limit access to natural resources for academic study, because the prior discovery of valuable information in non-commercial research may undermine the value of benefits-sharing agreements. There is a very real incentive for the NPS to favor research involving benefits-sharing agreements over academic research.

It is not entirely clear if the DEIS and the benefits-sharing agreements contemplated by the National Park Service (NPS) pertain to the noncommercial, academic research conducted by the members of the organizations we represent. The DEIS originated from the intent of the NPS to engage in the issuance of CRADA under the Federal Technology Transfer Act (FTTA). The NPS issuance of a CRADA to the Diversa Corporation in 1998 spurred litigation that resulted in a decision by the United States District Court for the District of Columbia that the NPS must first prepare an environmental impact statement. *Edmonds Institute, et al., v. Babbitt, et al., 42 F.Supp.2d 1 (DDC 1999)*. This history, together with the 21 June 2001 benefits-sharing newsletter [“Usually, “benefits-sharing” refers to agreements between biodiversity prospectors (sometimes called bioprospectors) and the National Park Service that return benefits to the park when the results of cooperative research lead to the development of something that is commercially valuable”] suggest that the NPS is focusing primarily on research conducted for the purpose of identifying commercially valuable resources. Further, the need for a benefits-sharing agreement is explained under the Preferred Alternative (Alternative B) in terms of commercial applications: “...if research activities involving research specimens collected from units of the National Park System resulted in useful discoveries, inventions, or other

commercially valuable applications, a benefits-sharing agreement would be required to provide the terms and conditions for sharing with the NPS benefits resulting from their further development and use." (*emphasis added*). Section 2.4.1, at page 41. In other places, however, the DEIS is less clear. For instance, at page 12, it states that the benefits-sharing guidance is needed to address "the NPS's interest in the financial and other benefits from the results of research involving park research specimens." This distinction between financial and "other" benefits implies that the benefits of academic research are among those that will or may be covered by benefits-sharing agreements. Further, section 2.7.3 (page 57) relates an alternative that was considered but not analyzed: Exempt Academic Researchers from Benefits-sharing Agreements. This section states that "Because many university researchers are supported or otherwise affiliated with corporate or other for-profit research institutions, there is no rational basis for an across-the-board benefits-sharing exemption for academic researchers...To exempt all academic researchers from benefits-sharing agreements could also create unintended loopholes for those supported or otherwise affiliated with corporate or other for-profit research firms."

The potential commercial value of a resource may not be contemplated or recognized at the time the resource is first collected. The DEIS implies that a CRADA (which we use here to refer to all benefits-sharing agreements, whether arising under the FTA or otherwise) may or will be required for every collection of resources, for all purposes, including the development of noncommercial (i.e., traditional, academic) scientific knowledge.

*Conclusion*

The natural resources found in the National Parks, which are owned by the American people, should be made available for scientific research, subject to the stewardship obligations of the National Park Service imposed by the NPS Organic Act and other statutory authorities. A benefits-sharing policy, however, may not be in the best interest of scientific research or to the public that benefits from that research and may prove detrimental to the NPS' effort to meet the Congressional mandate to make the National Parks available for scientific research. This DEIS fails to accurately assess the impacts both to the natural resources and to scientific research.

We hope that our input proves useful to the NPS in completing the development of its benefits-sharing policy, and thank the NPS for considering our comments.

Sincerely,  
  
Elijen Paul  
Executive Director

May 7, 2002, Tuesday

SCIENCE DESK

**Biologists Sought a Treaty; Now They Fault It**

By ANDREW C. REVKIN (NYT) 2090 words

A treaty enacted nine years ago to conserve and exploit the diversity of species on earth is seriously impeding biologists' efforts to catalog and comprehend that same natural bounty, many scientists say.

They say the treaty has spawned paralyzing biological bureaucracies built on the widespread belief that any scientist collecting samples -- whether for a drug company or a dissertation -- is bent on stealing genetic material and making a fortune.

As a result, biologists say, in many tropical regions it is easier to cut a forest than to study it.

"Something that was well intentioned and needed has been taken to an illogical extreme," said Dr. Douglas C. Daly, a curator of Amazonian botany at the New York Botanical Garden, who has worked in Brazil for 20 years in partnerships with Brazilian scientists, but recently had to wait a year and a half for a new research visa.

"The net result has been that it's kept biologists out of the forests," Dr. Daly said. "That plays into the hands of the forces of uncontrolled development. If a tree falls in the forest and there's no biologist there to hear it, it definitely doesn't make a sound."

Some officials in restrictive countries have begun to concede as much. For example, Brazil, which in 2000 stopped all exports of biological samples, even to Brazilians working abroad, has convened a National Council of Genetic Resources charged with finding a way to resume controlled exchanges.

The parties to the treaty, the Convention on Biological Diversity, met last month in The Hague and adopted voluntary guidelines aimed at distinguishing between "bio-prospecting" and basic science. But the parties, numbering 183, have yet to negotiate the details, and even after they are complete, signers are free to maintain existing rules.

The United States was involved in the talks, and the Clinton administration signed the treaty. But the Senate, lobbied by agriculture and drug companies, has never approved it. The Bush administration is reviewing whether to pursue ratification.

Scientists and some officials from restrictive countries agree that the solution is a regulatory system that is more streamlined for scientists who cede any right to profit from their findings. But creating such a system may be nearly impossible, because many universities, botanical gardens and other research institutions, besides conducting basic studies, also seek to exploit discoveries and, sometimes, have partnerships with drug companies.

In many countries, the fight against what is called biopiracy has proved politically popular, linking the interests of conservative nationalists, indigenous tribes and anti-globalization groups. In the hinterlands, the police and, sometimes, rural villagers have detained or chased out scientists.

Over the decades, there have been just enough examples of furtive expropriation of natural resources to fuel such fears, scientists say. Those include Brazil's loss of its rubber monopoly to Britain in the 19th century -- rubber trees thrived in British-controlled Malaysia -- to recent efforts by some companies to commercialize substances from tropical plants and animals without seeking permission or paying royalties.

Some countries are so eager to thwart biological thievery that they are going beyond the vague terms in the treaty.

At a meeting in February in Cancún, Mexico, representatives of Brazil, China, India, Mexico and nine other countries -- together controlling perhaps 70 percent of the world's biological diversity -- formed the Group of Allied Mega-Biodiverse Nations. The coalition would, among other activities, certify "the legal possession of biological material" and negotiate terms to transfer it.

Existing and proposed restrictions in countries with biological resources are all aimed at controlling research by drug and biotechnology companies. But evidence has grown that they are harming the most basic field work, even observational studies of wildlife in which nothing is taken away. The restrictions not only affect northern scientists probing southern forests, but also local scientists.

Dr. Ricardo Callejas, a professor at the University of Antioquia in Medellín, Colombia, specializes in the 2,000 species in the black pepper family. Dr. Callejas said fears of biological theft seemed particularly intense in South America, adding that it was "much, much easier to get permits for collecting in the Philippines and Vietnam" than in Colombia.

His discipline is taxonomy, basic analysis of the subtle differences among species and a field with little commercial appeal. Even so, Dr. Callejas said, he and his graduate students had been accused of biopiracy and booted from one village while on a collecting trip. He added that he longed to collect in a dizzyingly rich area in western Colombia, the Choco forests, but that the treaty had made the effort impossible.

"If you request a permit," Dr. Callejas said, "you have to provide coordinates for all sites to be visited and have to have the approval from all the communities that live in those areas. Otherwise, go back to your home and watch on Discovery Channel the new exciting program on dinosaurs from Argentina. I am still waiting after 14 months for a permit for collecting in Choco."

Delays, fees and research restrictions in countries like Brazil and provinces like Sarawak, the Malaysian part of Borneo, have caused many scientists simply to abandon the critical, difficult work of charting the still largely unexplored maze of species.

In some cases, scientists have been detained and their collections destroyed. In the Brazilian Amazon in 1998, an American geographer studying the forest for hints of ancient cultivation

methods was placed under house arrest by the federal police in Santiaem, and his boat, equipment and samples were seized.

The scientist, Joseph M. McCann, who now teaches at the New School for Social Research in Manhattan, had all the appropriate permits and visas. He said that he eventually got back his gear and the title to his old riverboat, but that most of the collection of pressed plants rotted because the police had stored it outside. The plants had been destined for a Brazilian herbarium, not a pharmaceutical laboratory, he said.

Graduate students and postdoctoral researchers have been affected most of all, from both developing countries and from the North.

At the New York Botanical Garden in the Bronx, André M. Amorim, a visiting botany professor from the State University of Santa Cruz in Bahia, Brazil, has had trouble completing his doctoral research because of the ban on shipping even the tiniest leaf fragment.

His work focuses on Brazilian lianas and related vines and shrubs, and it requires advanced molecular and genetic analysis using equipment in New York.

"This is a real problem when Brazilian researchers are working in other countries," Mr. Amorim said.

In some places, restrictions have forced biologists to pack up and leave or to avoid the least-studied regions like the Amazon, where the classification of species lags, and focus on more accessible places like Hawaii or Puerto Rico.

In Sarawak, Dr. Navjot S. Sodhi of the National University of Singapore abandoned a project to survey the bird species in several national parks after tighter research restrictions took effect in 1998.

"Sarawak is the best place on earth to work, because there's so much rain forest left and the people are so nice," Dr. Sodhi said. "They provided free workers to help us, and we trained them in return and hired local guides. We were only collecting blood samples from birds to look for parasites and also collecting bird feces to study their diets."

But word spread that a potential AIDS drug had been discovered in the region. New rules greatly complicated his program, he said. "Now, to collect bird feces we had to get an export permit."

Officials began harassing his students.

"I couldn't take the nonsense any more, and we pulled out," Dr. Sodhi said. "I was willing to sign anything saying that we were not doing any bioprospecting."

But there was nothing to sign.

Officials at some companies that are sifting ecosystems for potential profits say it is appropriate that scientists from universities and other academic institutions play by the same tight rules.

"Academics have been kind of naive to the question of ownership of genetic material," said Eric J. Mathur, senior director for molecular diversity at Diversa, a company in San Diego that works around the world to find enzymes and other substances that could make valuable drugs or other products. "They think that under the guise of academia they can do whatever they want. But if their work results in any kind of invention -- and most come serendipitously -- you can be sure their institution will want to own it and make money from it."

Mr. Mathur said that the last year or so had finally seen the biodiversity convention "start to come of age." In a growing number of countries, he said, the general precepts of the convention have translated into workable contracts that, for the first time, clarify who owns what and how any benefits will be shared.

But many scientists and some officials say there is clearly the need for a system with two tracks, to separate and simplify work that clearly has no commercial application.

The impetus for the treaty, scientists note ruefully, arose largely from biologists, who in the late 1980's powerfully promoted the notion that rain forests could turn out to be medicine chests for the world. But the promise has rarely turned into profits, with just a handful of drugs and products reaching markets.

"It's never really panned out and was totally oversold," said Dr. George Amato, director of the conservation genetics program at the Bronx Zoo.

Dr. Amato's program has frequently been stymied in helping foreign researchers identify animal species and strains through using genetic analysis, because no material can be sent abroad. In one such effort, aimed at identifying a strain of yellow-headed Amazon parrots, the DNA ended up being tracked down in a stuffed museum specimen.

The worst side effect of the biology restrictions, many experts say, is that young researchers are being driven away from important ecosystems and fields of study.

In 1999, Christiane Ehringhaus, a German botanist pursuing a doctorate at Yale, was teaching Brazilian students and studying plants in the state of Acre in the Brazilian Amazon when newspapers implied that she was collecting seeds and insights from indigenous people in pursuit of potential drugs.

Although she is still in Acre, Ms. Ehringhaus said the resulting difficulties had prompted her to abandon botany altogether and shift to social and economic studies.

"First," she said, "they drove me completely away from medicinal plants and now from plants, period."

Prof. John H. Barton of the Stanford Law School, an expert on the biodiversity treaty, said the biggest weakness in the pact was its focus on biology as property. "It is much more about sharing the profits from genetic resources than it is about conserving biodiversity, about science," Professor Barton said.

Around the world, that focus has translated into warped expectations and suspicions, Dr. Callejas said in Colombia.

"I have trouble convincing my closest friends that what I do is because of passion, curiosity, a desire to know more about a group of organisms," he said.

Everyone around him, he added, is convinced, with all the talk of property rights and miracle drugs, that it is about money.

"The convention," Dr. Callejas said, has produced a "distorted view of what science is and who scientists are. And so now, we are the problem, not the solution."

*Received 1/26/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

I, Kevin Winker, Curator of Birds of the University of Alaska Museum of the North (the State of Alaska's bird collection), submit the following comments on the Benefits-Sharing Draft Environmental Impact Statement (DEIS):

I am very frustrated by the NPS's apparent inability to deal effectively with the highly contentious specimen ownership issue. Many in the museum community have been at odds with this issue for many years. NPS assertion of ownership is unique among the Federal land management agencies that I regularly deal with, and, as the comments from the Ornithological Council demonstrate, stem from a dubious legal basis. The cloud that this issue causes to overshadow NPS relationships with scientists has strong negative effects: it discourages specimen-based scientists from working on NPS lands the opposite effect intended by the 1998 National Parks Omnibus Management Act, which encouraged scientific research in National Parks.

The benefits that NPS is spurning by not effectively dealing with scientists on this issue are myriad. Two publications treat just some of these benefits: Suarez, A. V., and N. D. Tsutsui. 2004 (The value of museum collections for research and society. *BioScience* 54:66-74); and Winker, K. 2004 (Natural history museums in a postbiodiversity era. *BioScience* 54:455-459).

To see specimen-based scientists treated fundamentally differently than other consumptive users of NPS flora and fauna is insulting, and it operates against the interests of NPS itself in obtaining an improved understanding of these resources. And these are renewable resources. Fishermen, subsistence hunters, berry pickers, and now commercial developers of NPS biological resources are apparently all more important to NPS in this regard than scientists who collect specimens to learn more about our public resources. This has to change! It clearly discriminates unfairly between user groups that have similar consumptive effects on Park resources.

The DEIS further undermines the role that museum researchers might play in enhancing our understanding of national biological resources. The Ornithological Council comments provide pages of detail on how this is likely to play out; the New York Times article appended to the the OC's comments shows how similar directions in permitting have greatly hampered biodiversity scientists elsewhere.

Several years ago, Dan Gibson and I assessed the specimen-based knowledge of birds in Alaska's National Parks and found that this index was AN ORDER OF MAGNITUDE

LOWER in Alaska's National Parks than on other Federal lands in this state. This reflects a longstanding rift - in part due to ownership issues - between specimen-based scientists and NPS. Insofar as this rift seriously retards the development of important new information about avian resources (at least) on National Parks (again, an order of magnitude lower than other Federally managed lands in this state), NPS needs desperately to re-examine how its policies in this arena are working directly against its missions to be effective stewards of public resources and to promote scientific investigation in National Parks.

In sum, this DEIS has fundamental flaws stemming from ownership issues that need to be effectively dealt with BEFORE (not after) development of a new permitting structure aiming at commercial bioprospectors. Ultimately, NPS cannot continue to unfairly discriminate between different consumptive users of the biological resources in our National Parks. Policies that presently put noncommercial scientists who return substantial benefits to the NPS well behind fishing, subsistence hunting, and bioprospecting are in the long run damaging to our public resources.

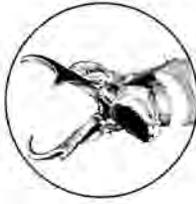
Sincerely,

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29 January 2007

NPS Benefits-Sharing EIS  
PO Box 168  
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To Whom It May Concern:

The following is a response on behalf of the American Society of Mammalogists to the Benefits-Sharing Draft Environmental Impact Statement issued by the National Park Service in September 2006. The American Society of Mammalogists was founded in 1919. It is the world's oldest and largest organization devoted to the study of mammals. We strongly support the conservation and responsible use of wild mammals based on current, sound, and accurate scientific knowledge. We have a long history of adopting positions on issues concerning the responsible management of mammals, their habitats, scientific collecting, care of research collection, and conservation issues based on our collective scientific expertise.

We feel that this Environmental Impact Statement is flawed because the underlying assumptions concerning ownership of all items (including wildlife) located on parks are erroneous. National Park Service policies based on those false assumptions create significant hardships for the scientific community. These policies also are counterproductive for the National Park Service because they hinder the acquisition of information necessary for management of the biological resources found within the parks. Management and conservation decisions need to be based upon data collected and analyzed by the scientific community working in conjunction with park managers and the National Park Service should be establishing policies that encourage scientific study in the parks.

Although operational definitions of "wildlife" differ from state to state, the underlying concept concerning the ownership of wildlife in the United States is that the People (citizens) own wildlife, which is under the stewardship of the individual states for the benefit of their citizens. Stewardship exceptions focus upon migratory, threatened, rare, or endangered species found in the United States that are regulated (but not owned) by the federal government. The Office of the Solicitor, U.S. Department of the Interior must be aware that this concept is well established.

American Society of Mammalogists RE: NPS Benefits-Sharing EIS Page 2

Implicit in the document under review is the concept that the National Park Service owns wildlife on the lands that it manages. If this false premise were true, the National Park Service would be unique among all land-owning, land-managing, and tenant institutions, organizations, and individuals having control of land in the United States. Current policy of the National Park Service appears to be based on the false precept that anything (including wildlife) found on federal lands is, *ipso facto*, federal property.

Current National Park Service policy concerning scientific collections of wildlife clearly must be considered an action that restricts research activities that could improve understanding of park resources (see statement under ES.3.1 on page xvi). Researchers, especially those based in colleges and universities, are reluctant to expend time, effort, and money (especially scarce state and federal funds) to work on National Park Service lands when the specimens vouchering their work are claimed as property by the National Park Service.

Reference note 27 (cited on page 13 of Chapter One and explained on page 32) states, "Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property." Aside from the non-scientific and anti-science implications in that statement, current National Park Service policy requires that the specimens must be kept with National Park Service labels and apart from other collections; that National Park Service permission must be obtained before any researcher can examine them; and the specimens cannot be transferred to a third party. This perception of ownership is maintained even when non-National Park Service public or private funds are used to support the research vouchered by the specimens themselves.

The National Park Service false premise of ownership of wildlife and subsequent control of biological specimens collected on National Park Service lands also is contradicted by the language in the Organic Act of the United States Geological Survey. There is nothing in the NPS Organic Act that implies ownership of wildlife. Management responsibility yes, but not ownership.

If an alternative must be chosen, it would have to be Alternative A. However, as explained here such a decision is based primarily on the erroneous perceptions concerning National Park Service "ownership" issues. Instead, if a benefits-sharing partnership were to be established based on the commercialization of wildlife or any wildlife derivative, that partnership should be with the governments of the States involved for the benefit of their citizens who are the real "owners" of wildlife in the United States.

Thank you for your consideration of these issues. The American Society of Mammalogists would be happy to provide additional information as you continue with your efforts to develop sound management policies for our national parks.

Sincerely,

  
Dr. Robert M. Timm, President  
American Society of Mammalogists



**National Parks Conservation Association**  
*Protecting Our National Parks for Future Generations*

Benefits-Sharing DEIS Team  
P.O. Box 168  
Yellowstone National Park, WY 82190

January 29, 2007

Dear Reviewer:

On behalf of the National Parks Conservation Association, we appreciate the opportunity to submit comments on the Benefits Sharing draft Environmental Impact Statement.

Formed in 1919, NPCA's mission is to protect and enhance America's National Park system now and for future generations. NPCA and our 325,000 members have a long-standing interest and involvement in the Benefits Sharing issue, as it applies to icon national parks such as Yellowstone, and across the national park system.

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The nation's parks contain some of the world's most pristine natural resources, many of which are found nowhere else in the world. A substantial number of these resources have not yet been adequately studied. For example, a rough estimate tells us that 99 percent of Yellowstone's microbes have not been studied or named. The study of life in our national parks is an important use of national parks.

NPCA believes that the parks should be available for such research, subject to appropriate limitations. Research in parks is among the most important means of demonstrating not only the value of preserving parks, but also of preserving other elements of our natural heritage.

We appreciate the willingness of NPS staff, especially from Yellowstone (Sue Mills in particular), who have been generous with their time and expertise in answering our questions on this issue.

Following are NPCA's general and specific comments and concerns regarding the dEIS:

**I. General**

The notion of developing Benefits Sharing agreements raises many significant, and legitimate, questions and concerns relative to exploitation and commercialization of parks. We believe that the alternative that best upholds NPS policy and regulation, protects parks and visitor experience and also provides for full public disclosure of Benefits Sharing agreements is Alternative B1. NPCA's general position on the Benefits Sharing issue is as follows, and several points will be more specifically addressed following the general comments.

The National Parks Conservation Association supports benefits sharing agreements between the National Park Service and research entities as described under Alternative B1, under the following conditions:

- 1) Park resources will not be directly or indirectly adversely affected as a result of implementation of a benefits sharing agreement. Further, research activities cannot diminish visitor experience. All park resources must remain unimpaired for future generations.
- 2) The NPS process for negotiating and entering into benefits sharing agreements must be transparent - fully open and accessible to the public. The public should have the right to view any agreement, including the agreement's financial terms and the underlying research permit. NPS serves as the trustee of these national treasures that belong to the public. Only through an open process governed by full public disclosure can NPS hope to alleviate skepticism and concerns regarding commercialization of these treasures, and gain public support.
- 3) Any and all scientific information resulting from any agreement must be provided to the NPS. While monetary compensation should be a part of a benefits sharing agreement, the NPS should focus on securing benefits that help NPS and the public protect park resources and further understanding of our natural environment. Furthermore, it is imperative that NPS assure any final decision includes foolproof internal mechanisms which suppress any

temptation of park managers to enter into such an agreement based upon park financial needs in other operational areas.

4) Monies that are received as a result of benefits sharing agreements should be employed to directly benefit resource protection, as opposed to other park needs or other general government budget items. They cannot and should not be viewed as a revenue stream that substitutes for Congressional budgetary support of the park.

5) No benefits sharing agreement should be developed that results in resources being used for commercial purposes in violation of 36 CFR § 2.1 (c)(3)(v). Any research contemplated under Benefits Sharing agreements cannot result in the direct commercial use of those samples removed from parks.

## II. Specific Issues and Concerns

### 1) Disclosure of Benefits Sharing Agreements

A) *Reasons given in the 'impact analysis' regarding negative impacts of Alternative B1 do not comport with the Purpose and Need for the EIS.*

Pages 122-123 of the dEIS disclose possible effects of alternative B1, including: 1) limiting payment equitability, 2) creating an artificial 'rate ceiling', 3) discouraging some research, and 4) discouraging establishment of benefits-sharing agreements. The dEIS also states that "mandatory disclosure would limit the NPS's ability to negotiate 'equitable' performance-based payment rates..." The dEIS also suggests that full disclosure "...could affect the amount and timing of monetary benefits actually provided to the NPS." Finally, the dEIS suggests that alternative B1 could reduce the number of benefits sharing agreements because researchers would not want to disclose certain information, and that this alternative may require disclosure of information "...that could otherwise be exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA)..."

The stated "Objectives of the Proposal and its Alternatives (The Purpose of the EIS)" (dEIS, pp. 14-17), include: 1) Identify the role, if any, of the NPS in the event a researcher wishes to commercialize his/her research results involving study of NPS research specimens, 2) Strengthen conservation and protection of resources managed by the NPS by deepening understanding of biodiversity and physical and biological processes, 3) Ensure that the NPS research permitting process is independent, objective and unaffected by actions proposed in this dEIS.

The impacts disclosed regarding alternative B1 focus on the possibility that NPS may not be able to gain the maximum dollar return in a benefits sharing agreement and the possibility that some researchers would be discouraged from either research or pursuing a benefits sharing agreement.

Given the stated purpose and need for this EIS, none of the stated impacts are valid reasons for not selecting alternative B1. Maximizing profit and maximizing research in the park is not the stated reason for undertaking this EIS, in fact, they may even run counter to the purpose and need for the EIS.

NPCA supports a plan that provides a consistent, fair and open process for developing benefits sharing agreements that assure park resources and visitor experience are not impacted, and one that makes the conscious decision with promoting appropriate research with the public's right to understand the full details of agreements. Alternatively, we would be gravely concerned about a plan that is driven by a focus on maximum monetary gain and/or maximizing research at the expense of one or more of these core issues. As such, it is clear that the stated impacts of Alternative B1 are not consistent with the Purpose and Need for the EIS.

Despite the stated concern over less revenue, the dEIS then closes its impact analysis on p. 123 by declaring that "...it is anticipated that any potential loss of monetary benefits is captured within the estimated range of monetary benefits presented in this dEIS."

B) *Alternative B1 Impact analysis issues are not significant enough to warrant selection of a different alternative.*

National Parks are set aside as icons of America's history and natural wonders. The public has a tremendous stake in these special places, owned by every American, and the duty to preserve an open government and provide a full understanding of the details of the government's negotiations on the public's behalf, and with the public's resources, is absolutely essential to this process. Full disclosure is even more important as it applies to Benefits Sharing, given the significant amount of existing public skepticism over the potential for inappropriate commercialization and the need to continue building public support for the program.

The dEIS suggests that full disclosure could go beyond FOIA's requirements, and that some sensitive information could be made available in the public realm and possibly fewer benefits sharing agreements could be developed and less revenue could be generated under Alternative B1. NPCA believes that, were these the real 'impacts' of selecting alternative B1, that would be an acceptable tradeoff. Because of what they are—national treasures that must remain intact for future generations—the impacts listed are certainly an acceptable tradeoff. The tradeoffs discussed for alternative B1 are acceptable when weighed against the public's right to know the full details of benefits sharing agreements that involve national park resources.

C) *Types of information that should be disclosed to the public*

NPCA understands that there may be some items relative to disclosure that may be of no interest to the public but may be the type of information that could be damaging to a researcher. It is appropriate to further define the types of information that should be disclosed.

However, we disagree with 2.3.4, "Protected CRADA Information" in the Model CRADA (Appendix A, p. 190), and we believe that language should be struck from the model CRADA. We believe that this language would allow a researcher to shield important information related to financial terms that would make it difficult for the public to understand the financial terms of the agreement. We are similarly concerned about 10.3, "Protected CRADA Information" (dEIS, p. 199), which we believe could result in the loss of the knowledge gained from the research conducted under the CRADA to the public. Since sharing the results of research conducted using park resources is one of the most

important benefits to be gained in the benefits sharing agreements, we oppose being able to designate any "Generated Information" as "Protected CRADA Information." This section should be rewritten to assure all research conducted under the terms of the CRADA and research permit are available to the NPS and the public.

NPCA is not interested in the public release of trade secrets or personal information, tax records, or information about the researcher's company or organization, such as Background Intellectual Property (as defined on p. 189), or other inventions that have no direct connection to the research, for which the research permit is issued.

In addition to the terms set forth in the Model CRADA (other than the points mentioned above), Appendix A (dEIS p. 185), NPCA is specifically interested in the agreement's financial terms, including royalty rates, up front payment rates, and the underlying metrics used to derive an agreed upon cash payment. It is also important to understand a detailed description of the biological materials, the discovery or development, process, function, anticipated use and market for the product. We would also like to see a detailed description of the non-monetary benefits provided to the NPS to be included in the CRADA. Finally, all reports made by the company and all subsequent audits (as described in the Model CRADA, 4.4 "Records", p. 193) conducted by NPS, or NPS agent, must also be made available for public review.

*D) Third party review/audit*

Section 4.4, "Records" provides NPS the opportunity to select an auditor to examine a collaborator's books and records to verify reports by the collaborator. NPCA requests that this provision be extended to an agency or organization acting in the public interest. Third party scrutiny and oversight will assure the public that agreements are being followed and the public is receiving the full benefit described in the CRADA.

2) Guarding against inappropriate influence and commercialization  
NPCA supports the provisions of alternative B1 that help guard against inappropriate influence of potential benefits on the issuance of research permits and also measures proposed to guard against commercialization of parks. While it is clear that commercial use of park resources is already expressly prohibited, we remain concerned that this prohibition could be eroded with the wrong decision. We therefore support the ongoing commitment to separate the research permitting process from the negotiation of benefits sharing agreements. In addition, we support the additional mitigation measures identified for Alternative B1 that will further secure against motivation to issue research permits based on benefits sharing agreements. This includes:

- 1) The assurance that separate individuals would manage preparation of research permit issuance and benefits sharing negotiations.
- 2) Full compliance with NEPA and public disclosure for each Benefits Sharing agreement. Only through a full, transparent and open vetting process will the public be able to understand the impacts, benefits and tradeoffs associated with individual benefits sharing agreements.
- 3) Full compliance with NPS regulations and policy directives to assure that park resources are protected against impairment or other adverse impacts.

- 4) NPCA believes that the rigorous research permit review process currently used in Yellowstone, outlined on p. 144 of the dEIS, should be applied to the entire NPS system, with the addition of peer review of research proposals.
- 5) Assuring that research permit issuance precedes the development of a benefits sharing agreement.

In addition, we request that NPS consider additional mitigations that will help guard against inappropriate, repeated collection of park materials. We are particularly concerned about the possibility of a researcher returning to the park with a request for a new research permit following successful development of a commercial application from research conducted on samples previously collected. To avoid this, we request that research permits specify that no collection of duplicate samples, whose purpose is to collect more of the same material as previously collected, will be permitted.

Also, the research permit review process outlined on p. 144 provides only for an internal NPS review. We request that this review process explicitly state that NPS will also seek outside academic peer review of research permit applications prior to approval of permit applications. While this may be deemed outside the scope of this EIS, we hope NPS will consider it as appropriate.

3) Types of Benefits to be Shared

We support a focus on assuring for a range of the types of benefits identified under alternative B1. Non-monetary benefits will include: Knowledge and research relationships, training and education, research-related equipment and special services. It is critical that all monetary benefits be dedicated to protection and/or restoration of park resources. While any monetary benefits should be negotiated to assure that the park in question receives a fair return for the use of the public's resources, NPCA is most interested in assuring that the non-monetary benefits described are secured as a first priority, as we believe it is a critical tool to provide the public with new scientific knowledge about park resources. Through the sharing of research, training, education and equipment, non-monetary benefits will provide the greatest overall benefit to the parks and the American public who own these lands.

4) Park Funding and Benefits Sharing

NPCA is acutely aware of the funding shortfall prevalent throughout the national park system and the temptation to view Benefits Sharing as a new revenue stream for parks. We believe that language in the final decision that assures any monetary benefits from an agreement goes towards resource protection or restoration activities and not towards day-to-day operations will help prevent inappropriate use of monetary benefits. However, we would appreciate a more rigorous look at this issue and additional provisions included in the final EIS that will provide better assurances park units cannot use Benefits Sharing revenues for day-to-day operations.

- 2) Exclusion of NPS units where such activity is otherwise prohibited  
Please conduct and disclose appropriate analysis to understand which NPS units may have enabling legislation that contains guidance that would prevail over this service-wide policy.

12515-7463  
page 7 of 7

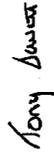
6) Additional Costs associated with development of Benefits Sharing agreements  
NPCA is concerned about the additional costs to be borne by individual parks and the agency as a whole as a result of implementation of Alternative B1. Not only will significant existing staff time and resources be required to develop and administer agreements, but NPS may need additional staff expertise that it currently does not have to assure NPS negotiates the best possible benefits sharing agreement. All staff time and all other costs associated with the negotiation, development and administration of benefits sharing agreements should be reimbursed and included in the benefits sharing agreement, or as provided for under the Federal Technology Transfer Act of 1986.

7) Full NEPA analysis, disclosure and public review  
All benefits sharing agreements/CRADAs must undergo full NEPA analysis, disclosure and appropriate public review in order for the NPS and the public to understand the potential environmental impacts of each agreement.

8) Compliance with Wilderness Act  
Please assure the final selected alternative and EIS complies with all provisions of the Wilderness Act of 1964.

On behalf of the National Parks Conservation Association and our 325,000 members, we appreciate the opportunity to provide these comments on the Benefits Sharing Draft Environmental Impact Statement.

Sincerely,



Tony Jewett  
Senior Director  
Northern Rockies Regional Office



Tim Stevens  
Yellowstone Program Manager

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26 January 2007

NPS Benefits-Sharing EIS  
PO Box 168  
Yellowstone National Park, WY 82190

To Whom It May Concern:

The Systematic Collections Committee of the American Society of Mammalogists (ASM) offer these comments on the Benefits-sharing Draft Environmental Impact Statement (DEIS). The mission of the Systematic Collections Committee is to advise curators worldwide in matters relating to collections administration, curation, and accreditation, and to maintain a directory of all mammal collections in the western hemisphere. The Committee also surveys existing collections approximately once each decade and maintains a list of curatorial standards for managing a collection-accreditation program under the auspices of the Society.

While we feel the ideas set forth by this proposal for a benefits-sharing policy may have some merit, particularly with regard to the development of commercial products, we are concerned that the proposal is worded to the effect (and in fact, much of the ideas presented are based on the premise) that the National Park Service (NPS) owns the wildlife (and products derived from this wildlife) for which it has stewardship and responsibility. An example of such wording is found in reference note 27 (cited on page 13 of Chapter One and explained on page 32) which states,

"Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization....The sale of

2

collected research specimens or other unauthorized transfers to third parties is prohibited."

Such conditions have direct implications for the institutions that house natural history collections that include specimens collected from within national parks. Some (but not all) of the specific potential ramifications of this premise of NPS ownership of specimens collected in national parks include: the recall at any time of any or all specimens ever collected in a National Park by any NPS employee; the need to segregate and separately manage such specimens from other specimens in an accredited scientific collection; the need to obtain permission from the NPS to allow qualified scientists to examine such specimens, or to make available data from such specimens to other parties; and the inability to transfer such specimens to third party scientists or scientific institutions.

These ramifications severely jeopardize the integrity of scientific research collections, the activities they support, and the ability of museum administrators, collection managers, and curators to effectively study and manage these irreplaceable resources. A fundamental tenet of specimen-based scientific research is that specimens should be made freely available for all relevant and appropriate scientific uses; that specimens be sent on loan to researchers at other institutions as standard policy and managed by the museum that houses the specimens; that collections at a single institution be housed in a manner that is integrated and effective for their curation and management; and that specimens not be transferred out of a scientific institution/collection by a governmental or other agency except when there is a clear case for misconduct or mismanagement. Indeed, the policies proposed by NPS could significantly hinder the study and conservation of the biodiversity housed within U.S. national parks by substantially inhibiting the normal conduct of scientific research.

Some years ago, the American Society of Mammalogists passed a resolution (2003, *Journal of Mammalogy* 84(4); pg. 1485) calling for the Department of the Interior and the National Park Service to work with the scientific community in developing a policy that allows the permanent retention of biological specimens collected on National Park Service lands by accredited institutions with a history of curatorial responsibility in maintaining scientific collections. We urge the NPS to address this issue and to work with the scientific community to resolve a policy that is not only unacceptable to that community, but also dangerous for the study and conservation of the irreplaceable resources housed within our national parks. We invite administrators of the NPS to tour an ASM accredited collection and discuss this issue with collection managers and curators of that institution to get more details on why we view this issue as extremely important.

Until this issue of ownership is resolved, the Systematic Collections Committee of the ASM would urge the selection of Alternative A as proposed in the DEIS.

Sincerely,

William T. Stanley  
Chair, Systematic Collections Committee

**Comments**  
 Park: Washington Office  
 Project: Benefits-Sharing in the National Parks (ID: 12515)  
 Document: Benefits-Sharing Draft Environmental Impact Statement (ID: 10763)

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**Comment Form**

City: SEATTLE State/Province: WASH  
 Postal Code: 98144  
 First Name: PHILIP Middle Initial: L  
 Last Name: BERLAND  
 Organization: WASHINGTON BIOTECHNOLOGY ACTION COUNCIL  
 Member:  
 Official Representative: VICE-PRESIDENT  
 Address 1: 3827 S. Mc Clellan ST. SeaTac, Wash. 98149  
 Address 2:  
 Country: USA  
 E-mail: philberland@washingtonbiotech.com, etc

Keep my contact information private

**Rationale:**

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Topic Questions Instructions:  
 Topic Questions:

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**Comments or Requests:**  
 ATTACHED

Many of the National Parks are unique not only in their beauty but in their biodiversity. It is not surprising, therefore, that some species may be found only within them. Some of these species do have properties which can be utilized for human health and well-being. The Washington Biotechnology Action Council (WashBAC), a 16 year old NGO involved in State, national and international issues concerning biotech, has long opposed the NPS-Diversa sort of agreement, an egregious example of the privatization of a public good. Corporate give-aways along these lines are inconsistent with the purposes of the National Parks, and should not be tolerated. We therefore, welcomed the 1998 litigation and the 1999 court decision; it is outrageous however, that it has taken NPS 7 years to do a draft EIS.

The alternatives presented by the NPS do not include the approaches that WashBAC would favor. The modest use of a park's resources for human benefit can be unobjectionable. In the Diversa example, the taking samples of micro-organisms in no way disrupted Yellowstone's ecological stability. The problem was that substantial benefits have flowed to a very limited number of private interests, and this is not a suitable use of a public treasure.

Therefore, among the possibilities presented to us, WashBAC favors Alternative C. We could support a variant of Alternative B which included the following characteristics: a) there would be no ecological disruption from the activity; b) there is FULL public disclosure (no claims of CBI in regard to the public's property); c) the term "commercial" is replaced by the term "private sector"; and d) the proportion of direct monetary benefits is high and significant. We would also not oppose a public entity following such criteria. Since the NPS alternative B does not adhere to these elements, we reject it and urge you to do so as well. We are particularly concerned that NPS has labeled one approach the "environmentally preferred" option when the preference appears to be based on ideological, not environmental considerations.

*Philip Berland*  
 Vice-President  
 Jan 16, 2007



**National Parks and Monuments Committee**

2801 Oakton Manor Court  
Vienna, VA 22124

January 26, 2007

NPS Benefits-Sharing EIS  
P.O. Box 168  
Yellowstone National Park, WY 82190-0168

Dear EIS Team:

These comments are offered on the Benefits-Sharing Draft Environmental Impact Statement.

Units of our national park system represent major ecoregions that are home to the vast majority of the species that make up our natural world. The Sierra Club is very supportive of scientific research occurring in our national parks and aware that on occasion biological resources will inevitably result in discoveries with may have economic, social and environmental values. However, the Sierra Club believes that wildlife and biological resources of the national parks should not be exploited for purely commercial purposes. Yellowstone and the other national parks were designated as national parks to protect them from exploitation and to ensure they are managed "in such manner and by such means as will leave them unimpaired for the enjoyment of future generations."

At present economic benefit arising out of national park research or its resultant commercial use is not required to be shared with the public. The proposal assessed by the Benefits Sharing Draft EIS attempts to address this issue. The Sierra Club recognizes that national parks as repositories of biodiversity, and that scientific research that occurs in the national parks on occasion may end up being important in the development of pharmaceuticals and other commercial products. Since our national parks are owned by the American public, the American public should profit from any commercial applications developed from research in national parks. However, we believe that scientific research permitted in the national parks should be geared to pure science and not commercially-driven science.

The Sierra Club is concerned that the size of the National Park Service scientific staff is very limited at present and that this staff needs to focus its time on science in the public interest, not developing, negotiating and managing Commercial Research and Development Agreements (CRADAs). The Sierra Club has concerns regarding how much time would be taken away from research in the public interest, while NPS officials and outside contractors devote time and money to drafting CRADAs and then monitoring the CRADAs.

The EIS should make clear that the proposed action does not change research permitting procedures and that the findings of all permitted research under all alternatives will continue to be accessible to the public.

The EIS should emphasize the need for permitted research for:

1. Revision in management practices to accommodate species adaptation, habitat change and other factors that have already resulted or will result from climate change;
2. Revision in the management of parts of ecosystems outside national parks necessary to stop, reverse or mitigate adverse impacts, including those that have already resulted or will result from climate change; and
3. Educational use at grade school, high school and university levels, and for the general public.

The EIS should better describe that the benefits of permissible research. The Sierra Club is very concerned over impacts that extractive activities for commercial purposes would have on the 84.4 million acres of the National Park System, including millions of acres now designated as Wilderness Areas.

Thank you for the opportunity to comment. The Club wholeheartedly backs the continuation of important scientific research occurring in our national parks. We, however, have concerns that research with commercial applications, not end up dominating scientific research in national parks because of the financial incentives the National Park Service would receive from this research. Scientific research permits need to be based on the importance of the work not on financial returns to the National Park Service.

Sincerely,

John F. Byrne  
Chair



Public Employees for Environmental Responsibility

2000 P Street, NW • Suite 240 • Washington, D.C. 20036 • 202-265-PEER(7337) • fax: 202-265-4192  
e-mail: info@peer.org • website: www.peer.org

January 25, 2007

National Park Service  
Benefits Sharing DEIS Team  
P.O. Box 168  
Yellowstone National Park, WY 82190

Dear National Park Service (NPS) Benefits-Sharing Team:

Public Employees for Environmental Responsibility (PEER) offers the following comments on the Benefits-Sharing Draft Environmental Impact Statement (DEIS):

**A. Points of Agreement**

**1. The NPS May Enter Into Benefit-Sharing Agreements.**

PEER agrees that the National Parks Omnibus Management Act of 1988 (NPOMA) authorizes the Secretary to "...enter into negotiations with the research community and private industry for equitable, efficient benefit-sharing agreements," resulting from scientific study in the national park system. 16 U.S.C. 5395 (112 STAT. 3500).

**2. This DEIS Cannot Cover All Prospective Benefits-Sharing Agreements.**

The DEIS acknowledges that the National Park Service (NPS) cannot adopt a single EIS that covers all future benefit-sharing agreements. Each proposed specimen collection, or other intrusive research, whether subject to a benefit-sharing agreement, requires NEPA review. It is impossible for a programmatic NEPA document to anticipate, much less assess, the impacts of benefit-sharing agreements throughout the national park system.

**B. The DEIS Ignores Relevant Laws.**

The DEIS misapplies the Federal Technology Transfer Act (FTTA) and disregards the Wilderness Act. We examine each law separately.

**1. Federal Technology Transfer Act of 1986**

The DEIS states that each national park is a "laboratory" in the meaning of the FTFA. Thus, the DEIS reasons, benefit-sharing agreements should take the form of a Cooperative Research and Development Agreement (CRADA), as authorized by the FTFA. PEER does not dispute that the NPS may enter into benefit-sharing agreements (BSAs) under NPOMA. PEER asserts that CRADAs are now an improper instrument for several reasons:

The DEIS quotes the FTFA's definition of a laboratory as "a facility...owned by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government." 15 U.S.C. 3710a(d)(2). While one could stretch the research aspects of the NPS to transform each park into a "laboratory," there is no evidence that the 1986 Act, or its amendments, meant to include each national park system area as a "national laboratory." Nothing in that Act's language or its legislative history refers to a national park system or its areas as "laboratories."

A review of the legislative history reveals that Congress enacted FTFA for the named "national laboratories." Among these are "facilities" operated by the Department of Energy (e.g. Los Alamos National Laboratory, Sandia National Laboratory, Lawrence-Livermore National Laboratory etc.), the Environmental Protection Agency research laboratories, the National Institutes of Health and the Agricultural Research Service in the Department of Agriculture.

If the 1986 FTFA covered the NPS and each park is a "laboratory" in the meaning of the law, then the enactment of benefit-sharing language of NPOMA in 1998 would be unnecessary. Each national "laboratory" park could have entered into CRADAs without the enactment of the NPOMA section that authorizes "benefit-sharing agreements." The DEIS, by relying on the FTFA and CRADAs, implicitly posits that Congress acted superfluously when it enacted NPOMA section 205(d). NPOMA itself makes no reference to CRADAs and the FTFA.

Neither the NPS Director nor the Secretary of the Interior was aware, in the period contemporaneous with the FTFA, that the FTFA governs the national park system as laboratories. If the FTFA governs the national park system as laboratories, the NPS has been in substantial noncompliance with several provisions of that law. In brief the FTFA did the following:

- Made technology transfer a responsibility of all federal laboratory scientists and engineers.
- Mandated that technology transfer responsibility be considered in employee performance evaluations.
- Established principle of royalty sharing for federal inventors (15% minimum) and set up a reward system for other innovators.
- Legislated a charter for Federal Laboratory Consortium for Technology Transfer and provided a funding mechanism for that organization to carry out its work.
- Allowed current and former federal employees to participate in commercial development of the research fostered by the CRADA, to the extent there is no conflict of interest.

The National Park Service, governed by the FTFA since 1986 (if we were to trust the DEIS), has yet to implement a single one of the above actions:



- Where is the "technology transfer responsibility" found in the performance evaluations of employees? The answer, in short, is "NOWHERE."
- Does the NPS Director sit as a member of the Federal Laboratory Consortium for Technology Transfer? NO.
- Has the NPS set up a mechanism to allow current and former federal NPS employees to participate in commercial development of the research fostered by the CRADA? NO

In short, the NPS disregards the CRADA provisions of the FTTA, expect for that portion that may provide a revenue stream or monetary benefits to the negotiating park ("laboratory").

The FTTA language on CRADAs also requires that "an agency shall make separate determinations of the mission or missions of each of its laboratories." 15 U.S.C. 3710a(e). Where is the NPS determination of the mission or missions of the Yellowstone National Park Laboratory, or the Sequoia National Park Laboratory? NOWHERE. The NPS has never made the required FTTA determinations of the mission or missions of each of its nearly 400 separate "laboratories."

The FTTA-CRADA "shoe" does not fit. As the DEIS states, the concept that parks may employ CRADAs arose in Yellowstone in 1998. We suspect it was developed in a burst of creative zeal as the Lab Director (superintendent) of Yellowstone National Laboratory sought a way to reap monetary and other benefits from DIVERSA Corporation's research on thermophiles in hot springs. Yes, a federal Court ruled early in 1999 that parks could enter into CRADAs under the FTTA. But, that stretch of the FTTA occurred without any reference by plaintiffs, defendants or the court to enactment of NPOMA in December 1998. NPOMA now governs "benefits-sharing agreements," (BSAs) not the FTTA. The NPS must leave behind the inappropriate CRADA tool found in the FTTA and use the more relevant, current and park specific law – NPOMA.

**2. The Wilderness Act**

Over 40 million acres of the national park system are designated wilderness. The Wilderness Act states that in wilderness, "there shall be no commercial enterprise," except for "commercial services" necessary for realizing the recreational or other wilderness purposes of the Act. The exception covers guide services for hikers, horsemen, fishermen and, in non-NPS wilderness, hunters. Commercial bio-prospecting for commercially viable products by a business enterprise, as authorized in the NPS-DIVERSA CRADA, does not qualify for the "commercial services" exemption.

The Wilderness Act prohibition on commercial enterprises precludes commercially motivated bio-prospecting by commercial enterprises. Yet the DEIS makes not a single mention of the Act. The DEIS doesn't care to discuss, let alone apply, the Wilderness Act prohibition.

Let us accept, for arguments' sake, that FTTA and CRADAs were the applicable law, then the FTTA "does not limit or diminish existing authorities of any agency." 15 U.S.C. 3710a(f). Thus, the Wilderness Act mandate imposed upon the NPS is neither limited nor diminished by the FTTA. FTTA does not repeal or overrule the Wilderness Act prohibition on "commercial enterprise."

Should the NPS alternatively decide that NPOMA is the authority for BSAs, rather than the FTTA, NPOMA provides no explicit exception to the commercial enterprise prohibition of the Wilderness Act. As a general rule of statutory interpretation, any notion that NPOMA (or the FTTA) implicitly repeals the commercial enterprise prohibition of the Wilderness Act is highly disfavored.

**C. Alternative C Protects the Parks.**

PEER endorses Alternative C. Alternative C allows the NPS to enter into benefits-sharing agreements. Alternative C differs from Alternative B in that it disallows agreements with entities whose research is commercial in nature, motive and purpose. There is a significant distinction between independent scientific research that fits under the NPS research mandate to conserve the parks and that could yield a commercial application down the road, and research that is strictly commercial in nature. An example of the former is the development of the multimillion-dollar polymerase chain reaction process. Alternative C recognizes that distinction. Under Alternative C, the NPS would not sign a benefits-sharing agreement that is a purely commercial undertaking.

No one in or outside of the NPS can logically dispute that bio-prospecting, like other forms of prospecting, while a relatively new method of resource exploitation, is exploitation nonetheless. There is a commonsense distinction between commercial exploitation and purely scientific investigation. Commerce is qualitatively different from educational or scientific activity of a similar nature due the very different forces that drive it.

**D. Alternatives B Fail to Protect Parks.**

The DEIS fails to erect a system for managing BSAs to ensure that agreements serve the protection of national park system resources. For example, Exxon-Mobil researchers could approach a park manager seeking a BSA to conduct seismic surveys in a park to determine oil deposits in and around the park. Alternative C would bar a BSA with Exxon under the described circumstances. But, without a doubt, this type of BSA could occur under Alternatives B. If we are wrong, then the Final DEIS must state so and explain why. Otherwise the DEIS is a vague and unformed document whose results have neither been sufficiently plumbed nor assessed.

The seismic research example given above could occur under both of the B Alternatives because neither B Alternatives bar any commercially motivated research. Seismic research is only one of many conceivable scenarios where research by commercial

Perhaps the NPS is willing to subject the parks to commercial exploitation in the name of research just to get a few of the monetary crumbs that fall from the table. We oppose that as a legitimate rationale for commercialization of the parks. But, at a minimum, if the NPS adopts either of the B Alternatives, the NPS must make clear that any BSA with a commercial enterprise, for research whose purpose is commercial, may not take place in designated wilderness.

**E. Alternative B2 Can Lead to Implications of Corruption.**

If the NPS adopts any B Alternative, we urge that the NPS adopt Alternative B1. Under that alternative, there must be full public disclosure of the benefits, monetary or non-monetary, that are exchanged between the parties to the BSA. Keeping such information secret is a despicable betrayal of the public trust.

For the park employees' sake, keeping such information secret will lead to inevitable suspicion of corruption. The long history and time honored reputation of the NPS must not be subjected to any such suspicion. NPS signatories to BSAs may trade away the public interest for their own enrichment, either in their current positions, or after retirement, through the "revolving door." When powerful commercial interests are at stake, such practices have occurred on a large scale in other agencies. Don't fool yourself, NPS employees are not all Boy or Girl Scouts. There is no legitimate justification for keeping secret the benefits, monetary or non-monetary, that are exchanged between the parties to the BSA.

**F. Benefits Must Go to NPS Headquarters.**

A means to ensure that park managers meet the highest professional standards in negotiating and approving BSAs is to direct all monetary benefits to a central account in the NPS Headquarters in Washington, D.C. Perhaps that account should be under the management of the Chief Scientist, and/or the NPS Leadership Council. The central account should be devoted solely to the research needs of the national park system. In this way, the Service's most pressing research needs are supported first.

Deposit of monies from BSAs in the generating park has some distasteful attributes. Keeping monetary benefits in one park contributes to a "soft" corruption of doing sweetheart BSAs because the monetary benefit accrues to "my account." If the account is not the beneficiary, the manager will be more circumspect ("honest" may be a better word) about whether a given research proposal will impair park resources. For example, one of the methodologies used by bio-prospector involves "in situ enrichment selection." By "in situ enrichment selection" PEER means enrichment of hot springs with any substance, or altering the pH of any body of water, for the purpose of finding an organism that thrives and/or outcompetes other organisms in the artificially induced state. Such experiments aim to locate organisms or enzymes whose genetic composition makes them best suited for specific industrial practices. This is a fundamental impairment of the body of water. Yet, if the approving official counts the monetary benefits that could accrue

directly to his/her account, will their judgement not be affected? Saying "NO" becomes that much more difficult.

Scientific study is a two-edged sword. Research, including research that involves the collecting of biotic resources, is important to further the conservation mandate that Congress imposed on the NPS. However research also raises more than a theoretical potential for harm to park resources for purposes that are unrelated to the NPS mission. Another recent example involved proposals to research drill in the wilderness of Katmai National Park in Alaska. All scientific research is not allowable within parks. Research, especially research that disturbs or removes biological fabric or involves activities prohibited by the Wilderness Act (16 U.S.C 1131(b)), must surmount a high hurdle before the NPS may permit it. Some research cannot meet the legally applicable tests.

The national park system is one system. It is not an amalgam of affiliated areas, each one open for business. Sending monetary benefits to a central account reinforces the unity and common purpose of the national park system. Nothing in NPOMA mandates that the benefits from BSAs be deposited in the individual park.

**G. NPS Must Establish Principles of Federal Employee Participation.**

PEER suspects that at the end of this DEIS comment period, the NPS ignores our remarks and continue to insist that its conduct is authorized by the FTAA. If so, then NPS conduct is also governed by the FTAA. The FTAA mandates two things as discussed earlier in these comments. The FTAA:

- Established principle of royalty sharing for federal inventors (15% minimum) and set up a reward system for other innovators.
- Allowed current and former federal employees to participate in commercial development of the research fostered by the CRADA, to the extent there is no conflict of interest.

Ethics issues relating to the FTAA are complex and numerous. Agencies that are actually governed by the FTAA (not, like the NPS, which imagines that it is) have developed such ethics standards. The NPS has not even thought about it. That is but one indication that the NPS never actually believed the FTAA applied to it until the DIVERSA Agreement led it to grasp this flimsy rationale.

Before entering into a single benefits-sharing agreement, including the DIVERSA-Yellowstone CRADA, the NPS must adopt standards to implement these parts of the FTAA that guard against conflicts of interest or corruption. The ethics standards must be reviewed by the Department of Justice and be placed before the public.

**H. Alternative B is Unworkable.**

Researchers who develop commercial applications derived from NPS research permits have no incentive to seek out or enter into CRADA agreements with NPS. The

cumbersome 30-page model CRADA with profit-sharing as well as detailed reporting requirements is something an entrepreneur would seek to avoid at all costs. Why would an industry seek out a government agency as a non-contributing profit-sharing partner?

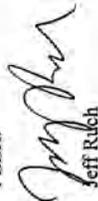
Under Alternative B, the issuance of research permits would be unchanged. Researchers are not required to enter into any contracts to implement a CRADA. Rather, the obligation to enter into a CRADA only arises when or if useful discoveries are developed. That event may well take place long after the research permit has expired.

The DEIS spells out no means by which NPS tracks or learns that a useful discovery with potential commercial application has occurred. Thus, it is unlikely NPS will be able to enter into a CRADA before the discovery is commercially exploited.

In the event that NPS was able to discover the discovery, it lacks any legal means to force the commercial researcher to negotiate a CRADA with it. This legal impotence will be particularly pronounced if the researcher has entered into contracts with third-parties who have no contractual connection with NPS.

As a consequence, it is unlikely that NPS will ever realize a monetary revenue stream from the CRADA alternative it proposes.

If you have any questions about our comments, please feel free to call me at (202) 265-PEER.



Jeff Rutch  
Executive Director



## Greater Yellowstone Coalition

P.O. Box 1874 • Bozeman, Montana 59711 • (406) 586-1393 • fax (406) 556-2839 • gyc@greateryellowstone.org

Benefits-Sharing DEIS Team  
Yellowstone Center for Resources  
P.O. Box 168  
Yellowstone National Park, WY 82190

January 29, 2007

Dear Benefits-Sharing DEIS Team,

Please accept these comments from the Greater Yellowstone Coalition on the Benefits-Sharing DEIS. We appreciate the opportunity to comment on this document. While a decision on benefits-sharing will have service-wide implications we recognize that Yellowstone National Park is the park likely to be most impacted by this decision.

**GYC recommends the National Park Service (NPS) select Alternative B1: Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions.** This alternative should be implemented in a manner that insures park resources remain unimpaired, the process for entering into benefits-sharing agreements is transparent, and clear guidelines are established to insure park managers do not enter into benefit-sharing agreements under pressure to meet budget or fundraising targets.

National parks should be open and available for research, with appropriate limitations. Increasing knowledge through research in national parks is an important value of our parks and one that the public understands and respects. New knowledge of our parks and their natural heritage assists in demonstrating the value of preserving pristine areas for conservation.

At this time, separate NPS policies and regulations exist to guide research agreements between parks and researchers. It is critical that the research permitting process remain separate from benefits-sharing agreements and that research permits not be awarded based on their potential to provide revenue or other benefits to the park. As currently written, Alternative B1 does not undermine the current NPS research-permitting process.

Current NPS regulations (36 CFR 2.1) prohibit the commercial use or sale of research specimens. Alternative B1 does not conflict with these regulations. Given that the commercial use of knowledge derived from specimens via research is not prohibited, benefit-sharing as proposed under Alternative B1 has the potential to benefit our parks by increasing the knowledge about our parks and the ability NPS has to share new knowledge with the public.

Helena Field Office • 162 North Woodward • Helena, MT • (406) 534-0101 • fax (406) 532-0646  
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[www.greateryellowstone.org](http://www.greateryellowstone.org)

Benefits-sharing agreements between NPS and commercial entities should be supported under the following conditions:

- 1) Park resources should not be directly or indirectly adversely affected by the research or specimen collection process. Also, visitors and their experience and enjoyment of parks should not be adversely affected by research conducted within parks. Park resources must remain unimpaired for future generations.
- 2) The process for entering into benefits-sharing agreements must be open to the public and transparent. The public ought to be provided with an opportunity to comment on the agreement and the final agreement must be available to the public. If this process is not done openly, the public will lose faith that NPS is acting on its behalf and the public will lose its ability to advocate for and ensure the best interest and outcome for our parks.
- 3) Any financial compensation that results from a benefits-sharing agreement should be dedicated to the conservation of resources protected and managed by NPS. In general this should include scientific research within the park and educating the public about park resources. No monies from benefits-sharing agreements should leave NPS, nor should they be used to support general park operations and maintenance that is the fiduciary responsibility of the US Congress. NPS must adopt and enforce clear guidelines and procedures to ensure that park managers are not tempted to enter into agreements to meet existing budgetary needs within parks.

NPS should consider placing a percentage of all royalties into a funding pool that could benefit parks that don't have the opportunity to enter into benefits-sharing agreements, but have demonstrated research needs. The funding pool could be administered and shared at the regional level.

It is conceivable, albeit unlikely, that any one park could enter into a benefits-sharing agreement that provided royalties that exceeded the research budget of a park. NPS should prepare for such an instance, and develop a process for sharing royalties with other park units within the given park's region. This could benefit parks that have small research budgets and would otherwise never be able to undertake special research projects.

- 4) Above and beyond any financial compensation or non-monetary benefits received from commercial entities, NPS should benefit from the sharing of all knowledge gained from the research.
- 5) Scientific research and specimen collection activities in national parks should continue to be governed by existing NPS regulations and through the existing NEPA process.
- 6) The NPS should review the benefits-sharing program every five years to assess lessons learned, evaluate opportunities to strengthen the program, ensure the research permitting process remains insulated from the benefits-sharing agreements, and demonstrate that any benefits accrued are not negatively affecting congressional

spending on park programs. The public should be given the opportunity to comment on the reviews and view the final reports.

The Park Service currently supports Alternative B2 with optional disclosure of the terms and conditions governing benefit-sharing agreements. GYC does not support this alternative, and urges NPS to designate Alternative B1 as its preferred alternative in the Final EIS.

Thank you for the opportunity to comment on this document. If you have any questions about these comments, you can call me at 406-586-1593.

Respectfully,



Amy McNamara  
National Parks Program Director

# Representative Comments from Individuals

12515-4	Rick Pierides	12515-150	Martha B. Ashton-Sikora
12515-6	Jo A. Schaper	12515-166	N/A
12515-21	Jonathan M. Frey	12515-1401	Don Masterson
12515-32	Brent Eubanks	12515-1903	Mary Jo Veverka
12515-36	Daniel Toman	12515-4602	Karen Eble
12515-37	Kathleen Moon	12515-5083	Gordon Rands
12515-38	Louis F. Good	12515-6718	George & Frances Alderson
12515-39	Alicia Siegel	12515-6719	Seven Dunsmore
12515-56	Kept Private	12515-6721	Necia Refes
12515-59	Kept Private	12515-6724	Edwin J. Potts
12515-61	Craig C. Zandstra	12515-6733	Michael Roberts
12515-68	R. Ferguson	12515-7116	Laura Pace
12515-69	Kept Private	12515-7241	Jennifer Vollmer
12515-71	Kept Private	12515-7429	Robert Moss
12515-74	Sue Voelkel	12515-7444	Katie La Salle-Lowery
12515-79	Chad E. Adams	12515-7455	Jesse Turner
12515-83	Ryan T. Minton	12515-7461	Leonard P. Hirsch
12515-84	Kathy Freeman	12515-7466	Oren Kennedy
12515-85	Philip Skehan	12515-7473	Alan Carlton
12515-88	Rob Kimmich	12515-7476	Stephen Brown
12515-89	Nancy C. Jacques	12515-7477	Noah Jackson
12515-92	Kept Private	12515-7485	June Anna-Fey
12515-95	Pam Racow	12515-7487	Mary Ellen Anderson
12515-102	Kept Private	12515-7490	Michael Powers
12515-105	Eric Prescott	12515-7497	Frances Lamberts
12515-112	Jonathan Matthews		

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12515-6  
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*Received 9/29/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I held research permit OZAR-00006 on Riverways for my undergraduate thesis work. I prefer alternative B3, which both benefits NPS and gives some flexibility in negotiation with researchers regarding financial matters.

One thing which I would like clarified would be the word 'commercial.' What comes to mind first, of course, is the PCR research from Yellowstone in which information derived from actual samples are those generating substantial revenue for the researcher and his or her company.

What does not seem to be addressed here is a case where information recovered in the course of research is sold for its editorial (not scientific or manufacturing) value. For example, I've written and sold articles and photographs about my study site for insignificant amounts of money--less than \$100 total. Not all research on the parklands ends up in scientific journals, (which are generally no-pay or you pay venues).

I note in your summary that you are required to abide by intellectual property rights laws--presumably this would allow me (and others) to continue to incorporate research information obtained from researchers in informational, non-technical articles without requiring a fee payment to the NPS, and continue to permit publication of such information with a modest profit to the writer where the primary intent is information, entertainment, education or persuasion, not manufacturing or testing.

Other than this clarification, if the NPS can get some compensation back from ventures where samples taken from the park are then used to make piles of money, AND that money then goes back to NPS sites affected, or at least, back into resource management at the parks, I am all for Alternative B3.

Jo Schaper

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*Received 9/28/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

The height of absurdity, government needs and must be open and I strongly object to any language that would prevent terms of any agreement from being kept secret from the public. These are our parks and our heritage. They do not belong to large pharmaceuticals, lest of all, foreign corporations. As a member of the public I have the absolute right to know who is making money off our parks. Secret arrangements, behind our backs, does not do justice to the American people!

Rick Pierides

12515-21  
page 1 of 1

*Received 10/06/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

Bioprospecting is an important means of advancing our society. Prospecting in the deep seas has led to pharmaceutical advances ranging in drugs which treat inflammation and arthritis to those which help in the treatment of HIV. However, it is the way in which bioprospecting is done which must be carefully scrutinized.

If the plan is to examine the features of the parks such as Yellowstone's thermally active areas, but not deface or alter in any way their current state, then bioprospecting should be allowed to proceed. What humanity may learn from organisms which have the ability to survive such extremes in environment could be enormous. However, if the exploration and collection of such species and minerals is not watched carefully you run the risk of altering a landscape and ecosystem to the point of destruction.

I completely support bioprospecting in the parks as long as there is a close eye, and complete scrutiny, and the prospecting being done.

You cannot expect an ecosystem to survive, or for humanity to learn for such prospecting, if the prospecting involves gouging the earth.

I hope this issue will be resolved with the utmost respect it deserves.

Sincerely,

Jonathan Frey

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page 1 of 1

*Received 10/22/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

In principle I support allowing commercial bioprospecting in our National Parks. However, any such scheme must make protection and preservation of the wild ecosystem an utmost priority. This includes requiring whatever environmental impact statements and field oversight are necessary to ensure the collecting is done in an ecologically sensitive manner.

Secondly, and such scheme must be transparent and open to the public. First and foremost, the terms and conditions of the agreements between the Park Service and the companies in question must be available for review. The Parks Service represents taxpayers and citizens such as myself, and acts on our behalf to protect and nurture the Parks. If you wish to negotiate agreements concerning the parks, those agreements MUST be part of the public record.

Brent Eubanks

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*Received 11/04/2006 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

Thank you for to opportunity to respond.

I support option 2, shared benefits, with two caveats...

I did not find in any of your document details on guidelines and/or rules for extraction, when and if a material of interest is discovered. It is one thing to allow commercial access for research, but in the event of a viable discovery, how will the park protect its philosophical and physical mission to the public when extraction begins?

Secondly, having been in the film industry and knowing how easy it is to hide profits from shareholders, it is imperative that the benefits-sharing criteria is spelled out clearly and a third party review board is in place to insure proper reporting on the part of the commercial party.

Kathleen Moon

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page 1 of 1

*Received 10/31/2006 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

I am writing to express my opposition to the commercial exploitation of our National Parks. Our government has an honorable history of making its scientific research available to all citizens, in the public domain, like the USGS survey maps I use often. Opening our National Parks to private economic gain, with no thought of the public good, is directly opposed to this tradition. Scientific research is a laudable endeavour, but only if conducted in the open so the knowledge gained may be shared by all, and not locked away by private greed. I strongly support Alternative C and oppose all forms of Alternative B, or any other avenue that would not require public ownership of the knowledge gained from public land.

Daniel Toman

Received 11/07/2006 via NPS's Planning, Environment and Public Comment (PEPC) website

On the surface this appears to be a good idea, Alternative B. But one aspect of it is a very bad idea and could lead to unintended consequences. That aspect is the part of the proposal that states that any benefits should flow to the park where the project takes place. That is a terrible idea.

Yes, the taxpayers are due some of the benefits that would accrue from any commercial exploitation of park resources. But the money should go into a national NPS pool and not to one park or area. Then individual parks would submit proposals for interpretive and resource management projects on an annual basis. The money should only be used for those purposes.

Otherwise there is a very clear conflict of interest for individual park superintendents, especially in these times of tight budgets. There would be a much more objective review of proposals if parks knew they were not going to get all of the money generated but would have to compete for it. One example would be cave resources, particularly newly discovered caves or caverns. Who knows what is in them that might be of use someday? Some career driven superintendents just might look much more favorably upon some sort of exploitation proposal if dollars were dancing around in their heads.

So I'd say this proposal is fatally flawed. If you change it so that all of these proposals are reviewed and approved nationally by a team of primarily scientists, and that any benefits go into a national pool, I'd say do it. But not this proposal which is nothing more than Yellowstone's greed thinly disguised as some sort of national program. Don't do it! Revise it and re-issue. As written and proposed now, this is a bad, bad idea that will cause more problems than any money generated will ever solve.

Louis F. Good

Received 11/11/2006 via NPS's Planning, Environment and Public Comment (PEPC) website

I support alternative C of the EIS. Research conducted on publicly owned lands should be done by public employees, non-profit researchers, or academics (including students) strictly for the benefit of the general public who own them.

I strongly oppose any plan to allow extraction of biological, chemical, or mineralogical material from our national parks by any private or publicly-traded corporate entity for commercial/profit-driven purposes. In such cases, the public subsidizes private profits by incurring at least some of the costs; raw materials in the current instance. Beyond the monetary value of the extracted material is the potential loss of revenue from tourism. Visitors come expecting to see aesthetically pleasing landscapes. Commercial collection activities may involve disturbing the park grounds. Most importantly, the land will require time to recover and may never return to its original condition.

Over the past two decades, commodification has been the lens through which many aspects of our lives in America are viewed. How much is it worth? How much will it cost? How much will be made? But not everything is meant to be exploited for financial/material gain.

Our national parks have a value which far exceeds any potential monetary worth.

Theodore Roosevelt knew this when he wisely established the national park system nearly one-hundred years ago. Yellowstone and all the other national parks are natural treasures to be enjoyed by all Americans, by visitors from around the world, and especially by future generations.

I am opposed to Alternative B2. Not only for the reasons stated above, but others as well. This option treats public park lands as though they are private property. Resource collection/extraction activities would be conducted in accordance with a confidential agreement between the corporate entity and the NPS. But the NPS is a public agency, created to preserve, maintain, and protect our national parks and national monuments on behalf of the public. Any agreement involving a public agency that lacks transparency is unacceptable.

Under Alternative B2, NPS staff will be responsible for negotiating, processing, and managing all Commercial Research and Development Agreements (CRDAs). This will consume a considerable portion of time and resources, especially as more companies learn about the program.

The more applicants there are, the more effort required to vet them, to negotiate and handle CRDAs, and to schedule and monitor collection activities. There is a potential for

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increased disturbance of wildlife and wildlife habitats. And as stated above, commercial collection activities will leave the land disturbed. It may take years to recover, if it recovers at all.

Alternative B2 stipulates that should the commercial research company turn a profit, the NPS will receive a portion of the funds. It is possible that the cost of processing the applicant(s) may equal or exceed the payment amount. The NPS may need to conduct a cost/benefit analysis.

It is possible that the private entity may not turn a profit immediately. Can the NPS absorb the cost of doing business on this scale? How long?

It is possible, in the interim between resource collection and final production, that the corporate entity decides to retain a greater share of the profits. In a worse-case scenario, the corporate entity may fraudulently claim not to have earned a profit. In either situation, it is possible that the terms of the confidentiality agreement may force the NPS into binding arbitration. Otherwise, the NPS may be forced to file suit to receive the monies owed. It is not likely that the financial compensation would sufficiently exceed all the costs incurred by the NPS (normal costs plus legal expenses).

RECAP: Research on publicly-owned lands should involve public, non-profit, or academic researchers. The goal of any of these groups should be to further the scientific body of knowledge in their field, benefitting the general public.

Research conducted on publicly-owned lands should not have the profit motive as its paramount concern. Whether it is the collection of biological material, extraction of oil or other mineral resources, or collection of lumber - the private companies benefit disproportionately from government giveaways or inexpensive leases. Other costs to the NPS involve interaction with private sector entities throughout the process. Finally, either failure to turn a profit, corporate attempts to renege on the agreed distribution of profits, or corporate fraud must be evaluated in terms of the cost to the NPS. Legal representation may be required, adding to the costs incurred by the NPS to administer this program.

Any agreement that does not include automatic public disclosure and instead seeks intentionally to keep all documents confidential is unacceptable when the property in question belongs to the American public and one of the parties to the agreement is a publicly funded federal agency.

Commercial collection activities are more likely to cause damage to native landscapes and disturb resident wildlife. The resulting damage will be visually unattractive, possibly causing a decline in regular tourist activity. Ecological recovery may be an issue.

Thank you for your time.

Alicia Siegel

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*Received 11/28/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I am writing to support the alternative that prohibits scientific research involving NPS specimens if associated with the development of commercial products.

The parks are not meant to be commercial resources, nor are they meant to be self-supporting in any way.

Other federal lands have been and are used as commercial resources by the public and by businesses. Let's not sell our parks too.



Kept Private

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*Received 11/28/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

As a concerned United States citizen, I am firmly opposed to patenting life forms or any type of genetic material. The notion that this process could be allowed in our National Parks, I find very disturbing. Accordingly, I am dismayed that, without public debate, the Environmental Impact Statement on so-called "Benefit-Sharing" provides only 3 options, all of which assume that such patenting and exploitation for private gain will take place. Why is there no option to rule out bioprospecting altogether?

Since the option I would prefer has not been placed on the table, I can only advocate option C, to allow exclusively "noncommercial or public interest research." In so-doing I recognize that our National Parks are common property of the people of this nation, set aside to be preserved in good stewardship for all time. As such, only the public interest should be served by any research on these lands. Commercial prospecting would not only entail some inevitable damage to our Parks, but violates the mission and spirit for which they were inaugurated.

Kept Private

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*Received 11/28/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

To Whom It May Concern,

As a citizen, I'm submitting my comment as part of the public comment period for the September 15, 2006, court-ordered (EIS) on the document, entitled "Benefits-Sharing". I do not agree with any of three options given. As a result, I ask for you to resubmit this comment period to allow a fourth choice. This would be "D" to not exploit the parks genetic treasures now or in the future. Privatization has been gaining strength for past number of years in the Park Service. This is bad because the people who work for the parks do so for the love they have for our national treasures, and are willing to work in a government job that pays less than the private sector. We do not want corporations to patent genetic codes, plant, and animal life from public lands for their own benefits.

Please rethink this shortsighted proposal and thank you for your time.

Craig C. Zandstra

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*Received 11/30/2006 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

The very idea that genetic codes can be patented is unethical to begin with, and the practice should not be encouraged or facilitated. Patents are supposed to be used to protect inventions and to encourage innovation. Allowing patenting of already existing genetic codes accomplishes neither.

That aside, if a corporation obtains patents on genetic patterns of plants and animals that live in the national parks, then they could attempt to enforce those patents and monopolize access to the plants and animals possessing the genetic patterns. This would effectively remove or restrict public access to the national parks. This is not acceptable.

Kept Private

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*Received 11/29/2006 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

I used to work on intellectual property (IP) issues for the National Center for Supercomputing Applications and have some familiarity with how businesses manage IP.

Bioprospecting transfers value from the public domain to private hands. What is in the public domain should remain in the public domain, therefore no private IP should be allowed from bioprospecting in national parks.

Bioprospecting effectively takes public assets and limits access to their benefits so that some individual and institutional investors can benefit.

That is an unfair tradeoff which does not serve the public interest.

If the science is really compelling, leave the resulting IP in the public domain to maximize public benefit.

R. Ferguson

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page 1 of 1

*Received 12/01/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I am strongly opposed to bioprospecting in our national parks.

These public lands were set up in the public interest, as indicated by these statements, among many others: (1) Public lands were to be set aside "for the benefit and enjoyment of the people." (2) A single national park system is to be "preserved and managed for the benefit and inspiration of all people of the United States." (3) The purpose of the national park system is "to conserve the scenery and the natural and historic objects and the wildlife therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations."

The purpose of the national park system, the public interest, and the public trust would be violated by allowing private interests to exploit the resources of our national parks for their own gain.

Ample experience has shown that large corporations trying to patent life forms and biological/genetic material do not have the interests of the public at heart, but are seeking to maximize profits at almost any cost.

Please preserve our national parks as havens rather than as raw material for commercial exploitation. Do not allow such an invasion of our publicly safeguarded areas to occur under any circumstances.

Kept Private

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*Received 12/01/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

Please consider this electronic transmission as my formal commentary on the DEIS - Benefits Sharing in National Parks.

First and foremost, the notion of National Parks is a unique American ideal that stood as an example for other nations to emulate.

National Parks, as places for self-willed nature and humans to interact in non-consumptive ways must not be compromised with for profit activities that most likely will harm biological diversity, ecological integrity and ecosystem integrity.

Commercial activities that "fit" with the park ethic include visitor services such as overnight accommodations, food services, guide and packer services. When the overcommercialization of National Parks, I would argue that these activities ought to be withdrawn, and left to the private sector land that is already compromised with development.

Therefore, I am in favor of Alternative "C". Cease all commercialization of park biodiversity including but not limited to soil organisms, plants, insects, amphibians, reptiles, birds, mammals, bacteria, fungi, protists, algae and minerals. This is part of the Commons, held and protected in perpetuity for future generations of humans and non-humans.

The for profit motive, short-sighted, adolescent and greedy corporate psyche ought not to be the tail that wags the dog in America's National Parks. Wildlife Refuges ought to be treated in the same manner.

Sincerely,

Danielle M. Wirth

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*Received 12/06/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I agree the preferred alternative should be adopted as expressed in the DEIS - that is allowing benefits-sharing agreements. If benefits-sharing agreements are not allowed for any reason, my second choice would be to not allow the persons or companies to continue their research in the national parks. A person or company should not be allowed to benefit from their research in a national park, without having to share some of that benefit with the NPS. A wise private landowner would certainly require some sort of benefit-sharing agreement from the same persons if the private landowner allowed such research on their property. United States citizens who use and enjoy the national parks, as I do, should not be denied similar benefits. I consider the money received from benefit-sharing agreements a benefit to all US citizens, not just to the NPS, when it is used for the maintenance and continued preservation of the national parks.

It was not clear, and I perhaps missed something in the document or it is beyond the scope of the document, as to where the money received from the benefit-sharing agreements is to be used once received. Does this money go into a fund to be distributed to NPS as a whole, or is money received from research in a specific park, for example Yellowstone, returned for the benefit of that particular park? Whether or not addressed in the statutory scheme allowing for benefits-sharing, this should be addressed if only for public information in the DEIS.

chad e. adams

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page 1 of 1

*Received 12/01/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

As a former student of environmental resource management, I must say how appalled I am at the prospect of the National Park Service entering into agreements with companies that would patent natural organisms for private profit. The truth of the matter is that the NPS has no legal right to sell off the natural resources that it holds in the public interest. That's like the CEO of a company deciding to sell the company without getting the approval of the shareholders first.

I don't care that bioprospecting is already going on; it should be halted altogether. Let me be clear: I am not against research. People do research on public lands all the time. But research done on public lands should be done for the public good only; therefore, I support alternative C of the DEIS for the "benefits-sharing" program. Ideally, though, it should be amended to explicitly state that research done on public lands is for the public good only.

I oppose alternative A and all versions of alternative B of the DEIS.

The NPS is entrusted by the American people to carry out the mission of ensuring the health and survival of our natural resources for future generations. Selling these resources off to private companies is the surest way to fail in this mission. Companies are not beholden to the public. The conflict of interest here is glaring.

If the NPS is not getting enough funds to sustain our parks, then it is our government's responsibility, not that of private companies, to come to the rescue. That's what our tax dollars are for.

And what's more, selling exclusive rights to organisms, essentially, to life itself, is immoral, and no one on earth has the right to do it. It's madness.

Some things are simply not for sale. Keep our public lands public. Don't sell our children's backyard to ACME.

Sue Voelkel

*Received 12/08/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

First, let me say that I am pleased to see that the issues of benefits sharing is still being considered in Yellowstone. It is certainly a beneficial way to encourage a responsible stewardship towards bioprospecting. Kudos.

Second, it needs to be stated that in regards to sustainable development, bioprospecting could not be closer to fitting the bill. Despite the detritus circulating among fanatical pseudo-environmental groups, bioprospecting is NOT an exploitation of our public lands or the wildlife inhabiting them (as purported by the Edmonds Institute). The impact to our environment in regards to bioprospecting is negligible; in some cases, it is nonexistent.

Furthermore, I would like to note that I view bioprospecting as being consistent with the NPS mandate, that is, to preserve and conserve (in not so many words). The knowledge gained through bioprospecting activities far outweighs its environmental "impact" (if it can be stated as such) and in a world slowly falling to the loss of microbial diversity, bioprospecting does well to work against these decreases while at the same time providing for sustainable solutions to a number of industry problems (including but not limited to the development of alternative fuels and efficient, non-synthetic industrial processes).

As for the issue regarding commercialization of the Park: it is moot, for regardless of benefits sharing, there will always be researchers in the Park, searching for and finding the small bit of microbial diversity to meet their own ends. In my mind, benefits sharing does nothing to detract from this; instead, it makes it more legit and more regulatory, and allows the Park to work directly with scientists, thus establishing healthy relations between the public and private sectors of this facet of the scientific industry.

Now, on to the EIS:

To be short and sweet, I will state that I support Alternative B3, allowing for benefits sharing through bioprospecting with no disclosure of rates.

B1 would be my second choice, but in light of B3, B1 could potentially stymate the Park in terms of their negotiating power for benefits sharing agreements.

B2 is my last pick of this alternative, and seems to me a product of uncertainty. Making disclosure of terms and rates optional could potentially lead to further complications on this matter; thus, I would shy away from it.

Thank you for considering my comments in this matter. Best of luck in closing the EIS process with regards to benefits sharing!

Ryan T. Minton

*Received 12/08/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I strongly support Alternative C. I oppose all versions of alternative B. There should be no bioprospecting in national parks. The mission of the NPS is to protect parks and everything they consist of for future generations. The mission is NOT for parks to turn a profit. The brilliant decision to form a national park system to protect our natural heritage should not be undermined in any way.

Kathy Freeman

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To allow a person or organization to use government facilities, resources, personnel, or finances for personal profit without capturing a reasonable share of that profit stream for the Nation is a clear violation of the Government's fiduciary responsibility to its People. Scenario A clearly violates that responsibility, and is therefore unacceptable.

To prohibit commercially oriented research which could lead to important economic, health, or technological benefits to the nation simply because it is commercial in nature is equally a violation of the Government's fiduciary responsibilities. Thus Scenario C is also unacceptable.

The only responsible NPS policy is some flavor of Scenario B: the authorization of for-profit research with benefits-sharing between the Parks and outside researchers.

4. CRADAs and MTAs. Research activities fall broadly into three classes: (1) those with no obvious possibility of commercialization; (2) those designed deliberately to be commercial; and (3) those which are not intended to be commercial, but could possibly result in a commercial application.

Because it is impossible to know in advance whether a research activity will generate a commercial product, all researchers should be required to sign CRADAs and MTAs with the NPS. No research activity by any non-NPS entity should be permitted on Park domains until a CRADA has been signed, and no samples or specimens should leave Park facilities without a signed MTA.

These agreements are the documents which protect the NPS's legal rights to a share of the financial and material profits that derive from either research activity on Park property or the use of Park resources.

CRADAs and MTAs are long-standing and proven procedures used widely by government and academic institutions both for commercializing their knowledge and intellectual properties and for ensuring that they capture a fair share of the profit streams that result from such commercialization.

5. Bioprospecting. Bioprospecting is an activity that is rarely successful. Collecting campaigns typically require that between 5,000 and 100,000 samples be collected and screened for each sample that becomes a serious candidate for commercialization. Most bioprospecting campaigns end in failure.

Since R&D costs escalate exponentially following preliminary drug discovery screening, industry does its best to terminate unsuccessful drug candidates as early in the process as possible. This is not always true of academic bioprospectors.

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*Received 12/10/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I would like to offer comments on the National Park System's (NPS) Draft Environmental Impact Statement (DEIS) on benefits-sharing with those conducting research in America's National Parks.

The Benefits-Sharing DEIS is a comprehensive document that confronts a serious issue concerning Park resource usage: whether the Park System should receive a share of commercial benefits derived from activities conducted either within the Park System or using Park resources.

The DEIS describes the policy options that are available for addressing this issue, and does a very good job of presenting and documenting the pro's and con's of the several policy options that are available.

1. The Park's Missions. My understanding is that the primary mission of most NPS Parks is the biological conservation of unusual and important ecosystems, and that its secondary missions are to promote Park-related education, recreation, and scientific activities.

These functions are different, and sometimes conflict with one another. It is the responsibility of Park management to strike a sensible balance between these sometimes conflicting activities.

2. Research at National Parks. The National Park System has for decades permitted scientific research to be conducted on its lands and with specimens and samples collected in its Parks.

Most of this research has been curiosity-oriented, basic research conducted by academic and government researchers funded primarily or exclusively with public monies.

However, some applied research has been conducted in the Parks, or with Park resources, either by for-profit firms funded by private capital or by government funded academic and government scientists some of whom may be interested in commercializing their findings and discoveries.

The proposal to allow applied research by profit motivated researchers will change nothing about Park research activities provided these activities are governed by the same set of rules that govern existing basic research.

3. Benefits Sharing. The Federal Government, and it's several departments and agencies, are fiduciaries for the citizenry of the United States. As such, their first responsibility is to act in the best interest of the American People.

6. **Bioprospecting Sample Requirements.** Preliminary screening of biological samples for a bioactivity of interest can be accomplished with small amounts of material in the range of a few grams to a few tens of grams for macro-organisms, and even smaller amounts for most microorganisms.

Early stage R&D activities require larger amounts of material, typically in the kilogram range. Mid and late stage R&D require very much larger quantities of material, often hundreds or thousands of kilograms.

7. **Environmental Impact.** The chemicals and macromolecules that generate bioactivities of interest are of three sorts: (1) molecules that can be produced by self-replicating cells or organisms, for example, microbial fermentation or tissue culture; (2) molecules that can be manufactured, for example by chemical synthesis or genetic engineering; and (3) molecules that can only be obtained by isolation from cultivated or wild-harvested material.

Self replicating cells and organisms require minimal, often near microscopic, amounts of initial sample; thereafter, their bioactive agent(s) can be produced in the laboratory by fermentation or tissue culture. The collection of such samples has negligible environmental impact.

Molecules manufactured from non-self replicating sources require substantially greater amounts of material, often in the kilogram range or greater, to accomplish the chemical structure elucidation or gene isolation that is prerequisite to manufacture. The kilogram collection of material can have a serious negative environmental impact when the species of interest is small and uncommon.

Materials that can only be wild-harvested, at least in the short run, can lead to massive environmental damage. Entire forests of pacific yew trees, on both public and private lands, were clear cut to obtain usable amounts of the anticancer drug taxol in the late 1980s and early 1990s. Much of this harvesting was done illegally by poachers, and some of the poachers were from foreign countries.

8. **Micro-Invasiveness.** Because bioprospecting has the ability to inflict substantial environmental damage, the NPS should adopt a strict policy that only micro-invasive collecting will be permitted in its Parks.

This policy would favor the collection of cells or organisms which can self-replicate, and discourage the collection of those which cannot.

Plants require special comment. Historically, plant bioprospecting has required the collection of large amounts of wild-harvested material. Except for large or extremely abundant species, this scale of harvesting should not be permitted within the Park System.

However, plant tissue culture techniques have improved greatly in recent years, and it is now possible to produce sizable quantities of bioactive materials in plant tissue culture, thereby obviating the need for large scale wild-harvesting.

The NPS may wish to consider a policy restricting plant bioprospecting largely or exclusively to plant cell cultures, which can be established from very small amounts of plant material.

9. **Species Abundance.** In most ecosystems, a small number of species account for 90% or more of total biomass. The remaining 5 or 10% of biomass is partitioned between hundreds or thousands of rare or uncommon species. Bioprospecting campaigns have historically focused on large or (seasonally) abundant macro-organism species that are easy to collect in bulk volume.

Great care must be exercised by the Parks in permitting the collection of uncommon and rare macro-organisms. A kilogram collection of lady slippers or orchids could virtually exterminate a Park's population of these species.

10. **Collecting Campaigns & Field Stations.** Bioprospectors usually mount short campaigns designed to collect as many samples as possible. These samples are transferred to a repository, often thousands of miles away, where they are stored until needed. Fermentation or screening generally takes place months or years later, when it may be difficult or impossible to recollect more of the active samples. Because the duration of storage is unpredictable, the decay of bioactivity and extinction of microbes can be substantial. For these reasons, initial samples are usually collected in large quantities.

An alternative strategy is to screen samples as they are collected either in field stations or at laboratory facilities at a nearby university or Park headquarters.

With microscopic fungi, cultures established within 2 or 3 hours of collection generate a rich diversity of species outgrowth. With time, the number of species that can be recovered decays noticeably, and after a few days only very common and very hardy species can be cultured. The great majority of these will have already been collected and screened by others, and their useful bioactivities discovered and patented. They are therefore not commercializable by the current collectors.

With plants, rapid screening has the advantage of allowing the immediate recollection of more sample of active species.

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Royalties are a share of the net profits that a commercial product makes when sold in the market place.

13. Financial Implications of Bioprospecting for the NPS. The financial implication for the NPS, whose primary function is to provide access to biological samples that others screen and develop, is that opportunities for profit sharing are rare beyond the initial phase of sample collecting.

Royalties from a successfully commercialized product are extremely rare, while samples that generate milestone payments are not common. Although milestone payments and royalties will occasionally occur, and are sometimes lucrative, upfront fees will provide the most dependable stream of benefits-sharing income.

14. Upfront Fees. The minimum fee that all outside researchers should be required to pay is an application fee designed to cover the costs to the NPS of reviewing applications and deciding whether or not to issue Park Research Permits.

If a Permit is granted, an access fee should then be levied. This fee should be large enough to recover the costs that the Park will incur for supporting and monitoring research activities by outsiders. The access could be either in the form of a single all-inclusive fee, monthly or quarterly fees, or, where sizable numbers of samples are to be collected, a per sample or per specimen charge. These several kinds of access fees are not necessarily mutually exclusive.

15. Monetary Benefits Models. At least five types of researchers are likely to conduct activities in NPS Parks: (1) academicians; (2) government scientists; (3) very small businesses; (4) small businesses; and (5) well established large and mid-sized businesses.

The two monetary models proposed in the DEIS correctly recognize that there are sometimes substantial differences in the abilities of these researchers to pay monetary upfront fees.

Well established corporations have deep pockets, and can afford to pay substantial upfront fees.

Small businesses with angel or venture financing have limited capital, and may not be able to afford the substantial fees that large corporations can pay.

Academicians and government scientists often have little capacity to pay more than nominal upfront fees. The same is true of very small businesses, which in bioprospecting are likely to consist of a university scientist and one or two graduate students or post-doctoral fellows working without salary.

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As a biologist who has spent considerable time doing research at marine laboratories, I have a strong bias in favor of working at field stations whenever possible. The NPS might want to consider establishing field stations in some of it's Parks.

It might also be worth establishing permanent laboratory facilities either at a Park headquarters or at a site immediately adjacent to a Park, perhaps in collaboration with a nearby university or research institute.

Offering such facilities to outside scientists represents a value-adding service that can command a premium upfront fee.

To the extent that Park personnel actively collaborate in research activities, it is possible in some instances that they, and therefore the Park, might qualify as a co-inventor of a patentable invention. This would permit the NPS to capture a greater share of royalties under the CRADA.

11. Private Sector Risk-Reward Relationships. In the private sector, the share of profits to which one is entitled is determined primarily by two factors: (1) the amount of risk assumed, for example, the proportion of total capital investment that one provides; and (2) the degree of value-adding that one contributes.

For example, the total cost to produce and sell a patentable pharmaceutical drug averages about \$ 1.8 billion. These costs include discovery, basic research, development, clinical research, regulatory requirements, clinical trials, manufacturing, quality control, advertising, marketing, distribution, liability and litigation costs, and taxes.

Most drugs fail to earn sufficient revenues to cover these costs, and thus are net money losers. A small handful of drugs make a net profit. These must pay both for themselves and for a number of failures.

12. Pharmaceutical Profit Sharing. Private sector profit sharing in the biotechnology and pharmaceutical industries typically involves three types of payments: (1) upfront fees; (2) milestone payments; and (3) royalties.

Upfront fees in bioprospecting include application fees, access fees, facility rental fees, and sample collection fees.

Milestone payments are granted when certain predetermined accomplishments are achieved, for example, licensing a product to another company, completing a successful clinical trial, or gaining regulatory approval from the Food and Drug Administration (FDA).

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It is therefore sensible to have a graduated structure for upfront fees that varies with the financial resources of each research entity. Large corporations should pay full upfront fees. Academicians, government scientists, and very small companies should pay nominal or no fees. Small company fees should be intermediate, and take into consideration each company's financial position.

There is an important caveat. Academic and very small company bioprospectors often work in collaboration or have sponsored research agreements with large corporations. Indeed, large corporations sometimes use these small bioprospectors to avoid the fees they would have to pay if they were themselves the research party of record. As part of the Park Permit application process, the NPS should determine whether such collaborations or agreements are in effect, and adjust fee rates accordingly.

To the extent that milestone payments are linked to financial payments received from third party companies or organizations, there is less rationale for graduated fee rates.

Royalties from commercial sales should be uniform regardless of the type of researcher.

16. Nonmonetary Benefits. The DEIS correctly notes that there is considerable potential for a Park to profit materially from nonmonetary benefits.

Some years ago, a biology department at a noted research university reached an agreement with a large pharmaceutical company in which the company took over an entire building, completely renovated it, fully equipped it with state of the art laboratory equipment, and used it for pharmaceutical research for a multi-year period. At the end of that time, the building and all of its equipment and facilities reverted to the biology department.

Arrangements of this sort may be very useful in developing and equipping field stations and laboratory R&D facilities at NPS Parks.

17. Disclosure of Financial Information. Many private corporations are highly secretive about their financial arrangements, and will not establish a research collaboration if terms are made public.

Since many Parks are surrounded by non-Park lands with similar biota, potential collaborators can and do collect at nearby locations just outside the Park. Some will even do unauthorized collecting in the Park itself, which is easily done with microscopes.

The NPS will best be served by not having a strict policy regarding the disclosure of financial terms of agreement. Mandatory transparency will significantly reduce the number of commercial parties willing to engage in benefits-sharing research, and these are precisely the parties that can provide the most benefits to the Parks.

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18. Financial Terms. Another reason the NPS should be cautious about revealing financial terms is that once made public, these terms will become a de facto standard for parks and countries around the world.

Parks and countries differ considerably in what they can offer a researcher. Yellowstone (YNP) offers nearby airports with car rental facilities and a good road network to and from the Park. There are nearby universities with which outside scientists can establish collaborations. Within the Park itself, there is a good road and transportation system, hotel and restaurant facilities, a knowledgeable scientific and ranger staff, electricity, clean running water, sanitation facilities, good external communications, limited research facilities, and some exceptional microhabitats and ecosystems.

Many of the lands and parks that seek to attract bioprospecting, particularly in the third world, offer none of these amenities. To collect samples at a well known Marine Reserve in the Philippine Visayas, one must first acquire a live-aboard boat, fully provision it with food, water, supplies, and research equipment. The reserve, a small island and surrounding littoral, has no permanent inhabitants, no water, electricity, sanitation, food, or shelter. While the marine littoral surrounding the reserve is attractive, there are thousands of islands between the Visayas and the Solomons that offer similar biota.

For-profit companies will pay fair value for access to an attractive research environment, but how much they will pay depends on what a park or country can offer in return. A park like YNP can attract premium fees because of the excellent staff and facilities that it offers. Many others cannot.

19. Ad Hoc Review Committee.

In the mid 1980s, the National Cancer Institute's (NCI) Developmental Therapeutics Program (DTP) initiated a radical change in the technology that it used in its national anticancer drug discovery program. One of the changes was to strongly emphasize marine and plant natural products as a source of screening samples, i.e., bioprospecting.

To assist in this task, the DTP established an Ad Hoc Review Committee made up of distinguished scientists from around the world to serve both as a brain trust to help design and implement the new screening program, and to oversee and critique it.

Roughly 50 scientists served on the Ad Hoc Review Committee. About half were Americans, the rest from other countries. There were people from governments, academia, and industry. Their specialties included cell biology, preclinical drug development, tumor biology, clinical cancer research, clinical oncology, statistics, pattern recognition analysis, computer programming, information technology, natural products chemistry, synthetic and medicinal chemistry, fermentation, and industrial pharmacology.

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*Received 12/11/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I support the National Park Service Alternative C in Section 2.1 of the Benefits-Sharing Environmental Impact Statement concerning our National Parks.

Alternative C will prevent funneling of resources for managing commercial efforts away from public programs. It will assure that the results all research in the Park system will be placed in the public domain. I oppose plans to place research results in the hands of private commercial interests, which would treat the knowledge they gain as private property.

Alternative C will prevent bio-prospecting and protect the Parks for many generations.

-Rob Kimmich  
Salem, Oregon

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The Ad Hoc Review Committee was instrumental in the development and implementation of the new screening program. It is doubtful that the project would have been successful without its help. Committee members were reimbursed for out-of-pocket expenses, but otherwise worked pro bono.

If the NPS decides to implement a benefits-sharing program, it might wish to consider creating a similar committee to assist in its development.

Philip Skehan

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page 1 of 1

*Received 12/14/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

To Whom It May Concern:

With reference to Benefits-Sharing Environmental Impact Statement:

I write in favor of Alternative B1, benefits-sharing with mandatory disclosure of all terms and conditions.

I am not in favor of the preferred alternative with optional disclosure. These lands are our national heritage; I want to know exactly what is occurring on them, who is benefiting, and how.

This is not a distrust of park service personnel. On the contrary. Dedicated park service personnel I know, being an environmental consultant, hold dear the missions of their work. Washington, however, does not, especially in the last 12 years. Industry cronies appointed to head environmental agencies, illegal tampering with scientific documents, all-out warfare against environmental protections by the Bush Administration, systematic cuts in spending to the Dept. of the Interior and National Park Service combine to shrink any semblance of trust in the marching orders federal agencies receive from the top.

I want to see the Park Service benefit from the services they have provided for years. I also want public oversight, and I never want to see benefits-sharing become an excuse to further shrink Park Service budgets!

Thank you,

Nancy C. Jacques



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*Received 12/14/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I do not think that the Benefits sharing program will be beneficial to the parks ecosystems. The whole point of the National Parks is to preserve the natural beauty of this country. Letting logging and mining happen will destroy this natural beauty.

Kept Private

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*Received 12/15/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I support the No-Action Alternative for the Benefits-Sharing in the National Parks Draft Environmental Statement. This would allow research involving NPS specimens, that may lead to the development of commercial products to continue, in the parks, but without any obligation to share any resulting benefits with the NPS. A modification of the Preferred Alternative, in which scientific benefits and in-kind services would be shared with NPS by the researchers, but no royalty benefits paid, would be the ideal solution. In, the first place, the parks are publicly owned and paid for by the public, many times over, through Federal taxes, entrance and camping/backcountry fees, and boating registrations. It seems pure and simple greed on the part of the NPS to expect more financial gain from work that does not destroy the environment, yet could serve the furtherance of science. Second, entering into an agreement for financial gain by the NPS is just more red tape for researchers to deal with, not to mention the law suits that would inevitably follow this greed.

Pam Racow

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page 1 of 1

*Received 12/15/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

Thank you for your careful consideration of the field of impact in the Benefits-Sharing Draft Environmental Impact Statement. Extending that field to the social environment shows the kind of innovation and creativity necessary for meeting the challenge of new technology.

However you have failed to consider a significant part of the social impact.

On page 272 of the DEIS you mention that "A number of people were concerned about topics that are outside the scope of this EIS, such as whether or not the NPS should support U.S. intellectual property laws." But you have defined the scope of the investigation as extending beyond just the physical environment to a social one. Therefore you need to consider the ethical impact of your proposals on how the NPS carries out its mission, and the impact on the culture at large.

On page 106 you describe the purpose of the NPS as conservation not only of park resources, but also of "park values." What are these? Section 1.4 of the 2001 Edition of National Park Service Management Policies emphasizes that conservation is for "the common benefit of all the people of the United States."

Any action the NPS takes on the issue of benefits-sharing will impact the larger culture. This is not just a question of law, it is a question of a basic cultural paradigm: the value of the Commons.

Popular economic theory today holds that the market is the source of wealth; this results in the privatization of natural resources we used to consider were held in common by all. Patents on genes in agricultural plants force farmers to buy seed every year, instead of planting some from last year's harvest. Patents on medicines the World Health Organization has identified as "essential for priority health care" make them out of reach for many people. Patents on results of scientific research actually make research more difficult (see <[http://sippi.aaas.org/survey/AAAS\\_IP\\_Survey\\_Report.pdf](http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf)>).

NPS's decision on the subject of benefits-sharing will support the spread of privatization -- or it can affirm the value of the Commons. Each time we give our Commons to corporations, we get further locked in to the market mindset. The mandate of the NPS asks us to be more creative than that: to find a solution that will foster the common good.

Kept Private

*Received 12/16/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

To Whom It May Concern:

I vehemently oppose commercial bioprospecting in our National Parks. These are natural treasures that should be allowed to remain pristine for the public and wildlife.

While I do support the public interest research that takes place in the parks, I am opposed to the National Park Service's plans to enter "Benefits-Sharing" agreements with private corporations seeking to commercialize their research.

Corporations should not be allowed to mine, exploit and profit from living organisms that we, the people, ought to be stewarding.

Allowing commercial bioprospecting runs counter to the mission of our National Parks. The natural resources on our public lands must be preserved, protected and -- most importantly -- remain public for the public's benefit. This is why I oppose alternatives "A" and "B" in the National Park Service's Draft Environmental Impact Statement (DEIS), entitled "Benefits-Sharing".

Alternative C, as its title implies, is the only option that "Prohibits Research Specimen Collection for Any Commercially Related Research Purpose." With that in mind, I support "Alternative C".

Sincerely,  
Eric Prescott

*Received 12/18/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

Dear Park Service,

Bioprospecting in our National Parks is a horrible idea! These lands are supposed to be protected from commercial, natural resource exploitation. That was the point of establishing them, in the first place. How could someone in the National Park Service not get this? Alternative C is the only one that is true to the mission of the National Park Service. It is embarrassing to you, who claim to be stewards of our National Parks, that you are actually considering -- and supporting! -- commercial natural resource exploitation in our National Parks. Shame on you!

Please do the only honorable thing by continuing the historic mission of the National Park Service: protecting our National Parks lands from commercial natural resource exploitation, preserving them for their natural values and the enjoyment of the American people in perpetuity.

Sincerely,

Dr. Jonathan Matthews



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*Received 12/23/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I am simply a U.S. citizen. I object to research in national parks that is commercial and for private profit. These parks belong to the citizens and any profit from the parks should be put back into the parks' upkeep. I support option C.

It is truly disappointed that we have to spend our time defending almost everything from the clutches of commercialism. You, the National Park Service, are supposed to protect our parks instead we find you trying to exploit them. Is there any government official that can be trusted?

Martha B. Ashton-Sikora

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*Received 1/11/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

Isn't this going to invite unwarranted and invasive research in the hopes that it will create "benefits"? Extra money going to the NPS is a great thing, unless it is harmful to the parks and wildlife therein, in any way.

N/A

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page 1 of 1

*Received 1/12/2007 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

Dear PEPC Benefits-Sharing,

Please select Alternative B1 in the final NPS Benefits Sharing Plan. Alternative B1 best protects park resource and visitor experience, while assuring the public the right to review any agreement between NPS and a private researcher or company.

In addition, the following points are critical to include in any final Benefits Sharing plan:

- Park resources and visitor experience must not be directly or indirectly adversely affected.
- The public should have a right to view the entirety of any agreement.
- All scientific information resulting from any agreement must be shared with the park, and any compensation received should be used to benefit resource protection and research.
- No benefits sharing agreement should be developed that results in resources being used for commercial purposes. Any research contemplated under Benefits Sharing agreements cannot result in the direct commercial use of those samples removed from parks.

The creation of new scientific knowledge in national parks is a significant benefit which is compatible with the conservation of the resource and undiminished public appreciation under this alternative. I urge you to select Alternative B1 to implement the Benefits Sharing Plan. Thank you for considering my views.

Sincerely,

Don Masterson

12515-1903  
page 1 of 1

*Received 1/12/2007 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

Dear PEPC Benefits-Sharing,

Please select Alternative B1 in the final NPS Benefits Sharing Plan. Alternative B1 best protects park resource and visitor experience, while assuring the public the right to review any agreement between NPS and a private researcher or company.

In addition, the following points are critical to include in any final Benefits Sharing plan:

- Park resources and visitor experience must not be directly or indirectly adversely affected.
- The public should have a right to view the entirety of any agreement.
- All scientific information resulting from any agreement must be shared with the park, and any compensation received should be used to benefit resource protection and research.
- Agreements with scientists, research and other organizations should include explicit park ownership rights related to discoveries and any resulting intellectual property rights.
- Agreements should not be so one-sided as to discourage scientific research within the parks.
- Compensation through royalty or similar agreements should directly benefit the park from which the scientific discoveries were made.
- No benefits sharing agreement should be developed that results in resources being used for commercial purposes. Any research contemplated under Benefits Sharing agreements cannot result in the direct commercial use of those samples removed from parks.

I urge you to select Alternative B1 to implement the Benefits Sharing Plan. Thank you for considering my views.

Sincerely,

Mary Jo Veverka

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page 1 of 1

*Received 1/13/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

Dear PEPC Benefits-Sharing,

Please select Alternative B1 in the final NPS Benefits Sharing Plan. Alternative B1 best protects park resource and visitor experience, while assuring the public the right to review any agreement between NPS and a private researcher or company.

In addition, the following points are critical to include in any final Benefits Sharing plan:

- Park resources and visitor experience must not be directly or indirectly adversely affected.
- The public should have a right to view the entirety of any agreement.
- All scientific information resulting from any agreement must be shared with the park, and any compensation received should be used to benefit resource protection and research.
- No benefits sharing agreement should be developed that results in resources being used for commercial purposes. Any research contemplated under Benefits Sharing agreements cannot result in the direct commercial use of those samples removed from parks.

I urge you to select Alternative B1 to implement the Benefits Sharing Plan.

National parks belong to all of us - all their resources. Therefore all individuals should have the benefit of any research conducted in the park.

Thank you for considering my views.

Sincerely,

Karen Eble

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page 1 of 1

*Received 1/13/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

Dear PEPC Benefits-Sharing,

Please select Alternative B1 in the final NPS Benefits Sharing Plan. Alternative B1 best protects park resource and visitor experience, while assuring the public the right to review any agreement between NPS and a private researcher or company.

In addition, the following points are critical to include in any final Benefits Sharing plan:

- Park resources and visitor experience must not be directly or indirectly adversely affected.
- The public should have a right to view the entirety of any agreement.
- All scientific information resulting from any agreement must be shared with the park, and any compensation received should be used to benefit resource protection and research.
- No benefits sharing agreement should be developed that results in resources being used for commercial purposes. Any research contemplated under Benefits Sharing agreements cannot result in the direct commercial use of those samples removed from parks.

I am a supporter of commercial research, and of the private sector's ability to generate useful advances based on the profit motive. But the ability of business to do so does not depend upon unfettered access to ALL of the financial benefits. The entity that is the source of the raw material or phenomenon upon which the discovery is based and the profit is generated also deserves to benefit. In this case, that means that resources should go to preserving, protecting, and maintaining the environmental amenities in the National Parks.

I urge you to select Alternative B1 to implement the Benefits Sharing Plan.

Sincerely,

Gordon Rands

*Received 1/16/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

Please include our comments as follows on the draft EIS on Benefits Sharing dated September 2006. We have visited many units of the National Park System, from nearby Harpers Ferry to great western parks such as Yosemite and Olympic. The protection of those parks under the nonimpairment standard of the National Parks Act is important to us.

We favor the use of national parks for research that draws upon the natural organisms and ecosystems that are protected in the parks, as long as it does not compromise the protection of the parks. We believe the benefits flowing from that research should be shared with the national parks to advance their conservation.

We also believe the agreements under which that research is done should be a matter of public record. In the past, concessioner agreements were kept confidential, which has led to many abuses, and we hope that will not be repeated in the Benefits Sharing program.

We favor Alternative B1 because it fosters research under conditions that will protect the resources of the parks and the experiences of visitors, and it also keeps the agreements open to public scrutiny.

We urge the following as essential elements of the final Benefits Sharing policy:

1. There must be no adverse effects on park resources or visitors' experiences.
2. All agreements must be subject to public review in their entirety.
3. Scientific information generated as a result of the agreement must be shared with NPS, and any financial consideration received for that information must be used to advance protection and research with respect to park resources.
4. No park resources must be used directly for commercial purposes (such as the sale of research specimens or samples). The noncommercial purposes of the parks must be maintained intact, or it would soon lead to abuses like those in the national forests.

We feel that Alternative B1 meets these objectives. Thank you for this opportunity to comment. Please keep us informed of future public reviews on this subject.

George & Frances Alderson

*Received 12/11/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

This letter is a comment on the concept of bio-prospecting in the National Parks. I support Alternative C. No bio-prospecting. Period. To allow commercial research in the parks goes expressly against the original purpose of the Park Service ' which is to protect these areas from exploitation. As I understand it, Alternative B allows commercial enterprises to remove biological organisms from the parks, which goes against the basic mission written into the formation of the National Parks Service.

Alternative B requires parks staff to allot part of their time for managing these commercial ventures, which puts the cost of maintaining these agreements on the American people, an unlawful misuse of public funds for private financial gain. As this deal-making goes public and more citizens find out about this bargaining, you may expect that this will cause an uproar.

Do the right thing. Choose Alternative C and refrain from dirty politics.

Seven Dunsmore

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*Received 12/08/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I must strongly protest and oppose any move to allow any commercial 'bio-prospecting' in our national parks. This is just 'Selling off America and its resources.'

To commercially mine the genetic resources of plants, animals and microorganisms in any area that belongs to us, the public, is simply raping the land. These resources are not the federal government's to sell: They belong to all of us.

We must not allow the exploitation of our parks' genetic treasures! I prefer to leave the parks stand as they are with absolutely no interference.

However, if I must choose one, I support Alternative C. I want NO Commercial Bio-prospecting in the National Parks.

Read Teddy Roosevelt's words as he was setting land aside for the future denizens of our country. He had prophetic vision. These lands must be left as pristine as they are!

We must stop opening our public lands for anything other than to honor the pure nature and the beauty of these-sacred places. We need these areas to survive. They help clean the poisons from our environment and provide a survival area for what is left of our wildlife.

They also provide solitude for the masses (like myself) who live in the cities and suburbs; visiting these parks and seeing the magnificence there is like going to church. These lands are definitely God's Country and should be left to stand as they are.

The National Parks Service has been assigned stewardship of our precious lands, to preserve and to protect them.

Do not allow private commercial companies to own or use any genetic resources of plants and animals in our parks. Alternative C is the only choice acceptable.

Necia Refes

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*Received 11/30/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I do not want any bioprospecting in our country's national parks. I hope you do not approve any plan which permits this no matter what the financial benefits. Our parks have been set aside to protect them from exploitation of any kind including bioprospecting.

I understand that alternative C allows research in the parks, but not commercial research. Of all the proposals this is the best unless there is an alternative of no change at all.

All versions of alternative B are unacceptable. Please do not implement any of these. I hope we can keep our parks as they were intended to be--for the enjoyment of future generations.

Edwin J. Potts

*Received 11/09/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I am writing to you to comment on the "Benefits-Sharing" plan contained in the Draft Environmental Impact Statement (DEIS) regarding bioprospecting in US national parks. First, let me say that I support Alternative C. I want NO commercial bioprospecting in the National Parks. Second, let me say that it shames me that the American government has sunk to the level that our national parks - which were meant to preserve our natural heritage in perpetuity - are being threatened with commercial exploitation by businessmen conducting back-room deals. The process by which this DEIS has come about is a disgrace, and the fact that the public only gets 90 days to review and comment on the 340 page document is ludicrous. Furthermore, the name "Benefits-Sharing" is a laughably Orwellian term. This plan would privatize the benefits of the national parks, removing resources so that only the wealthy few can benefit from them.

Research in our national parks should be conducted for the public good, not for private gain. Research should be conducted in a way that preserves the park as completely as possible. Neither of these conditions would be met under options A, B and B2, and therefore I oppose options A, B and B2 in the DEIS. I support option C.

Alternative B2 is appalling. Not only would private companies be free to make deals for exploiting the national parks, but citizens would never be able to find out the financial details of the plan. There would be no oversight, and without oversight the potential for bad deals is tremendous.

Furthermore, our national parks are understaffed as they are, and option C in the DEIS is the only option that would allow the park staff to continue on their mission on the public's behalf. Other options would divert time away into negotiating Commercial Research and Development Agreements (CRADAs). Not only would the public lose its national park resources, it would also lose tax-funded working hours of national parks employees.

The national parks should remain national, and not be privatized. Our national parks are not for sale.

Michael Roberts

*Received 12/29/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I strongly urge you to adopt Alternative C, and to not allow "bioprospecting" in our national parks by commercial interests. Alternative C appears sufficient to allow legitimate research in the parks for the public interest, without opening the door to the exploitation that would doubtlessly follow if you were to allow these private, commercial interests in.

Alternative B would not only allow commercial exploitation, but 'confidential' arrangements as well. This is an obvious signal that these commercial interests know very well that their practices are offensive to many people and want the cover of secrecy to keep what they do from the public.

Sirs, these parks are national treasures belonging to the American people. Please defend them from the 'biomining' that would inevitable result from the initial 'bioprospecting', and leave a bio-devastation in our parks comparable to that left by mineral mining throughout the West.

Laura Pace

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*Received 10/30/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

I have been involved in research for over the past 20 years, including on-the-ground research products in numerous national parks across the US. NPS research projects I have and are currently involved with directly benefit the parks and aid to expand the marketability of the products involved. I have also sat on the board of a foundation that has a CRADA with a government agency to help stabilize the government research program that all members of the foundation benefit from. The foundation has voluntarily contributed a minimum of \$0.5M to the research program annually for 10 years. The relationship between the research agency and the foundation is extremely close with meetings quarterly and a firm understanding of the benefits, costs and risks of each institution involved. As I commented on the Benefits-Sharing DEIS, I relied heavily on my experience with past and current research projects and the foundation CRADA.

Although I believe the National Park system should benefit in some way from research conducted in the Park or with Park specimens, I do not agree that the preferred alternative, as outlined, is the solution. It is important to understand that researchers and companies that develop commercial products have related Costs. Will NPS contribute to the cost of the research at the same percentage rate that they will benefit from a commercial product? Park preservation/operation costs are an important contribution. How would they be assessed as a contribution to the product development costs? Industry and University typically have set budgets/expenditures towards development of a product to aid in assessing profit needed to recoup development costs. Not all research leads to commercial, profit generating products; however, the developing costs of products that never make it to market or generate income must be accounted for. Typically non-commercial product research is covered by the profit generated by the few successful products. Successful product profit also is used to reinvest in the company research program as well as used to cover manufacturing and distribution costs. In reading the DEIS, I did not see how these back and future costs of the researcher or park will be accounted for. When considering Alternative B, NPS should remember that their funding comes from taxes. NPS should recognize their benefit from successful research results is an improved national economy. Companies stagnant with one patent don't employ nearly as many people as companies generating numerous patents, reinvesting for the future.

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#### COMMENTS

Alternative C is unacceptable. This alternative has the possibility of causing a missed opportunity that could benefit the US.

Alternative A: No action alternative is adequate and preferred over the Alternative B as it stands as outlined in the DEIS.

Pg 67, Note #10 for Section 2.4 states that NPS is currently able to enter into cooperative type agreements that will help achieve the NPS mission. This statement indicates that a change dictated by an EIS is not necessary for NPS to enter into agreements that would result in royalties to the park to be used for conservation and preservation.

Alternative A is preferred over Alternative B because, there is no impact to the researchers and, as stated in Chapters 3 & 4, there is no impact to NPS (except a 1.14% loss of funds to one park). Alternative B does negatively impact the researcher with no negative impact to the mission or resources of NPS.

Alternative B is unacceptable as outlined in the DEIS. Most notable, this alternative is unacceptable due to the lack of detail and clarity of when and which research projects must enter into a benefits-sharing agreement with the park. The direction appears clear at the beginning but later statements, such as, Section 3.5.3.

"If the study of those specimens resulted in discoveries or inventions that could have a commercial application, then any park could participate in benefits-sharing under Alternative B."

Is this misstated that "& any park could &" , indicating option, or they "would", indicating Parks would have no alternative but to enter into a benefits-sharing agreement?

"Based on past history, some park units are more likely to participate in Alternative B benefits-share program than others."

Are they "likely to participate" because they want to, or because they have the opportunity to? If Benefits-sharing agreements are always required when a commercially viable product is the result of research, Alternative B is unacceptable. Alternative B would be acceptable (with the following comments addressed) if parks had the choice, when a commercially viable product is involved as a research result, to enter or not enter into a benefits-sharing agreement. Parks may elect not to enter into the agreement if negotiation reveals that royalty payments, which would otherwise be reinvested back into research, will only cover park administration costs.

Suggest Alternative and modifications to Alternative B:

Understanding that each research venture would be negotiated separately, a guideline should be set forth to help determine compensation/royalty. If the national parks directly benefit from the discovery (example: product aids in the preservation of the park, or helps park meet other mandate) no compensation is required. If the national park mission is not directly benefited by the discovery, the park negotiates for compensation following a set of criteria that would include consideration of the researcher's costs and national park's costs to preserve the researched item. Researcher costs could include:

discovery costs, reinvestment of profit to additional research (including personnel, equipment, labs, etc.), taxes paid on profit, costs of product registration (incase of chemical, food or pharmaceutical) and cost of failed research towards similar products. Park cost could include preservation, maintenance, up keep, and visitor enjoyment disruption for the area where the specimen was collected or research was conducted.

Criteria would result in figuring cost due to the national park in relation to their contribution to the research/discovery. To fully accept Alternative B, I would need to see more detail on what factors would be considered during a benefits-sharing negotiation.

Specific Comments / Unacceptable provisions under alternative B:

Page 43 "The General Provisions provide an approval framework to allow sharing of scientific and monetary benefits resulting from improved cooperation between national parks and the research community." There is no discussion of the sharing of cost.

Cooperation between park and researcher will not improve if the researcher assumes all cost/risk and the park only benefits without risk. The DEIS should include more detail, in addition to the cost of issuing research permits, of the risk/cost to the park that makes NPS deserving of a share of the product profit.

Page 44 "Researchers . . . would be required to enter into a benefits-sharing agreement and negotiate with the park royalty or other monetary terms that are contingent on actual commercial development of a discovery of invention before using any such discovery or invention for any commercial purpose.

The time frame for developing the benefits-sharing agreement is not outlined. The realistic steps appear to be: prepare CRADA, review by regional director, review by Dept of Interior Solicitor Office, review by NPS director, signed by park superintendent. Signing by the researcher can include; review by company/institution lawyers, review by marketing personnel (typically 1 to 3 tiers)/board of directors/Institution heads, prior to signing

by the researcher or company official. This process can severely delay "time to market" while the negotiating time and approving park royalty will not result in a more clear idea of "fair value" as indicated in the DEIS. Delaying time to market typically results in loss of revenue through missed opportunity, salary/manufacturing/distribution overhead, delay of new product research, reduce stock value and can result in employee lay-offs. The steps from Discovery to Marketing, layed out on page 85, are not separate events, but overlap substantially to aid in reducing the time to market. Although a delay to market may be viewed as more "equitable" to the national parks, it can be devastating to a research company.

Section 3.5.4 Existing Administration Resources

Discussion of FTE for research permit applications is not a valid as any type of indicator for negotiation of a benefits-sharing agreement. As outlined in the DEIS, the two events are separate. As a researcher in industry I am well aware that negotiation for sharing of profit takes a great deal more time than 1.6 hours. Timeframes of negotiation range from 1 month to 2 years.

Section 2.4.3 Disposition of Benefits

"All benefits received by the NPS under any type of benefits-sharing agreement would be dedicated to the conservation of resources protected and managed by the NPS" In the private sector revenue not utilized for salary, benefits and operations is reinvested to future research. Future research is extremely important to our economy. I do not agree with potential research dollars being re-directed to conservation of our national parks when an option of directing funds to the Natural Resource Challenge exists. Alternative B would be more acceptable if dollars gained by NPS from benefits-sharing were applied to NRC.

Pg 47 Section 2.4.5.2 Penalties for non-compliance

It is unacceptable that there is no penalty or incentive for the park to negotiate an acceptable benefit-sharing agreement swiftly. This section allows for a park to purposely slow negotiation to force the researcher in to a compromising position to accept a less than reasonable agreement to assure timely market entrance. If a product launch is delayed due to poor negotiation the company can potentially suffer substantial economic set back, encouraging violation of the agreement (or yet to be agreement). There must be an incentive or penalty built into Alternative B in relation to the park, if one exists for the researcher. This further emphasis the lack of risk NPS has in the partnership.

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Section 2.4.6.1 Technical assistance to parks

The developed service-wide institutional record of benefits-sharing agreements must be easily assessable to the researchers and their companies for the same reason these would be beneficial to the parks ' to enhance institutional expertise and efficiency.

Section 2.4.6.2 Financial support for administration

This section is unacceptable and should be changed to indicate that benefits-sharing will only be implemented if an agreement is negotiated to substantially reimburse the park over the cost of the parks administration costs. When negotiating, the cost of the company lawyers and negotiators should be taken into equal consideration of the cost of the park negotiator. If royalties are only covering the cost of the administration, or slightly above the administration cost resulting in no real benefit to the park program, the benefit-sharing program is only resulting in wasting money that could be reinvested in additional research that could benefit the US.

Section 2.4.6.4

Implementation of benefits-sharing will inappropriately influence research permitting decisions, not on the side of the park, but on the side of the research companies. Research companies already need to jump through numerous government hoops to bring a product to market ' patent process, FDA/FIFRA process, tax process, manufacturing licenses, approval of product name, etc. Addition of an added government process, negotiating benefit-sharing agreements, will encourage researchers to go else where to collect/investigate specimens. This means potential discoveries based on park resources will be missed.

I understand the DEIS has tried to address this issue through use of a CRADA; however, the lack of penalty or incentive to the park to efficiently negotiate and process paper work reduces my confidence that the process will be efficient and not discourage research.

Pg 45 Disclosure options

If the Preferred alternative for benefit-sharing is accepted, I agree with alternative B2 for optional disclosure if the company is protected by FOIA.

General Comments

I am unclear how actively all scoping comments were considered in determining the alternatives, but some could distract and result in poor alternatives. The one of concern

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is 2.6.1.1. "...or scientific research must not be allowed if its goal is to discover useful products or processes from the study of nature."

Velcro, metallic paints, the least toxic EPA approved herbicide, biological weed control, and light without heat (glow-in-the-dark sticks and accessories) were all invented from the study of nature. Industry increasingly turns to the wonders of nature to meet society's wants and needs.

The document fails to discuss continued research of a product already on the market. How will product improvement or market expansion be addressed?

Would monetary benefits be paid to the park before or after taxes?

Jennifer Vollmer

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page 1 of 1

*Received 01/27/2007 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

Any proposal to collect any sort of fees for commercial activity in the parks, other than those for limited traditional franchises such as lodges and gasoline stations, is entirely unacceptable. It creates a financial incentive to permit activities which are detrimental to the Park Service's mission to preserve the natural and historical features of the parks.

Robert Moss

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and Public Comment (PEPC) website*

The benefits both to the Park Service and humanity that can be reaped by bioprospecting are too great to pass up. With benefit sharing agreements the Park Service may share in the benefits arising from such research.

The Park has not been harmed by any past bioprospecting, humanity has benefited, tremendous profits have been made (but not shared with the Park Service). Research permitted with the Park Service as a benefit sharing partner is a win-win scenario.

I support and approve of the current plan but do believe that mandatory disclosure of terms and conditions of any and all benefit sharing agreements must be a critical condition to avoid the appearance of impropriety and prevent benefit sharing agreements and bioprospecting from failing due to public perception of wrong doing.

-Katie La Salle-Lowery  


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*Received 1/29/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

I respectfully submit the following comments concerning the National Park Service Benefits Sharing Draft Environmental Impact Statement, hereafter referred to as the DEIS. I request that our comments be included in the official public record, carefully considered, and incorporated into the planning process, any further drafts, and the Final EIS/Plan and Record of Decision.

I recently left the Smithsonian Institution where for almost 18 years I was dealing with international environmental policy issues for the Smithsonian and from them, within the USG interagency processes. One of the processes which I have followed, and in fact been a substantive lead on, is that of "Access and Benefit Sharing." I have been part of the formal and informal discussions and meetings internationally at the UN Convention on Biological Diversity, the World Intellectual Property Organization, the World Summit on Sustainable Development, and many other fora. I am currently writing academic pieces on these experiences

I believe the DEIS, as presented, is seriously flawed. It does not satisfy the District Court's Order in *Edmonds Institute et al. v. Babbitt, et al.*, nor does it meet the requirements of the National Environmental Policy Act (NEPA). The DEIS has narrowly cast what should be a full range of alternatives into a false choice between commercial bioprospecting with increased benefits to the Parks and society, and no commercial bioprospecting with no increased benefits.

The NPS should either withdraw the DEIS, correct its deficiencies, and then issue a revised document for public review and comment as a Supplemental Draft EIS or choose Option A.

NPS has traditionally allowed scientific research, under specified conditions, to take place in the National Parks. This research has exceedingly rarely led to the consequences, scientific and financial, such as that accruing from the discovery of TAQ.

However, the NPS was put into an uncomfortable position, as they themselves admit, when they were asked why the US government did not get royalties from the TAQ polymerase patent. This desire to get a financial return (benefit) forces the defensive position in the NPS to both claim ownership of the biodiversity within the Parks and heightened control over all specimens taken from the National Parks and to develop the CRADA and benefit sharing concepts which this DEIS addresses.

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I strongly oppose opening up the parks for business partnerships. Also, I want to see profits from research or applications of research conducted in the parks to be shared with the parks - preferably received and managed by some 3rd party that could dampen conflicts of interests in generating revenue at the costs of compromising ecological integrity. Thank you for your consideration, and your dedication to the generations far ahead that will not remember our names.

all the best,

Jesse Turner

The desire to get the benefits is understandable, as is the desire not to have to come in front of Congress and explain why this apparently obvious idea is not good public policy.

However, it is not good public policy. It is not good public policy because there is no evidence that the potential benefits would efficiently outweigh the added costs of the regulatory and contractual systems which the benefit-sharing system as proposed would entail. Any benefits of a benefit sharing scheme must be weighed against the practical impact of such a scheme in terms of cost, on the actual use of research specimens and information. Globally, many countries have fallen into the same trap that the NPS has fallen into one of the policy arenas in which there actually is a slippery slope. The slope is the following: deciding that there is a desire to capture benefits from the commercial use of the biodiversity on lands; recognizing that this is extremely difficult to monitor and control once materials are out of one's position; not trusting one's contractual counterparts increasing control over materials (in this case specimens coming from Park lands); and setting up elaborate, expensive, anti-science systems of control and oversight with no analysis of the cost-benefit ratio of this system, clearly stifling scientific, especially taxonomic, research.

Some developed countries which have done careful analysis of the ABS issues for government lands have decided that the management costs and restrictions which would come from such a process are not warranted and therefore have chosen policies similar to Option A. No other developed countries have developed national procedures yet due to the complexity and understood sensitivity during global negotiations.

The costs to the NPS are in terms of the long-term management and oversight of this complex set of arrangements and in the many legal challenges which will come from its attempted implementation, but, perhaps more important are the resulting restrictions:

- “ To the thousands of researchers and their institutions who do research in the National Parks, the vast majority of which is non-commercially oriented;
- “ To the public in the reduced scientific information which this already complex system is resulting in, and;
- “ To the future when the necessary specimens which document the National Parks in this day and age are not widely available due to the difficult and onerous conditions which this policy forces the NPS to take.

Benefit sharing as a concept is being discussed and negotiated widely in the international arena. It is one of the elements in the U.N. Convention on Biological Diversity (which the U.S. has not ratified and the Congress has instructed NPS not to implement). The

experiences from other countries trying to implement ownership based models of benefit sharing have all created large bureaucratic and procedural impediments to research and development, and few have seen any substantial flow of benefits to them. All have seen a decrease of research opportunities and a decrease in the many non-monetary benefits which flow from pro-research policies and procedures. Some of the countries which have adopted such policies are now changing back to a less restrictive set of procedures, such as the Philippines and Brazil. Benefit-sharing concepts are being negotiated not only in the UNCBD, but also in the World Intellectual Property Organization, the World Trade Organization, and as part of many of our Free Trade Agreements. The NPS proposed policy will make our negotiations much more difficult in all of these fora.

This deceptively simple desire to have benefit sharing arrangements creates many unintended negative consequences to science, creates more uncertainty and ambiguity in any bioprospecting enterprise, and as written is too broad and vague, with no certain return. It is, as increasingly is being seen in the CBD discussions, a lottery. Some Parks may indeed provide a useful organism which creates an income flow, but most will not.

The benefit sharing debate, globally and in the NPS, is based on simplistic assumptions and models, all reinforced by the rather unique TAQ example that an organism is taken, important and commercially relevant properties are found, they are patented and commercialized. The reality is that this is an extremely rare case. First, access to materials is for non-commercial research in the vast number of cases. Very few of the specimens collected for commercial research will uncover any commercially interesting applications. The majority of commercially interesting findings, even those receiving patent protection, will not generate any income (many, if not most patents are defensive keeping others from using the potential, rather than resulting in a positive cash flow). Finally, most of these commercially interesting options will not be using the organism, as the TAQ example does, but a tiny part of the genome or part of a molecule discovered. Apportioning the property claim to part of a molecule is not a trivial exercise. So the regulations are set up to capture benefits from a tiny fraction of uses. One additional element of the slippery slope is that for the vast majority of basic science research specimens (as opposed to those specifically collected for bioprospecting), they are specifically collected to be held in perpetuity, to allow future generations to understand the biodiversity at a specific place and time. It allows us to understand change, variety and variability in nature. However, this leaves open a door (very small, but real) that someone in the future might use these specimens for commercially oriented research (the future and third party issues). Therefore some countries, and the NPS, to create more certainty that they will get their share, have made it costly and nearly impossible for the many repositories museums, research collections, botanical gardens and herbaria to in good conscience accept NPS materials any more.

The other benefits which do flow from research knowledge, education, information for management and planning these already are flowing and will continue to flow (to the NPS and the citizens of the United States) under all models.

Additionally, I will venture a guess that most respondents to this request for submissions are focusing solely on bioprospecting. However, the NPS preferred proposal states they it is intended to gain benefits from “useful discoveries, inventions, or other commercially valuable applications.” This statement is too broad and vague. Does the printing of a calendar of photos from the research (with copyright protection) fall under this mandate? (I note that the NPS does charge cost recovery and a location fee for commercial filming will they include a royalty fee also under this policy?) Would biomechanical inventions such as a clamp which was designed after watching the use of a spider’s mouth be covered? Would the development of a cancer fighting drug from a plant in Canada which was studied because it was related to a plant in an American National Park be covered, even if the American plant did not provide the ultimately useful product but was part of the discovery process? These are not just hypothetical examples for each type there are claimants in other parts of the world who are requesting benefits from such linkages.

These questions of reach and reach-through are fundamental and need to be addressed prior to any decision on whether or not to develop such a regime. On the face of it, the language proposed is a legal quagmire and will result in many lawsuits to define and demark questions like the ones asked above.

Most of the biological diversity found in our Parks are not unique to Park lands. If something was found within a Park but also outside of the Park, what claim for benefit sharing would the Park have?

The preferred option proposal will have effects contrary to many of the objectives of the Park Management Act. The tension between the scope and ambition of any benefit sharing system and its feasibility of practical implementation needs to be addressed.

While the financial windfall from capturing part of the profits of another TAQ are alluring, that siren call must be weighed against the probably loss of other benefits which are already being accrued, but not accounted for. Benefits already coming to the US public (the real owners of the biodiversity of the National Parks) from the research (commercial and non-commercial) on NPS lands include knowledge of the biodiversity and ecology of the regions, enhanced management capacity, and yes, new products. The benefit to the United States from the TAQ process has been enormous in health benefits, and our understanding of so many scientific processes. Each of these has created new products

and the tax revenues from them. Foregoing the royalties on a new TAQ, if it facilitates it being found more quickly, most probably would be an overall increased benefit to the U.S. public, and the world.

The potential (and in fact the high probability) that the costs of maintaining the necessary system and defending against the many court cases that will ensue from the vague and open-ended attempt to gain benefits from “useful discoveries, inventions, or other commercially valuable applications” will result in a decrease of funds for the maintenance and appropriate oversight of the Park and therefore have a deleterious impact on the conditions (environment) of the Park.

The real life existing procedures which the NPS has developed in recent years to try to capture benefits have not worked well. Other organizations and individuals are questioning the basis of NPS ownership of the organisms which might be studied, and therefore questioning their capacity to develop these procedures. Based on Supreme Court cases and the NPS Organic Act, these questions are very valid. These claims do create a conflict with the provisions in the USGS Organic Act of 1879 which clearly outline the responsibility of the NPS to deposit research collections at the Smithsonian or other repositories. Others question that having the benefit-sharing process, especially with a mandate to “make money” for the Parks, will skew Park decision making and permit approval towards bioprospecting and away from general research. This also has strong credence and examples from many parts of the world show that this is the result of increasing benefit-sharing status.

Most natural history collections currently will not take NPS collections under the conditions which Headquarters insist upon. They are expensive, create additional unfunded mandates, and for control purposes (to avoid misappropriation which might reduce benefit sharing as mentioned above) mandate dual systems of storage, curating, reporting and monitoring of the collections. These real costs are reducing the ability of the partners of the NPS in the academic, museum and research community from documenting the biodiversity and ecology of the National Parks as they have been doing since the inception of the system. In the research communities I have worked with, people are increasingly avoiding working in the National Parks, depriving the Parks and the U.S. public from the information and knowledge which such research would develop. (There are some exceptions, and some Parks are less restrictive in the conditions which they place.)

As we have seen in the international arena, the fear of biopiracy from third party or later use of specimens (which is theoretically possible, but extremely rare) is creating conditions

which are onerous on the research and collections community. From a strictly bureaucratic position, once you put the value on the specimen, you almost have to create this onerous system to avoid future embarrassments.

As is stated in the DEIS, benefits, should they ever be derived, “often don’t materialize until years or even decades after completion of the permitted research” (p5). The management costs to all users of Park resources are therefore an obligation of tracking and reporting for years and decades. These costs need to be seriously understood.

Thus DEIS is fundamentally flawed for 2 key reasons. First is it built on an improper analysis of law, specifically in their claim of ownership rather than sovereignty of the materials found in the National Parks. This claim has many implications, none of which are good for long-term management or resolution of the issues and all open up many long-term legal questions of control, shared resources, and multiple claims for the benefits (to the Park? To the NPS? To the general treasury for the real owners, the American people?).

The second reason is that they did not do an effective cost-benefit analysis of the proposals and the implications of a costly system on the long-term ability of the Park Service to manage the Parks. Many important questions were neither asked nor answered, the long-term management, oversight, and enforcement questions were not adequately addressed, and the real implications for the fundamental mandates of the NPS for research and science-based management of the Parks are being given short shrift by this proposed procedure.

While the Congress and Court have stated that the NPS may negotiate benefit sharing agreements, they have not mandated that they must do this. To address the desire to create an opportunity for the US government to benefit from successful commercialization of genetic resources found on our lands, is there a less heavy handed and much more precise process which could be developed?

Many of the costs are known and can be calculated. The benefits are a crapshoot. Until a legitimate cost-benefit analysis is done, the only conclusion is that implanting any option other than A will result in a decline of resources going into Park maintenance and management and therefore will have a deleterious impact on the environment of the Parks.

Leonard P. Hirsch

*Received 01/29/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

January 27, 2007

NPS Benefits Sharing DEIS  
P.O. Box 168  
Yellowstone National Park WY 82190

To the reviewer,

I am writing to state my opposition of the commercialized bio-prospecting which is proposed within the Benefits-Sharing DEIS. The US National Parks are formed to recognize and protect areas of defined significance to the people of the United States, and to steward the resource for the benefit of all citizens. In the case of National Parks that are created for natural treasures, the stewardship has always sided to the protection and preservation of the natural features for perpetuity of the nation.

Commercialization of the parks for natural area has help to a relatively low measure; mainly for the enhancement of managed access for people to come in contact with the natural area. Commercialized bio-prospecting is contrary to the stewardship mission of the parks. I am aware of the existing system for limited 'prospecting' of natural species within the parks, with friends who deal with academic biological studies, and with research from private corporations. The system that is currently in place admittedly works well, as stated within the DEIS. This allows low-impact surveys, with any beneficial results spread across the public. Commercialized bio-prospecting will entail a 'lock,' in the form of limited licensure or a patent on a specific natural process or item. The commercialized proposal does include a monetary kickback to the National Park, but the main payoff will be to a single entity - a private enterprise, citizen, or corporation.

Impact statement reviews for Parks necessarily default to preserving or protecting the Park as a foremost objective, with citizen access, then use will following. With a commercialized interest, as proposed with this 'Benefits-Sharing' DEIS, the 'burden of proof' is on the proposed impact to show how it will not endanger the integrity of the Park's purpose of preservation or protection. This DEIS shows a good fundraising scheme for the use of a natural resource. This proposal would have merit on lands managed for use as a natural

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resource, but I feel that it has absolutely no merit in dealing with our National Parks. They are held to a separate and higher standard of integrity. Because of this, I can only support the 'Alternative C; the Prohibition of Research Specimen Collection for Any Commercially Related Research Purpose' that is proposed within the document.

Sincerely,

Oren Kennedy



Copy placed on the DEIS website input area and separately mailed as backup only.

To:  
NPS Benefits-Sharing DEIS Team  
P.O. Box 168  
Yellowstone National Park, WY 82190

12515-7473  
page 1 of 1

*Received 1/19/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

I oppose any commercial exploitation by any commercial bioprospecting. Park resources should not be used at all for commercial purposes. National parks are for the protection of their natural resource, not commercial uses.

Alan Carlton

*Received 1/19/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

I am pleased to comment on this EIS from the perspective of a citizen who regularly visits and enjoys the National Parks--particularly for their scenic, recreational, and wilderness values. I am very proud of our National Parks System, the finest in the world, and I believe overwhelmingly seen as havens of natural resources to be enjoyed as Nature--not as commercial resources!

We do have huge tracts of federal lands outside the Parks, available for various forms of commercial-industrial exploitation. The National Parks should not take on this additional aspect.

I oppose EIS alternatives which might open the National Park System to commercial bioprospecting. I urge selection of Alternative C. No commercial bioprospecting.

Stephen Brown

*Received 1/18/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

Upon a recent return trip from one million acre Boundary Waters wilderness, I learned of the National Park Service's plan to facilitate bioprospecting on more than 84 million acres of land.

This proposal violates the spirit of the park service, devalues our public lands, and arguably continues the pattern of corporatizing our mountains, valleys, draws, and watersheds. Proposals such as these open our spaces to development of all kinds. Environmental impact analysis of roads, impacts of equipment on the soil, wildlife, soluble and non-soluble trash, and future development can never be adequately predicted once prospecting begins.

I am intimately familiar with the scale, scope, and magnitude of these projects. In the Boundary Waters, the wilderness area abuts others, effectively creating more than three million acres. In the Bob Marshall Wilderness, here in Montana, I've never packed enough food to walk across even half of the one million acre space and the connected Greater Yellowstone ecosystems of Glacier National Park and beyond. From walking all of these spaces, and others, I understand the intimate connections between these areas for wildlife, historic human populations, environmental health, and clean watersheds.

I urge you to strongly reject this proposal, citing the Wilderness Act and the dangerous precedent this sets for putting all public lands on boardroom tables instead of where they were meant to be: cartographic marks that, when combined, take days to climb and walk across. Places that we can keep sacred in stories and dreams for generations to come.

Noah Jackson

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*Received 1/20/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

Commercial enterprise in wilderness is prohibited by the Wilderness Act. Bioprospecting is a commercial activity.

Parks are to manage recommended wilderness the same as designated wilderness.

There is so little of our natural heritage left and it needs to be guarded and preserved, not sold off for any reason.

Thank you.

June Anna-Fey

*Received 1/26/2007 via NPS's Planning, Environment and Public Comment (PEPC) website*

I am completely opposed to the NPS allowing private corporations to have access to the park for profit making exploration.

PARKS NOT FOR SALE!

Mary Ellen Anderson

*Received 2/11/2007 via NPS's Planning, Environment  
and Public Comment (PEPC) website*

These personal comments are based on concerns over the current and future environment of the NPS and the advancement of basic scientific research in the NPS and are not intended to portray the positions of the organizations with which I have worked.

As implied in this EIS, the most important issues at hand are to insure that the NPS has measures in place to continue and to increase conservation of species and the "science for parks" in the NPS. The "science in parks" efforts will strengthen many fields of scientific research in the United States and improve the environmental management decisions made for the National Park System.

There are no evident benefits to Alternative C, which should not be implemented. Alternative C appears to be prone to undermine Objective 3.2 to some extent, which states, "Ensure that implementation of the alternatives does not discourage the conduct of research involving units of the NPS." Alternative C appears certain to make basic scientific research in the National Parks more difficult, and as stated in the EIS, there is the potential that this inhibition of research could be major. This "hands-off" or "no access" approach has several adverse impacts, some of which are immediately recognizable, others adverse impacts will become evident over time. Does the NPS want to take responsibility for trying to discern which species might lead to commercially valuable information and which do not? Where would NPS draw the line? Discerning these issues will most likely require more capacity to evaluate research proposals than the NPS currently has. Although the report states that less than 1% of all research activities would be prohibited under Alternative C, any species could, theoretically, contain bioactive compounds, enzymes, or interesting properties that might later lead to commercial benefit.

The EIS states that, under Alternative C, if a researcher inadvertently finds something of commercial value within a species, the adverse impacts of not being able to study this particular range from small to major. Does this mean, for example, if a botanist identifies a plant to have medicinal compounds, that this botanist can no longer study this plant species in the National Parks? Would this prohibit all other researchers from researching this species in the NPS as well? Excluding certain species from study in the NPS appears to counteract conservation measures for species. How can species be conserved if basic research on its systematics, ecology, and population biology cannot be conducted? In addition, Alternative C could create perverse incentives for people to collect target species illegally in National Parks. When such research is done without approval, it would be more likely to be done in environmentally harmful ways. In addition, if a researcher is

forced to study the plant outside of National park boundaries, no potential benefits will be shared with the NPS. One would hope that the NPS describes Alternative C simply as a requirement of creating this DEIS, rather than as a serious proposal. As long as the NPS is able to protect species present in the NPS appropriately and pursues legal action if species are collected or sold illegally, this approach would inhibit possible benefits to United States citizens.

The decision to implement either Alternative A or Alternative B rests on the true administrative burden to the NPS and the procedures under which benefits would be negotiated. The report states that, "Under Alternative B, individual parks would negotiate, implement, and monitor compliance with benefits-sharing agreements consistent with their current management of a variety of agreements with other entities."

The DEIS Report appears to focus on the potential benefits of BS in NPS, but it is not clear after reading this report if the true current or future costs of implementing a benefit-sharing system are reflected sufficiently. For example, the report mentions frequently that the MTAs used in Yellowstone take only 1.5 hours of a current staff's time, but perhaps there is an assumption that such MTAs are easily applicable to the administrative and management systems for all National Parks. Perhaps such MTAs are more applicable to some parks, such as Yellowstone, than to others. In addition, the estimates of the numbers of potential CRADAs per year (two to nine) may be far below what will take place in the future.

Although the administrative and other costs are evaluated quantitatively and concluded to be "negligible," this should be very carefully examined before committing to a benefit-sharing program that is mandatory for both researchers and the NPS. If the NPS will need a team of lawyers and scientists to evaluate agreements, this may well have substantial costs. In summary, if it is possible that any benefit-sharing system may be more expensive than the value of the benefits brought in, then the NPS should evaluate critically the worth of applying benefit sharing to the National Parks.

If it is clear that the administrative burden is far less than the benefits projected to occur by creating benefit-sharing, then the NPS should have a benefit-sharing system in place under one of the "Alternative B" proposals. (The three different Alternative B proposals should be more clearly distinguished than was done in the DEIS, perhaps with specific examples). Any benefit-sharing agreement should not take place at the same time as the research permit, since this could easily restrict basic research. Instead, benefit-sharing negotiations should be separate from the research permit process and should be triggered by the discovery of commercial value derived from the biological resource, and initiated by those

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who wish to commercialize the discovery. As stated in the DEIS, if any benefit-sharing system is implemented, it will be very important to insure that those people approving research permits do not discriminate against (or for) each individual research project which might lead to commercial benefits. There must be adequate measures to guard against the tendency to approve those projects which might bring benefits to the NPS while inhibiting other projects that do not have commercial interests from doing research on the same or a similar species. Separating the research permit process and the benefit-sharing process is the clearest way to protect against this tendency.

According to the DEIS, "most monetary benefits would be dedicated to scientific activities promoting the conservation of natural resources protected and managed by the NPS." It is true that any monetary benefits should be dedicated to promote "scientific efforts that promote conservation", but it should be more precisely specified how exactly such money would directly promote conservation rather than including it in any general NPS budget. For example, the original researcher who collected the species could have a role in defining how the species from which the commercial use was derived can best be conserved. Or if the species is abundant, the original researcher could recommend other species to which such monetary benefits could be directed.

The report also states that "monetary benefits could also be used to offset administrative costs of a benefit sharing agreement in accordance with the FTTA." While this idea has some merit, it is possible that the administrative burden of implementing benefit-sharing agreements could absorb most of the monetary benefits which should be directed towards science and conservation, or could exceed the actual value of the monetary benefits if additional NPS staff are added to manage all stages of the benefit-sharing. If any monetary benefits are taken, it appears that the administrative burden would be less if there were a clear up-front payment system, rather than a prolonged negotiated contract system for each separate CRADA.

In the discussion of benefits, there should be a focus on pursuing non-monetary benefits instead of monetary benefits for academic researchers and basic scientific research organizations. The ability of such organizations to improve the "science for parks" fall mainly within the non-monetary domain by providing knowledge and training. To a lesser extent, such organizations may be able to provide equipment and special services, as described in the report. A focus on monetary-benefits for such organizations is misleading and will quickly lead to disappointment.

One idea to examine during the benefit-sharing discussion is to require that most (if not all) of the benefits are non-monetary for commercial organizations as well. This

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approach might promote cooperation between those commercializing something derived from a biological resource collected in a National Park to work towards the desired non-monetary benefits that each park and commercial organization is uniquely suited to provide. For example, the commercial organization may be able to provide special services such as genetic work, or funding training opportunities (for Ph.D. and masters students, NPS personnel, academics). Focusing on non-monetary benefits might stimulate other novel and creative ideas and plans for how to enhance the education, research, and conservation efforts in the National Parks more than the approach of simply taking in monetary benefits. In addition, some organizations might be more willing to provide non-monetary than monetary-benefits for several reasons including: enhancing their public relations image or more willingness to provide special services that are less costly to give to the NPS than it would be for the NPS to obtain by using outside consulting services. This might be more favorable to the NPS as well, to more easily demonstrate the true scientific and conservation goals of the NPS to U.S. citizens, some of which may have a misperception that the NPS is "selling off" their natural resources.

If monetary benefits are an inevitable part of the future system adopted by the NPS for commercial use of biological resources, consider a tiered system in which non-monetary benefits are shared for a certain amount of the total royalties generated by each company. For example, if the value is less than \$1 million dollars per year, non-monetary benefits such as those described in the DEIS would be provided, but if total royalties exceed \$1 million per year, this would then trigger a negotiation of the percentage of the royalties that would be shared.

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When discussing the benefit sharing in the NPS, it is important to keep in mind that the United States is involved in the process of addressing issues similar and related to those in this EIS on an international scale under the Convention on Biological Diversity and other treaties. Whatever decisions are made for the US NPS may be seen to outside countries as setting a precedent for how access and benefit sharing negotiations should proceed.

I would be happy to share more comments on this topic in the future.

Michael Powers

*Frances Lamberis*

January 22, 2007

Benefits Sharing DEIS Team  
Yellowstone Center for Resources  
P.O. Box 168  
Yellowstone National Park, Wyoming 82190

**Re: DEIS Service-wide benefits sharing through commercial bio-prospecting in the national parks**

Dear National Park Service:

I appreciate your seeking public input to a proposal that will affect public lands dear and precious to all Americans--our national parks. Please accept my comments for your consideration, and for the public record.

I am aware of the research being conducted at one of these treasures that is close to me--the Great Smoky Mountains National Park. The ongoing research toward compilation of an All Taxa Biodiversity Inventory (ATBI) for our Park is of truly awesome scope and importance. It highlights many facets of the scientific exploration of our natural resources which are preserved in these public lands: the expertise which Park scientists bring to these studies, the wide range of additional expertise in specialty fields, through involvement of public research institutions worldwide, and the committed assistance from thousands of citizen volunteers. For example, for just one category of organisms, beetles, the working group of scientists collaborates with authorities at more than 40 institutions, in six countries, on three continents. Through the ATBI research effort, as of October 2006, 651 species new to science have been discovered and almost five thousand species not previously known to reside at the Park. Surely this Inventory study demonstrates unparalleled achievement in biological field science, through the public domain, with full transparency to and involvement of the public, and to the good aim of our better understanding of the resources which these public lands contain, and better ability of preserving them.

I am therefore surprised and dismayed to note in your DEIS that research, specimen collection and contractual arrangements for potential new commercial products derived from species found in the parks is "preferred" to be performed on a *commercial* basis. This, in my view not only fails to acknowledge and fully utilize the research capabilities of your Agency's own scientific staff but raises many questions, inadequately dealt with in the DEIS, concerning operational aspects of implementation of the plan, its monitoring and oversight, public transparency regarding proprietary-information rights that are sure to be claimed, and many others.

Most notably and fundamentally, the "preferred" plan would establish as new purpose for the national parks their use for the derivation of commercial profit, which the Parks' enabling legislation prohibits and which would therefore seem to be illegal on the face of it, and not wished for by the public. Commercial facilities and endeavors in the national parks are, and should remain, subservient to the needs of the public in enjoyment of their parks. Park use for extraction of resources for private, commercial profit--even with promise of "sharing" of some of the latter--should not be insisted.

Benefits Sharing DEIS Team, p. 2

I am, in short, not in favor of your preference regarding the indicated choices. I oppose all the DEIS options laid out in Alternative B. I urge that the Park Service honor and support its own scientists through implementing Alternative C.

As Professor E. O. Wilson says, bio-prospecting research will no doubt take on greater importance in the future, and can be benign. But such research and undertaking, where the public lands are involved, should remain in the public domain. Please do not institute commercial bio-prospecting ventures in our national parks.

Thank you for accepting my comments.

Sincerely,

*Frances Lamberis*

# Comments from Public Agencies and Tribes

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12515-76	Superintendent, Isle Royale National Park
12515-136	Comanche Nation
12515-6717	Bridgeport Indian Colony
12515-7462	United States Department of State
12515-7467	Shoshone-Bannock Tribes
12515-7501	Environmental Protection Agency
12515-7513	National Conference of State Historic Preservation Officers (NCSHPO)
12515-7515	Advisory Council on Historic Preservation (ACHP)
12515-7516	Superintendent, Mojave National Preserve
12515-7517	Fish and Wildlife Service

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page 1 of 1

*Received 12/04/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

Many federal agencies have the capacity to receive royalties from any patents or commercial gain developed from government resources or intellectual collaboration. The NPS should indeed be able to have formal benefit sharing arrangements and the requirement to do so should be included in the research permit process. The percentage is usually very nominal as the commercial developer of an application typically has high start up costs but something should come back to the public benefit when commercial entities utilize the public's resources. I would support these revenues returning directly to the NPS unit where the research originated.

Green, Phyllis A

[Superintendent, Isle Royale National Park]

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page 1 of 1

*Received 12/19/2006 via NPS's Planning, Environment and Public Comment (PEPC) website*

At this time, the Comanche Nation has no immediate concerns or issues regarding the EIS; however, we would like to be kept informed of any further developments concerning this issue. We look forward to receiving any additional reports or other information that is derived from the planning and preparation concerning this project.

We look forward to your reports as activities proceed.

Sincerely,

Ruth Toahy  
NAGPRA Coordinator  
Comanche Nation

ALL NILES  
AD-10/06-16  
OCT 27 2006

*Handwritten signature: M.C. →*



**Bridgeport Indian Colony**  
P.O. Box 37  
Bridgeport, CA 93517

(709) 542-7981 Fax: (709) 542-8146 e-mail: [biocolonial@yahoo.com](mailto:biocolonial@yahoo.com)

October 17, 2006

United States Department of the Interior  
National Park Service  
Attn: Mr. Michael A. Soukup, Associate Director  
Natural Resources Stewardship and Science  
1849 C Street, N.W.  
Washington, DC 20240

RE: **A3823(2300)**

Dear Mr. Soukup:

In response to your letter received, October 2, 2006, the following is being provided.

The Bridgeport Indian Colony does not agree with benefit-sharing with scientists.

There are too many great lands across our great country being destroyed as we speak. Allowing more destruction to continue for research to benefit only those involved for monetary gain is unforgivable.

How can one allow what god created to be used for commercial purpose - just to extract what is left of our natural resources.

For centuries, as documented in history, Native Americans suffered at the hand of generations of political gain even to the point of extermination. Don't do this to our beautiful lands.

National Park Service was created to protect and preserve the national parks not to tear it up.

In the Spirit of Tradition,

*Charlotte Baker*  
Charlotte Baker  
Tribal Chairperson

CC: Cultural Program



**United States Department of State**

*Bureau of Oceans and International  
Environmental and Scientific Affairs*

*Office of Ecology and Terrestrial  
Conservation*

January 29, 2007

NPS Benefits-Sharing EIS  
PO Box 168  
Yellowstone National Park, WY 82190  
Voice 307-344-2203  
[benefitseis@nps.gov](mailto:benefitseis@nps.gov)

Re: Comments on Benefits-Sharing Draft Environmental Impact Statement

Dear Sir or Madam:

The United States Department of State appreciates the opportunity to comment on the draft Environmental Impact Statement (EIS) on Benefits-Sharing. The National Park Service (NPS) plays an important management role over federal lands on behalf of the American people. Essential to that role is the management of and control over access to genetic resources of fauna and flora in our parks.

With advances in molecular biology and genomics, there is enormous potential for useful and unique genetic material to be discovered and utilized. The management of access to genetic resources and the sharing of benefits from the utilization of those resources is an emerging national and international issue.

Internationally, the United States has supported negotiating access to genetic resources and the sharing of any resulting benefits on a case by case, contract basis with the understanding that any negotiation should first and foremost encourage research and scientific innovation, not discourage it. We believe the NPS should implement a similar approach nationally.

Facilitating environmentally responsible research and scientific development through access to genetic resources on Federal Park lands is a priority. The negotiation of a benefits-sharing agreement should not, as we have seen it occur in many countries around the world, impede, prohibit or deter scientific research on national park lands.

As a general matter, it seems that full disclosure of benefits-sharing arrangements with respect to federal lands would be a good policy (Option B1). However, we understand that there may be circumstances when the terms and conditions of a benefits-sharing arrangement may be difficult to disclose for a private company. Therefore, Option B2 may also be appropriate in certain circumstances to the extent it is consistent with U.S. law (e.g. Freedom

of Information Act, Federal Technology Transfer Act). We also note that some developed countries (e.g. Nordic) which have done careful analysis of the costs associated with a benefits-sharing structure for government lands have decided that the management costs outweigh the potential benefits and have therefore have chosen policies similar to Option A.

We understand that NPS would have research permit issuance and access to genetic resources precede and be separate from any negotiation of a benefits-sharing agreement. We defer to your judgment on this matter and trust that relevant policy issues have been considered, e.g. the desire to not unnecessarily burden applicants with potentially unneeded steps against the pitfalls of having to enter negotiations with applicants twice.

Additionally, we encourage the NPS to consider including standard language in research permits requiring any molecular research results, such as genomic data, be disclosed through scientific publication of the genetic sequence in a national public repository such as GenBank or NCBI prior to commercialization. Requiring publication would help prevent the illegal patenting of organisms and parts thereof and provide a baseline to determine the validity of a commercially viable innovation that may be patentable.

Sincerely,



Daniel K. Balzer  
ABS Focal Point  
Office of Ecology and Terrestrial Conservation  
OES/ETC, Room 4333  
Department of State  
2201 C Street, NW  
Washington, DC 20520

# The SHOSHONE-BANNOCK TRIBES



FORT HALL INDIAN RESERVATION  
PHONE (208) 478-3700  
FAX # (208) 237-0797

FORT HALL BUSINESS COUNCIL  
P.O. BOX 306  
FORT HALL, IDAHO 83403

January 24, 2007

Benefits-Sharing EIS Team  
Center for Resources  
P.O. Box 168  
Yellowstone National Park, WY 82190

**RE: Review and comments to Benefits-Sharing Draft Environmental Impact Statement (DEIS)**

The Shoshone-Bannock Tribes (Tribes) has reviewed the Draft Environmental Impact Statement prepared by the National Park Service and submits the following comments.

**General Comments**

Bioprospecting utilization of natural resources located in the National Park System (NPS) for research and possible applicable knowledge created by such research is the commodity available for commercialization. The need for this DEIS is the outcome of a lawsuit between the National Park Service (NPS) and a research company. Currently the NPS does not promote the benefits sharing program and due to this circumstance there is a need to specify the rights and responsibilities of both the NPS and research parties. The DEIS proposes three alternatives and identifies the preferred alternative, Alternative B, which would provide a benefit sharing agreement between the researcher and the NPS (where the research originates), if the research produces possible revenue from future commercial application. The researcher and NPS will share monetary gain if Alternative B is implemented. The Shoshone-Bannock Tribes (Tribes) have concerns about bioprospecting.

**Cultural Resources**

Bioprospecting does and will continue to impact cultural resources the Tribes finds important. The Tribes define cultural resources as holistically consisting of many components in the natural and man-made environments. As succinctly stated by a tribal member, "our cultures involve knowledge systems developed, nurtured and refined by the people from the elements existing in our territory and traditions passed on by succeeding generations. Our many unique names, designs, symbols, songs, ceremonies

and stories are based upon our peoples' continuing relationship to the natural world. Cultural property, in our view, includes all components of cultural integrity, and therefore, heritage".

At risk are the Intellectual property rights of the Tribes from bioprospecting and benefits sharing. Plants, animals, minerals and landscape have and continue to be resources utilized for spiritual and subsistence to the Shoshone and Bannock people. Indian people have manipulated the landscape and environment through time to gain ecological benefits and in doing so have created an established ecological, traditional knowledge base. This knowledge is considered "prior art" and its value is well known in the pharmaceutical industry as many medicines originated from "prior art" knowledge.

Simply stating in the DEIS that Intellectual Property Right Laws will be followed is not sufficient to assure the Tribes that our traditional knowledge is protected.

As identified in the DEIS, Yellowstone National Park has the greatest amount of researchers applying and receiving permits to do research in the park. Shoshone and Bannock people living in Wyoming, Montana, and Idaho have used the natural and cultural resources in the Greater Yellowstone area from time immemorial according to the tribal history and the archaeological record. Accordingly, Tribes view the Greater Yellowstone Area as significant aboriginal land that continues to contribute and play an integral part in maintaining cultural beliefs and traditional practices. Tribal ethnography of this area is indicative of the significance of the Greater Yellowstone Area.

Research in the Yellowstone National Park concerns the Shoshone and Bannock Tribes. Yellowstone ethnographic study (2006) identifies tribes that have historically used the Greater Yellowstone area for the procurement of natural resources for sustenance. Shoshone and Bannock tribal members have resided on the Yellowstone Plateau and procured natural and cultural resources from the Greater Yellowstone Area like many generations before present. Additionally, the Fort Bridger Treaty provides the Shoshone and Bannock Tribes gathering and hunting access on unoccupied lands of the United States. Presently our tribal members continue to go to the Greater Yellowstone Area and exercise their cultural and traditional heritage. Moreover, research may impact a sacred area used for medicinal or spiritual purposes. For example, the hot springs are spiritually and culturally significant. As noted in the draft ethnography of Yellowstone National Park (Walker 2006) the concern is when a spiritual place overused by other uses may impact the spirits associated with the place and cause them to no longer reside there, therefore the place loses the ability to provide the cultural and spiritual needs of the Shoshone-Bannock Tribes. How will Tribes be assured resources that are important to them will be preserved for their needs?

Another concern not identified in the DEIS, where does the NPS identify in the researcher application process or benefit sharing agreement if no synthetic version can replicated, will the raw material from the national park be used? This might apply if research discoveries are of great value and is a significant contribution to the advancement of human health. Where is this addressed?

**Specific Comments**

- Section 2.2.3. Page 39 - Intellectual Property Rights will remain unaffected by commercialized knowledge created by research how will IP be monitored to ensure all IP laws are being met? It is documented the many of today's medicines are derived from traditional knowledge held by Indian people. Also true is that future discoveries relating to human health may in fact be not a discoveries at all. Tribal people possess the knowledge but keep it within the traditional knowledge base this type of knowledge is known as prior art.
- Section 2.4.1.1 Page 42. - Any tribe, tribal community or tribal member who has traditional or cultural knowledge that is associated with the research can be a participant in benefit sharing. This is a general statement and does not begin to address the complex issue of Indian tribes and their traditional uses of the Greater Yellowstone Area. Also problematic is if individuals are recognized as beneficiaries of benefit-sharing agreements how will this affect the tribe as a whole and do tribes recognize individual actions as representing the tribes as a whole.
- Section 2.4.6. Page 47 - what are the mitigation measures? Include the measures in an appendix.
- Section 2.6.1.7. Page 55 - Alternative A and B provide for tribal inclusion in benefits sharing, although the Alternatives are very different in how the tribes will participate. Not identified is how those tribes with treaty rights who do not participate in the research, and when the research utilizes the natural resources used by the tribes for subsistence or spiritual purposes will be mitigated. What mitigation measures provide for the loss of these cultural resources and intellectual property rights?
- Section 2.8. Pages 59 - explain how cultural and historic aspects will benefit from the monies generated by the benefit sharing and what specifically is targeted under cultural and historic aspects.
- Section 3.3.1. Page 79 - similar to the visitors experience in Yellowstone, the Shoshone and Bannock people's perception of a spiritual experience exist when they visit the park. The visit permits Indian people to experience the park and the natural resources and reconnect with the land, which is significant to them and also to their ancestors. Tribal people find the National Parks an important element in reaffirming their tribal identity. The condition of the park is vital to the level of enjoyment and spiritual and cultural experience of their heritage.
- Section 3.4.2. Page 84 - states there is no process or protocol to track third party researchers and the specimens they may have acquired. For park managers to effectively manage the researchers and the natural resources of the park the third party researchers must be monitored and at the very least park manager must have knowledge of where the research specimen are located and who has possession of

them. This lack of control provides for an opportunity for researchers to take advantage of the science and possible economic gain at the expense of the parks resources, Indian tribes and the public.

**Recommendations**

1. NPS establish a monitoring plan for transfer of cultured samples to third party researchers and in the case of pirating of natural resource from poachers whom may have the ability to replicate research for commercial application.
2. Tribes may in the future want to participate, as environmental researchers. Are provisions in place to accommodate the native researcher similar to affirmative action procedures?
3. Establish a monitoring plan to identify when and if a particular location for research activity is placing stress on or creating an ecological condition that results in the changing of ecological environment?
4. Shoshone and Bannock people have the right to self-determination and sovereignty over their own lands of natural and cultural resources. Indian people have ownership rights regarding traditional knowledge, biodiversity and genetic resources. Consultation needs to occur regularly regarding the research at Yellowstone National Park. Project information sharing will facilitate tribal monitoring of natural resource use.

If you should have any questions please do hesitate to contact Carolyn B. Smith, Tribal DOE Cultural Resources Coordinator, (208) 478 - 3706 or email [esmith@shoshonebannocktribes.com](mailto:esmith@shoshonebannocktribes.com).

Sincerely,



Alonzo A. Coby, Chairman  
Fort Hall Business Council

cc: Carolyn B. Smith, Tribal DOE  
Claudio Broncho, Policy Representative  
file



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

ASSISTANT ADMINISTRATOR  
FOR COMPLIANCE ASSURANCE

JAN 18 2007

Ms. Sue Mills, Project Manager  
NPS Benefits-Sharing EIS  
P.O. Box 168  
Yellowstone National Park, WY 82190

Dear Ms. Mills:

In accordance with our responsibility under the National Environmental Policy Act (NEPA), 42 U.S.C. Section 4321, et seq., and Section 309 of the Clean Air Act, 42 U.S.C. Section 7609, the U.S. Environmental Protection Agency (EPA) has reviewed the programmatic Draft Environmental Impact Statement (EIS) for Service-wide Benefits-Sharing (CEQ No. 20060378).

This Draft EIS analyzes the potential environmental impacts of benefits-sharing, or the sharing of monetary and/or non-monetary benefits, from commercial ventures through formal agreements between National Parks and researchers. The document evaluates three alternatives that the NPS believes promote fair and equitable benefit-sharing which can be used to protect park resources. Alternative A (No Action) proposes that no benefits-sharing agreements be implemented and research would continue without the establishment of a standard benefit-sharing agreement. Alternative B proposes to implement benefit-sharing agreements and offers three variations specific to the disclosure requirements: B-1 proposes mandatory disclosure of all terms and conditions; B-2 offers optional disclosure of all terms and conditions, adhering to standard confidential business protocols; and B-3 proposes no disclosure of any royalty rate or related proprietary information. Alternative C proposes to prohibit research specimen collection for any commercially related research and only non-commercial research would take place. The document identifies B-2 as the preferred alternative.

The Draft EIS discusses the authorities that affect the management of natural resources and ensure their protection within the Parks, including the NPS's 1916 Organic Act. The document clearly identified the NPS mandate, to "conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations". Further, the National Parks Omnibus Management Act authorized the NPS to enter into benefit-sharing

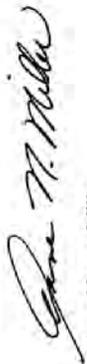
agreements with researchers and defined Parks as federal laboratories within the definition of the Federal Technology Transfer Act (FTTA). The type of benefits sharing agreement that is being considered by the NPS is termed a Cooperative Research and Development Agreement (CRADA). Additionally, the Draft EIS states that appropriate site-specific NEPA documents will be prepared for each future permit to collect research specimens.

EPA supports implementing the preferred alternative under existing authorities combined with full disclosure of CRADA information within confidential business information protocols. However, we suggest that the Final EIS establish mechanisms to ensure proceeds are focused on protecting natural resources in the Parks, and develop adequate enforcement protocols to ensure the terms of permits are followed so that natural resources would not be significantly impacted. In addition, EPA suggests that the Final EIS include information to clarify the range of research that has been permitted over the last 5-10 years. Lastly, we suggest including a sample permit in the Final EIS to clarify what types of information are required for issuing research permits.

Based on our review we have assigned a rating of Lack of Objections (LO) to the preferred alternative in the document. A copy of EPA's rating system is enclosed for your reference.

Thank you for the opportunity to review this Draft EIS. If you have any questions regarding EPA's comments, please contact me at 202/566-5400, or Elaine Suriano, of my staff, at 202/5640-7162.

Sincerely,



Anne Norton Miller  
Director  
Office of Federal Activities

Enclosure: EPA Rating System for Draft EISs

**U.S. Environmental Protection Agency Rating System for Draft Environmental Impact Statements**

**Definitions and Follow-Up Action\***

Environmental Impact of the Action

**LO -- Lack of Objections:** The Environmental Protection Agency (EPA) review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

**EC -- Environmental Concerns:** The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce these impacts.

**EO -- Environmental Objections:** The EPA review has identified significant environmental impacts that should be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no-action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

**EU -- Environmentally Unsatisfactory:** The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. EPA intends to work with the lead agency to reduce these impacts. If the potential unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the Council on Environmental Quality (CEQ).

Adequacy of the Impact Statement

**Category 1 - Adequate:** EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis of data collection is necessary, but the reviewer may suggest the addition of clarifying language or information.

**Category 2 - Insufficient Information:** The draft EIS does not contain sufficient information for EPA to fully assess environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new, reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses or discussion should be included in the final EIS.

**Category 3 - Inadequate:** EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data, analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the National Environmental Policy Act and/or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.

\* From EPA Manual 1640 Policy and Procedures for the Review of Federal Actions Impacting the Environment. February, 1987.

# NCSHPO

National Conference of State Historic Preservation Officers

HALL OF THE STATES SUITE 342  
444 NORTH CAPITOL STREET, NW WASHINGTON DC 20001-1512  
202-624-9465 FAX 202-624-5419 www.ncsppo.org

March 20, 2007

Ms. Sue Mills  
Yellowstone Center for Resources  
Yellowstone National Park  
Yellowstone, Wyoming 82190

RE: EIS on Benefits-Sharing

Dear Ms. Mills:

The National Conference of State Historic Preservation Officers has received the September 2006 *Benefits-Sharing Draft Environmental Impact Statement*. Michael Soukup, Associate Director, National Resource Stewardship and Science, asks in his cover letter of March 15, 2007, for the concurrence of the National Conference of State Historic Preservation Officers in the National Park Service's determination that the action would not affect historic properties.

First, under the Advisory Council's regulations for the implementation of Section 106, 36 CFR Part 800, no authority exists for the National Conference of State Historic Preservation Officers to concur with a federal agency's determination of significance or effect. The National Conference's role in the Section 106 process relates to the preparation and execution of nationwide programmatic agreements.

Second, the Benefits-Sharing project involves a decision about whether the National Park Service and scientists studying National Park Service resources would share any financial benefits derived from that research. In our opinion, the sharing any revenues from research is not an activity that constitutes an "undertaking" as defined in the National Historic Preservation Act.

Sincerely,  
*Nancy Schamu*  
Executive Director

cc: Jay D. Vogt, President, National Conference of State Historic Preservation Officers, and South Dakota State Historic Preservation Officer  
Kelly Yasaitis Fanizzo, Historic Preservation Specialist, Advisory Council on Historic Preservation



Preserving America's Heritage

May 23, 2007  
Ms. Sue Mills  
Environmental Protection Specialist  
Yellowstone Center for Resources  
Yellowstone National Park  
P.O. Box 168  
Yellowstone National Park, WY 82190

Ref: *Draft Environmental Impact Statement on Proposed Benefits-Sharing with Researchers*

Dear Ms. Mills:

On March 26, 2007, the Advisory Council on Historic Preservation (ACHP) received a copy of the September 2006 *Benefits-Sharing Draft Environmental Impact Statement (EIS)*, prepared by the National Park Service (NPS). Dr. Michael Soukup, Associate Director, National Resource Stewardship and Science of the NPS, requested, in his cover letter of March 22, 2007, that the ACHP review and comment on the document. Dr. Soukup noted that the National Conference of State Historic Preservation Officers (NCSHPO) concurred with the NPS' determination of no adverse effect for historic properties and included a copy of NCSHPO's response letter, dated March 20, 2007. In actuality, the NCSHPO letter presents the opinion that the proposed Benefits-Sharing does not constitute an undertaking as defined by the National Historic Preservation Act (NHHPA).

Benefits-Sharing involves the development of agreements between NPS and researchers carrying out research on lands controlled by NPS and the sharing of revenues from research when the results of research have commercial value. Based on a review of the draft EIS, the ACHP agrees with the opinion of NCSHPO. As presented in the draft EIS, the sharing of revenues from research does not appear to constitute an undertaking as defined by the NHHPA and its implementing regulations, "Protection of Historic Properties" (36CFR Part 800). Accordingly, pursuant to 36 CFR 800.3(a)(1) and 800.16(y), if the NPS concurs with the views of NCSHPO and the ACHP, it has no further obligations for compliance with Section 106 for the development and implementation of Benefits-Sharing policy and agreements with scientists who conduct research in NPS units.

Thank you for providing us with a copy of the draft EIS and for your request for our comments. If you have any questions or require our further assistance, please contact Dr. John T. Eddins at 202-606-8553 or via email at [teddins@achp.gov](mailto:teddins@achp.gov).

Sincerely,  
*Charlene Dwin Vaughn*  
Charlene Dwin Vaughn, AICP  
Assistant Director  
Office of Federal Agency Programs

ADVISORY COUNCIL ON HISTORIC PRESERVATION  
1100 Pennsylvania Avenue NW, Suite 809 • Washington, DC 20004  
Phone: 202-606-8503 • Fax: 202-606-8647 • [achp@achp.gov](mailto:achp@achp.gov) • [www.achp.gov](http://www.achp.gov)



**United States Department of the Interior**

NATIONAL PARK SERVICE  
Mojave National Preserve  
2701 Barstow Road  
Barstow, California 92311

IN REPLY REFER TO:  
#116 (MOJA)

January 4, 2007

Memorandum

To: Yellowstone Center for Resources at [BenefitsEIS@nps.gov](mailto:BenefitsEIS@nps.gov)  
From: Superintendent, Mojave National Preserve  
Subject: Comments on Service-wide Benefits-Sharing draft Environmental Impact Statement (DEIS).

Thank you for this opportunity to review the Service-wide Benefits Sharing draft Environmental Impact Statement. While the intent of the service-wide programmatic proposal is admirable, my science advisor, Dr. Debra Hughson, offers some interesting observations of the complexities and difficulties of managing research projects under this framework.

At present, the only research management tool available to national parks is the scientific research and collecting permit. "Bio-prospecting" and its potential for commercial exploitation extend beyond the limits of a permit and might, therefore, require the National Park Service to enter into an agreement with each associated party.

Another issue is the question of utility. The DEIS does not define how to determine the breadth of benefit from a biological source. There is potential for both direct and indirect benefits to result from the harvesting of a biological material. The NPS needs to identify the limits or extent of benefit sharing. It is extremely difficult to negotiate a priori benefits that have yet to be realized.

My staff has also identified other questions about the proposed action.

Page (Section)	Comment
xii (ES.2.2)	It is unclear how the NPS would enforce permit regulations once research has been completed. The NPS controls research activities only during the period of time when the researcher is operating under an active permit.
39 (2.2.2)	The Investigator's Annual Reports (IARs) are the only products the NPS requires and reliably receives from permitted researchers. Other research products, such as copies of publications, theses, dissertations, raw data, etc., are received only sporadically; the NPS has no mechanism by which to ensure their submittal.
41 (2.4.1)	It is not clear what incentive individual researchers would have to initiate benefits-sharing negotiations.

- 47 (2.4.5.2) The draft EIS does not explain how benefits-sharing agreements would be enforced or who would enforce them.
- 49 (2.4.6.4) The draft EIS is not clear regarding how CRADAs would be developed, implemented, or enforced.
- 135 (4.4.4.2) Use of research results for commercial purposes is untraceable and untraceable. Again, benefits-sharing agreements would not be enforceable.

If you have any questions, please contact Dr. Debra Hughson, Mojave National Preserve Science Advisor, at [debra\\_hughson@nps.gov](mailto:debra_hughson@nps.gov) or (760) 252-6105.

Sincerely,

Dennis Schramm

cc: Dr. David Graber, PWR Science Advisor  
Alan Schmitter, PWR Compliance Coordinator  
Dannette Woo Nolan, Mojave National Preserve Compliance Coordinator



United States Department of the Interior

FISH AND WILDLIFE SERVICE  
Washington, D.C. 20240



In Reply Refer To:  
FWS/AES/DCHRS/031640

JUN 13 2007

Ms. Sue Mills  
National Park Service  
P.O. Box 168  
Yellowstone National Park, Wyoming 82190

Dear Ms. Mills:

This letter is to acknowledge receipt of correspondence dated May 9, 2007, from Michael A. Soukup, National Park Service, regarding consultation on the National Park Service's programmatic/planning Benefits-Sharing Draft Environmental Impact Statement (DEIS). The DEIS describes conditions under which certain activities may be conducted and provides potential general standards for management. The NPS is requesting the Service's concurrence on the NPS determination of "no effect" under section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

In the DEIS, the NPS evaluates the environmental impacts of three alternatives concerning proposed actions under the potential implementation of benefits-sharing agreements with scientists who conduct research in one or more National Park System units. The Service understands the action area to include all of the approximately 400 units of the National Park System, including Yellowstone National Park. The document examines the concept of benefits-sharing agreements and impacts to natural resource management, without evaluating specific types of research or the potential impacts to federally listed species and designated critical habitat from implementing research and related activities.

Section 7 of the Endangered Species Act addresses consultation on federal agency actions to insure that any action authorized, funded, or carried out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of critical habitat. Although the NPS made a determination of "no effect", a determination of "not likely to adversely affect" would be more appropriate in that the Service agrees with the NPS that proposed research activities related to actions described in the draft EIS may require consultation for project-specific and site-specific impacts to listed species and designated critical habitat.

In further response, the Service may be able to support the broad concept of benefits-sharing agreements with scientists who conduct research in National Park System units, and appreciates the potential research and financial benefits to the maintenance of natural resources.



Ms. Sue Mills

If you have any questions, please contact the Chief, Branch of Consultation and Habitat Conservation Planning at (703) 358-2106.

Sincerely,

Richard E. Sayers, Jr., Chief  
Division of Consultation, Habitat Conservation  
Planning, Recovery and State Grants

cc: Michael A. Soukup, Ph.D.

**CORE TEAM (Yellowstone National Park, Yellowstone Center for Resources)**

<b>Name</b>	<b>Responsibility</b>	<b>Education</b>	<b>Experience</b>
Susan Mills	Project Manager, Servicewide Benefits-Sharing EIS	BA Biology, BA Psychobiology	23 years National Park Service
Ann Deutch	Writer, Servicewide Benefits-Sharing EIS, former Research Permit Coordinator	BS Outdoor Recreation, MA Biological Sciences	17 years National Park Service, 5 years private environmental education
Kevin Schneider	Management Assistant, Glen Canyon National Recreation Area; former Technical Writer-Editor, Yellowstone National Park	BS Natural Resources, Recreation and Tourism; Masters of Public Administration	9 years National Park Service
Alice Wondrak Biel	Technical Writer-Editor	PhD Geography	8 years National Park Service
Tami Blackford	Technical Writer-Editor	BA English	14 years National Park Service

**MANAGEMENT TEAM**

Mike Soukup	Co-Chair Servicewide Benefits-Sharing Management Group, NPS Associate Director, Natural Resources Stewardship and Science	PhD Limnology	31 years National Park Service
Tom Olliff	Co-Chair Servicewide Benefits-Sharing Management Group, Chief, Yellowstone Center for Resources (from 2006)	BS Forestry, MS Resource Conservation	21 years National Park Service
John Varley	former Co-Chair Servicewide Benefits-Sharing Management Group, former Director, Yellowstone Center for Resources (before 2006)	BS Zoology, MS Zoology	23 years National Park Service, 11 years Fish and Wildlife Service, 5 years Utah Division of Wildlife Resources
Suzanne Lewis	Superintendent, Yellowstone National Park	BA American History	28 years National Park Service
John Dennis	NPS Deputy Chief Scientist	PhD Botany	35 years National Park Service
Lindsay McClelland	Geologist, NPS Natural Resources	MS Geology	15 years National Park Service, 8 years Smithsonian Institution

<b>Name</b>	<b>Responsibility</b>	<b>Education</b>	<b>Experience</b>
Carla Mattix	Attorney-Advisor, Office of the Solicitor, Division of Parks and Wildlife, Department of the Interior	BS Aerospace Engineering, JD Georgetown University Law Center	12 years Department of the Interior, 5 years US Patent and Trademark Office
Jacob J. Hoogland	Chief, Environmental Quality Division, National Park Service	JD University of Utah College of Law	29 years National Park Service, experience in environmental planning and compliance, 106 compliance, and regulatory issues

### **INTERDISCIPLINARY TEAM**

Sarah Allen	Science Advisor, Point Reyes National Seashore	PhD Wildland Resource Science	14 years National Park Service, 15 years Point Reyes Bird Observatory
Thomas O. Clark	Integrated Resources Program Manager, Division Chief for Resource Mgmt. & Science, Capitol Reef National Park	BS Wildlife Management, MS Zoology	12 years National Park Service, 4 Bureau of Land Management, Wildlife Biologist, 5 Dept of Army, Ecologist, 3 Dept of Navy, Environmental Specialist
Judith Hazen Connery	Biologist (Natural Resource Specialist), NEPA Compliance, Acadia National Park	BS Natural Resource Management	26 years National Park Service
Carol B. Daniels	Research Coordinator, South Florida Caribbean CESU	BA Biology, MS Biology, PhD Marine Estuarine Environmental Science (specialization in Aquatic Toxicology)	6 years National Park Service, 10 years Environmental Protection Agency, Research Toxicologist
Nancy Finley	Chief, Resource Management and Science, Great Smoky Mountains National Park	BS Biology, MS Environmental Health and Toxicology	8 years National Park Service, 7 years U.S. Fish and Wildlife Service, Ecological Risk Assessment/ Toxicology
Russell Galipeau	Superintendent, Channel Islands National Park	BS Forest Resources and Conservation	26 years National Park Service

<b>Name</b>	<b>Responsibility</b>	<b>Education</b>	<b>Experience</b>
Ann Hitchcock	NPS Curator/Senior Advisor for Scientific Collections	MA Anthropology, AB Anthropology	28 years National Park Service
Ken McMullen	Overflights Program Manager, Grand Canyon National Park	MS Rangeland Ecology	24 years Department of the Interior, including 16 years National Park Service
Diane Pavek	Botanist/Research Coordinator, National Capital Region	BS Botany/Zoology, MS Botany, PhD Botany	8 years National Park Service, 2 years US Department of Agriculture
Stephen Rudd	Natural Resource Program Manager, Hot Springs National Park	BS Geology and Physical Geography, MS Geomorphology	27 years National Park Service
Gary Vequist	Associate Regional Director for Natural Resource Stewardship, Midwest Region	BS Zoology, MS Water Quality–Environmental Science	35 years National Park Service
Robert Winfree	NPS Alaska Regional Science Advisor	BS, MS, and PhD Wildlife and Fisheries Sciences	12 years National Park Service, 5 years other federal agencies, and 7 years in private sector marine biotechnology/aquaculture research & development

#### **CONSULTANTS**

Preston Scott	President/Executive Director, World Foundation for Environment and Development	BA History, BA Political Theory, JD University of VA	27 years
Mansir Petrie	Project Officer, World Foundation for Environment and Development	BA Grinnell College	5 years

# **Chapter 6**

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## **Glossary**

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**benefits:** non-monetary benefits can include but are not limited to knowledge and research relationships, training and education, goods, or special services. Monetary benefits can include but are not limited to agreement issue fees, research funding, payments under options, annual minimums, milestones, running royalties, or termination payments.

**benefits-sharing:** the equitable and efficient exchange of valuable *research results* arising from the study of biological research specimens.

**biological diversity:** the variability among living organisms from all sources—including, among others, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part. This includes diversity within species, between species, and of ecosystems.

**bioprospecting:** the search for useful scientific information from *genetic resources* or *biological resources*.

**biological resources:** *genetic resources*, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

**biotechnology:** any technological application that studies biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific uses.

**commercial purpose:** the sale, lease, license, or other transfer of any *research results* for value received, including but not limited to scientific research uses of any research results in the performance of any contract research or in screening compound libraries, or in the conduct of research activities that result in any sale, lease, license, or other transfer of any research results.

**Cooperative Research and Development Agreement (CRADA):** a research agreement authorized by the Federal Technology Transfer Act of 1986 that is defined by the statute as “any agreement between one or more *Federal laboratories* and one or more non-Federal parties under which the government, through its laboratories, provides personnel, services, facilities, equipment or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the mission of the laboratory”.

**environmental impact:** an effect of the proposed action or alternatives on resources.

**extremophile:** an organism adapted to environmental conditions that seem extreme from the human perspective, for example, very hot and/or very acidic environments.

**federal laboratory:** defined by the Federal Technology Transfer Act of 1986 as “a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government”.

**genetic material:** any material of plant, animal, microbial, or other origin containing functional units of heredity.

**genetic resources:** *genetic material* of actual or potential value.

**intellectual property:** ideas, discoveries, information, know-how, and other tangible or applied results of intellectual effort that have actual or potential value (degree of protection depends on local law and is therefore territorial).

**major impact:** an *environmental impact* that is severe or, if beneficial, has exceptional beneficial effects.

**minor impact:** an environmental impact that is slight but detectable.

**moderate impact:** an environmental impact that is readily apparent and has the potential to become major.

**negligible impact:** an environmental impact that is at the lower levels of detection.

**park:** as used in this FEIS, the term “park” refers to any unit of the National Park System including but not limited to national parks, national monuments, national seashores, etc.

**patent:** a property right granted by the Government of the United States of America to an inventor “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited time in exchange for public disclosure of the invention when the patent is granted. Any new, useful, and non-obvious discovery or invention that satisfies applicable statutory requirements (e.g., for utility patents, process patents, or petty patents) may be patented.

**permit:** a written authorization to engage in uses or activities that are otherwise prohibited, restricted, or regulated.

**research:** as used in this FEIS, the term “research” means short- or long-term scientific or scholarly investigations that may involve hypothesis-testing research or resource inventories and monitoring or other studies that rely on data collection and may include specimen collection.

**research activities:** the actions taken by researchers or their sponsoring organizations or companies in accordance with an approved NPS *Scientific Research and Collecting Permit* (including specimen collection and analysis conducted for scientific purposes).

**research permit:** an NPS *Scientific Research and Collecting Permit*.

**research results:** the data, discoveries, inventions, or other knowledge, processes, products, or applications gained from scientific research activities.

**Scientific Research and Collecting Permit:** a *permit* issued pursuant to 36 CFR 1.6 and 2.5 that is required for scientific activities in NPS units that involve fieldwork, specimen

collection, and/or have the potential to disturb resources or visitors.

**Specimen:** an individual, item or part; a sample, as of plant, animal, or microorganism. In the NPS, specimens may only be collected for independent research under the authority of an NPS *Scientific Research and Collecting Permit*.

## **Acronyms used in this EIS**

**AUTM:** Association of University Technology Managers  
**BMTA:** Biological Material Transfer Agreement  
**CEQ:** Council on Environmental Quality  
**CESU:** Cooperative Ecosystem Studies Unit  
**CRADA:** Cooperative Research and Development Agreement  
**FEIS:** Final Environmental Impact Statement  
**DOC:** Department of Commerce  
**DOI:** Department of the Interior  
**FOIA:** Freedom of Information Act  
**FTTA:** Federal Technology Transfer Act of 1986  
**IAR:** Investigator's Annual Report  
**IDT:** Interdisciplinary Team  
**MTA:** Material Transfer Agreement  
**NEPA:** National Environmental Policy Act  
**NPOMA:** National Parks Omnibus Management Act of 1998  
**NPS:** National Park Service  
**OMB:** Office of Management and Budget  
**RPRS:** NPS Research Permit and Reporting System

# **Chapter 7**

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# **Appendix A**

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## **Example Cooperative Research and Development Agreement (CRADA)**

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***Text that appears in bold italics and between double lines is provided as clarification to the reader. These explanatory text sections will be included in the Environmental Impact Statement, but they will not be included in any final (signed) CRADA.***

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**COOPERATIVE RESEARCH AND  
DEVELOPMENT AGREEMENT  
for a project between  
[NAME OF PARK UNIT] /  
NATIONAL PARK SERVICE  
and  
[NAME OF COOPERATING RESEARCHER]**

## **General Provisions**

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*The General Provisions open with an introductory paragraph that identifies the parties to the CRADA (including name(s), legal form (i.e., individual, partnership, corporation, etc.), and address of the collaborating researcher as well as the name of the collaborating unit of the National Park System). In the event research activities involved the use of traditional knowledge or other valuable input from a Native American community or other source, such groups would be included as parties and/or beneficiaries to any benefits-sharing arrangement as appropriate.*

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This Cooperative Research and Development Agreement (“CRADA”) is entered into by and between [name of cooperating researcher] (“Collaborator”), a [identify the cooperating researcher as either an “individual,” “partnership,” “corporation,” or other legal entity and the state of legal residence or state where organized or incorporated] and maintaining its principal office headquarters at [office or other official address including street, city, state, country, and postal code], and [name of unit of the National Park System] of the National Park Service (NPS), U.S. Department of the Interior.

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*The following series of introductory “WHEREAS” clauses outline and summarize the intent of the CRADA consistent with Title II of the National Parks Omnibus Management Act of 1998 and the Federal Technology Transfer Act of 1986. They also reaffirm the Superintendent’s “findings” associated with the activities authorized by the research specimen collection permit issued pursuant to 36 CFR 1.6 and 2.5.*

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WHEREAS, NPS and Collaborator wish to engage in cooperative activities to promote the conservation, protection, perpetuation, and management of biological diversity while undertaking scientific research that includes investigating potentially useful applications and processes that might result from research involving certain biological materials collected from [name of collaborating unit of the National Park System] pursuant to a permit issued under 36

CFR 1.6 and 2.5; and

WHEREAS, it is the intention of NPS to improve the conservation, management, protection, and perpetuation of park resources to the fullest extent possible consistent with the statutory mandate “to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations” (16 USC § 1); and

WHEREAS, it is the intention of NPS to cooperate in activities that “assure that management of units of the National Park System is enhanced by the availability and utilization of a broad program of the highest quality science and information” (16 USC § 5932); and

WHEREAS, NPS coordinates research activities, facilitates the exchange of research-related information pertaining to the natural resources found in units of the National Park System, and otherwise manages the use of national park resources for purposes of scientific study by Federal and non-Federal public and private agencies, organizations, individuals, or other entities (16 USC § 5935(a)), which will be supported by the cooperative research activities authorized by this CRADA; and

WHEREAS, Collaborator is dedicated to [*description of Collaborator’s principal scientific activity, which could include but not be limited to the discovery and development of new bioactive materials for chemical synthesis, diagnostics, industrial and pharmaceutical uses, etc.*], and agrees to cooperate with NPS to undertake beneficial scientific research relating to certain biological materials existing in and collected from [*name of collaborating unit of the National Park System*], to share information and data relating to such research, and to protect and monitor those materials and other resources at [*name of collaborating unit of the National Park System*] as required by NPS; and

WHEREAS, Collaborator agrees to apply the highest professional and scientific standards in its research and development activities undertaken at [*name of collaborating unit of the National Park System*], and to pursue the discovery and development of new materials or other research results from biological specimens collected from [*name of collaborating unit of the National Park System*] in ways that advance the “economic, environmental, and social well-being of the United States” consistent with the aims of the Federal Technology Transfer Act of 1986 (15 USC § 3701); and

WHEREAS, Collaborator agrees and recognizes that efforts by NPS to “conserve the scenery and the natural and historic objects and the wild life therein” contribute significantly to the research and development of potentially useful discoveries resulting from scientific research activities undertaken at units of the National Park System; and

WHEREAS, Collaborator further agrees and recognizes that the aforesaid protection of national park resources requires sophisticated interdisciplinary scientific work by NPS staff and coordinated effort by NPS management “necessary to assure the full and proper utilization of the results of scientific study for park management decisions” (16 USC § 5936); and

WHEREAS, NPS agrees and recognizes that Collaborator has invested and intends to

continue to invest significant time, expertise, and expense in research and development activities and management of technology that facilitates development of useful discoveries resulting from scientific research activities involving research specimens collected from [name of collaborating unit of the National Park System]; and

WHEREAS, the NPS Director has determined that [name of collaborating unit of the National Park System] is a “Federal laboratory” within the meaning of 15 USC § 3710a(d)(2) because it is “a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.”

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***Additional clauses may be added to describe and document the scientific and national park resource conservation purposes and intent of the cooperative research and development activities managed by the CRADA.***

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Now, therefore, in consideration of the promises contained in this agreement, the parties agree as follows:

## **Article 1. Legal Authority**

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***Article 1 of the CRADA cites the principal statutory authorities that govern the CRADA (including the clause that authorizes a collaborating unit of the National Park System that satisfies the statutory definition of a “Federal laboratory” to retain the financial benefits resulting from the CRADA).***

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1.1 This agreement is authorized under the National Park Service Organic Act, as amended, 16 USC §§ 1–4; Federal Technology Transfer Act, as amended, 15 USC §§ 3701–3715; and, the National Parks Omnibus Management Act of 1998 (16 USC §§ 5931–5936).

1.2 Payments accepted and retained by [name of collaborating unit of the National Park System] from Collaborator are authorized under 15 USC § 3710a(b)(3).

## **Article 2. Definitions**

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***Article 2 of the CRADA provides the substantive definitions that appear in the CRADA. The definitions that appear in the General Provisions are consistent with the definitions used in the Department of the Interior’s handbook entitled ‘Technology Transfer: Marketing Our Products and Technologies (A Training Handbook for the U.S. Department of the Interior),’ first published in May 1996, and are consistent with standard CRADA provisions used by many Federal agencies. Supplemental definitions have been adopted from the Uniform***

*Biological Material Transfer Agreement developed by the National Institutes of Health and published in the Federal Register in March 1995 (60 Fed. Reg. 12771 (March 8, 1995)). Additional explanations concerning the meaning of certain definitions appear below.*

*Defined terms are grouped according to topical related subject matter for more convenient reference. The rights and obligations of the parties provided by the CRADA flow from a careful structuring of operative definitions. While technical, the definitions appearing in Article 2 of the General Provisions reflect the operative definitions derived from the above-referenced sources. Additional definitions that are pertinent to an individual CRADA that do not contradict the definitions provided in Article 2 of the General Provisions may be provided as supplemental definitions in the Statement of Work.*

*Defined terms appear in bold-faced print throughout the CRADA.*

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## **2.1 Definitions Relating to the CRADA and the Parties' Employees**

### ***2.1.1 Cooperative Research and Development Agreement***

The term "Cooperative Research and Development Agreement" ("CRADA") means this document and all attachments describing research activities jointly undertaken by NPS and Collaborator.

### ***2.1.2 Collaborator's Assigned Employees***

The term "Collaborator's Assigned Employees" means those employees of Collaborator who are present at [*name of collaborating unit of the National Park System*] for a continuous period of more than two weeks.

## **2.2 Definitions Relating to Biological Material Collected from a Unit of the National Park System and Subsequent Research Use of Such Material**

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*The term "Natural Products" is defined with reference to "Research Specimens" so that it is clear that Collaborator is authorized to collect or use for scientific purposes only those naturally occurring materials covered in a permit issued under 36 CFR 1.6 and 2.5. This definition also reinforces the prohibition against sale or commercial use of Research Specimens but does not extend the prohibition to the results of Collaborator's research activities involving Research Specimens, Progeny, or Unmodified Derivatives. Collaborator also is not authorized by the CRADA to collect or use for scientific research purposes any "Natural Products" apart from the specific Research Specimens covered in a permit issued under 36 CFR 1.6 and 2.5.*

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### **2.2.1 Natural Products**

For purposes of this agreement, the term “Natural Products” means any naturally occurring **Research Specimen** located in or taken from [*name of collaborating unit of the National Park System*] pursuant to a permit issued under 36 CFR 1.6 and 2.5.

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*The term “Research Specimens” is defined broadly, and includes all specimens previously acquired by Collaborator from the collaborating unit of the National Park System pursuant to a permit issued under 36 CFR 1.6 and 2.5. Accordingly, research activities involving previously acquired samples would be covered by the benefits-sharing provisions contained in the CRADA.*

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### **2.2.2 Research Specimens**

The term “Research Specimens” means those items Collaborator has authority to collect under the collection permit or permits issued by [*name of collaborating unit of the National Park System*] to Collaborator (copy of permit(s) attached hereto in Appendix A), or which otherwise were originally and lawfully collected from [*name of collaborating unit of the National Park System*].

### **2.2.3 Progeny**

The term “Progeny” means any unmodified descendant from **Research Specimens**, such as virus from virus, cell from cell, or organism from organism, that are cultivated by Collaborator.

### **2.2.4 Unmodified Derivatives**

The term “Unmodified Derivatives” means substances created by Collaborator that constitute an unmodified functional subunit or product expressed by **Research Specimens** or **Progeny**. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of **Research Specimens** or **Progeny**, proteins expressed by DNA/RNA obtained from **Research Specimens** or **Progeny**, or monoclonal antibodies secreted by a hybridoma cell line.

## **2.3 Definitions Relating to Data and Data Rights**

### **2.3.1 Background Intellectual Property**

The term “Background Intellectual Property” (“BIP”) refers to a patent or patent application covering an **Invention** or discovery of either party, or a copyrighted work, a mask work, trade secret, or trademark developed with separate funds outside of the CRADA by one of the parties or with others. **BIP** is not considered as a **Subject Invention**.

### **2.3.2 Generated Information**

The term “Generated Information” means information produced in the performance of the CRADA.

### **2.3.3 Proprietary Information**

The term “**Proprietary Information**” means trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 USC § 552(b)(4), obtained in the conduct of research or as a result of activities under the terms of this CRADA from a non-Federal party participating in this CRADA, as provided at 15 USC § 3710a(b)(1)(A).

### **2.3.4 Protected CRADA Information**

The term “**Protected CRADA Information**” means **Generated Information** that is marked as being **Protected CRADA Information** by a party to this agreement and that would have been **Proprietary Information** had it been obtained from a non-Federal entity.

### **2.3.5 Subject Data**

The term “**Subject Data**” means all recorded information first produced in the performance of this CRADA.

## **2.4 Definitions Relating to Intellectual Property Rights**

### **2.4.1 Intellectual Property**

The term “**Intellectual Property**” means patents, trademarks, copyrights, trade secrets, mask works, and other forms of comparable property protectable by Federal, state, or foreign laws.

### **2.4.2 Created**

The term “**created**” in relation to any copyrightable software work means when the work is fixed in any tangible medium of expression for the first time, as provided for at 17 USC § 101.

### **2.4.3 Made**

The term “**made**” in relation to any Invention means the conception or first actual reduction to practice of such **Invention**.

### **2.4.4 Invention**

The term “**Invention**” means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 USC § 2321 *et seq.*).

### **2.4.5 Subject Invention**

The term “**Subject Invention**” means any **Invention** of Collaborator or NPS conceived or first actually reduced to practice in the performance of work under this CRADA.

## **2.5 Definitions Relating to Research Results**

### **2.5.1 Modifications**

The term “**Modifications**” means substances created by Collaborator which contain / incorporate **Research Specimens**, **Progeny**, or **Unmodified Derivatives**.

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***The term “Product” is defined to be distinguished from both “Research Specimens” and “Natural Products” (with focus on the potentially valuable results of Collaborator’s research activities involving Research Specimens). All benefits-sharing obligations relate to revenues or other benefits generated from “Products” as distinguished from “Research Specimens” or “Natural Products” as defined in the General Provisions. However, the term “Product” also includes valuable materials developed from “Progeny” and “Unmodified Derivatives” as defined elsewhere in Article 2.***

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### **2.5.2 Product**

The term “Product” means any Modifications, Subject Invention or any other commercially valuable or otherwise useful material, compound or useful combination of compounds, protein, or metabolite recovered, obtained, derived, resulting, or otherwise isolated by scientific research conducted on Progeny, Unmodified Derivatives or a Research Specimen originally acquired from [*name of collaborating unit of the National Park System*], or any derivative or analog of such material, compound, protein, metabolite or other isolate, or any discovery which is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 USC § 2321 *et seq.*) and developed from Progeny, Unmodified Derivatives, or Research Specimens originally acquired from [*name of collaborating unit of the National Park System*].

### **2.5.3 Commercial Purpose**

The term “Commercial Purpose” means the sale, lease, license, or other transfer of any Progeny, Unmodified Derivatives, Modifications, Subject Invention or Product for value received, including but not limited to scientific research uses of any Progeny, Unmodified Derivatives, Modifications, Subject Invention or Product by Collaborator in the performance of any contract research, screening compound libraries, or the conduct of research activities that result in any sale, lease, license, or other transfer of any Progeny, Unmodified Derivatives, Modifications, Subject Invention or Product.

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***The definition of the term “Net Sales” as used in the CRADA is based on a definition used by the Public Health Service (National Institutes of Health) in licenses authorizing use of biological materials.***

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### **2.5.4 Net Sales**

The term “Net Sales” means the total gross receipts for sales by Collaborator, its licensees or sublicensees of Progeny, Unmodified Derivatives, Modifications, Subject Inventions, or Product(s), or copyrighted works created using the results of research under this CRADA, and from otherwise making Progeny, Unmodified Derivatives, Modifications, Subject Invention(s), or Product(s) available to others without sale, whether invoiced or not, less returns and allowances actually granted, packing costs, insurance costs, freight out, taxes and excise duties imposed on the transaction (if separately invoiced), and the wholesaler and cash discounts in amounts customary in the trade. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by Collaborator, its licensee or sublicensees, or for the cost of collections.

## Article 3. Statement of Work

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*The "Statement of Work" is the detailed description of the research work to be accomplished pursuant to the CRADA and describes in detail what each participant will do to reach the stated objective(s) of the CRADA. Article 3 of the General Provisions simply references the Statement of Work which appears as an attachment to the General Provisions. For more detail about preparing a Statement of Work according to Department of the Interior guidelines, see the Statement of Work section.*

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3.1 Cooperative research performed under this CRADA shall be performed in accordance with the attached Statement of Work, which is incorporated by reference into this agreement. The parties may modify the initial Statement of Work by mutual agreement and incorporate it herein by amendment as set out in paragraph 15.9.

## Article 4. Reports

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*Article 4 contains the provisions that govern Collaborator's reporting obligations under the CRADA. The requirements are more detailed than the general annual reporting requirement that exists under NPS Scientific Research and Collecting Permits, and includes scientific as well as economic information relating to any products resulting from CRADA-related research. The more detailed scientific research reports are intended to be useful to park management in furtherance of the objectives of the National Parks Omnibus Management Act of 1998. In addition, the economic data reporting requirements are intended to assist with compliance of any financial obligations assumed by Collaborator pursuant to the CRADA.*

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### 4.1 Research Reports

As required by the collection permits that [*name of collaborating unit of the National Park System*] issued to Collaborator, Collaborator will prepare and provide to NPS a written report concerning the research activities authorized by the collection permits, which shall include, but not be limited to, such information as the Superintendent of [*name of collaborating unit of the National Park System*] may require, including, but not limited to, all information required under this CRADA. NPS shall have the right to use such reports for any Governmental purpose including but not limited to the conservation of natural resources at [*name of collaborating unit of the National Park System*]. In the event Collaborator asserts that particular information delivered to NPS is proprietary, Collaborator agrees to provide to NPS a nonconfidential non-proprietary summary of such information for public disclosure.

## 4.2 Payment Reports

Concurrently with each payment, or at such other time as payments are due, Collaborator shall submit a written report to NPS setting forth (a) the period for which the payment is made, (b) the amount, description, and aggregate **Net Sales of Progeny, Unmodified Derivatives, Modifications, Subject Invention(s), or Product(s)** sold or otherwise disposed of, upon which a payment is payable for such completed calendar year as provided under this CRADA, (c) the total gross income realized by Collaborator from the sale, licensing, or otherwise making **Progeny, Unmodified Derivatives, Modifications, Subject Invention(s), or Product(s)** available to itself and others without sale, during such completed calendar year, and (d) the resulting calculation pursuant to this paragraph 4.2 of the amount of all payments due thereon. If no payments are due NPS for any report period, the report shall so state.

## 4.3 Copyright Reports

Concurrently with each payment of royalties on copyrighted materials as required by Appendix B, or at such other time as payments are due, Collaborator shall submit a written report setting forth the period for which the payment is made, the amount and a description of the copyrighted works upon which a royalty is payable, the net sales or other income received therefrom by Collaborator, and the amount of royalties due thereon. If no royalties are due NPS for any report period, the report shall so state.

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***The recordkeeping provisions contained in paragraph 4.4 require Collaborator to keep documents necessary to allow verification of accurate payments due to NPS. Collaborator also agrees to allow audit of its books and records to confirm accuracy of payments and related calculations if deemed necessary by NPS. These provisions are intended to assist in compliance with benefits-sharing obligations.***

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## 4.4 Records

Collaborator agrees to keep records showing the sales or other dispositions of all works upon which payments are due under the provisions of this CRADA in sufficient detail to enable NPS to determine the payments payable hereunder by Collaborator. Collaborator agrees to retain the records for a minimum period of five (5) years from the date a subject payment is due. Collaborator further agrees to permit an auditor selected by NPS to examine its books and records from time to time during its ordinary business hours and not more often than once a year to the extent necessary to verify the reports provided for in this Article 4. NPS will bear the initial expense of the audit. If the audit indicates that NPS was underpaid royalties by at least ten percent (10%) for any calendar year, or five thousand dollars (\$5000.00), whichever is greater, Collaborator will reimburse NPS for the expense of the audit, together with an amount equal to the additional royalties to which NPS is entitled.

## Article 5. Collaborator's Benefits-Sharing Obligation

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*Article 5 creates the general benefits-sharing obligation under the CRADA, and includes instructions concerning method and place of payments, total estimated in-kind and financial contributions from Collaborator, plus interest in the event of overdue payments discovered during the course of an audit. Article 5 allows the parties to defer negotiation of specific benefits-sharing terms until such time as Collaborator desires to use its research results for some "Commercial Purpose" as defined in Article 2. However, Collaborator is prohibited from using any of its research results for any "Commercial Purpose" until the benefits-sharing terms required under Article 5 are completed. NPS is not obligated to approve any use of research results for commercial purposes desired by Collaborator.*

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5.1 Collaborator hereby agrees to make the payments and other contributions set forth in Appendix B, which shall be used by *[name of collaborating unit of the National Park System]* for natural resource conservation purposes only. Unless otherwise specified, Collaborator agrees to make all payments to NPS in U.S. Dollars, net of all non-U.S. taxes (if any), by check or bank draft drawn on a United States bank and made payable to *[name of collaborating unit of the National Park System]*." The parties estimate Collaborator's total contribution at a minimum of US\$*[insert dollar amount]* in funds plus future royalties, and in-kind services and resources valued at US\$*[insert dollar amount]*.

5.2 The contribution of *[name of collaborating unit of the National Park System]* shall be in the form of resource protection, labor, expertise, equipment, facilities, information, computer software, and other forms of laboratory support, subject to available funding.

5.3 Collaborator will make all payments to *[name of collaborating unit of the National Park System]* in accordance with provisions of Appendix B. All payments by Collaborator shall be mailed to the following address:

*[insert mailing address of Superintendent of collaborating unit of the National Park System]*

5.4 Any overpayments by Collaborator shall be offset against payments due the following year.

5.5 If an audit described in paragraph 4.4 above indicates that payments are overdue to NPS, an interest charge will be assessed on the overdue amounts for each 30-day period, or portion thereof, that payment is delayed beyond the periods described in Appendix B. The percent of interest charged will be based on the current value of funds to the United States Treasury as published quarterly in the Treasury Fiscal Requirements Manual.

5.6 Collaborator agrees to provide written notification to NPS when any **Progeny, Unmodified Derivatives, Modifications, Subject Invention** or **Product** is to be used for any **Commercial Purpose** not less than sixty (60) days prior to such use to ensure compliance with the provisions of paragraph 5.1 of this CRADA.

## **Article 6. Recognition of Contribution from [Name of Collaborating Unit of the National Park System]**

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*Article 6 contains a specific acknowledgement by Collaborator of the value of NPS's natural resources and conservation management expertise to scientific research and resulting discoveries.*

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6.1 Collaborator acknowledges that NPS retains ownership of the **Research Specimens**. If Collaborator desires to use or license **Progeny, Unmodified Derivatives, Modifications, Subject Invention(s), or Product(s)** for any **Commercial Purpose**, Collaborator agrees in advance of such use to negotiate in good faith with [name of collaborating unit of the National Park System] to establish the terms required to complete this Article 5.

6.2 Collaborator recognizes the value of the natural resources protected by NPS (including the **Research Specimens** Collaborator has collected from [name of collaborating unit of the National Park System]), and that the efforts and expertise that NPS has invested in the preservation, conservation, and protection of NPS natural resources will contribute significantly to the discovery of **Subject Inventions** and development of **Modifications or Product(s)** from **Research Specimens** collected from [name of collaborating unit of the National Park System]; and, as a result, Collaborator agrees that the U.S. Government has a compensable interest in any **Progeny, Unmodified Derivatives, Modifications, Subject Invention(s), or Product(s)** developed from **Research Specimens** collected from [name of collaborating unit of the National Park System].

## **Article 7. Patent Rights**

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*Article 7 contains the main intellectual property rights provisions of the CRADA and are consistent with the intellectual property rights clauses used in CRADAs by other Federal agencies. The provisions are intended not to interfere with any party's rights under U.S. intellectual property rights laws. However, paragraph 7.1 contains a reporting obligation which provides a mechanism for NPS to learn about all potentially patentable inventions resulting from research involving research specimens collected from units of the National Park System.*

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### **7.1 Reporting**

The parties agree to disclose to each other every **Subject Invention**, which may be patentable or otherwise protectable, within sixty (60) days of the time that an inventing party reports such **Subject Invention** to the person(s) responsible for patent matters in the inventing organization. These disclosures should be in sufficient enough detail to enable a reviewer

to make and use the invention under 35 USC § 112. The disclosure shall also identify any statutory bars, *i.e.*, printed publications describing the **Subject Invention** or public use or sale of the **Subject Invention** in the United States. The parties further agree to disclose to each other any subsequent statutory bar that occurs for a **Subject Invention** disclosed but for which a patent application has not been filed. All such disclosures shall be marked as “CONFIDENTIAL” under 35 USC § 205.

## 7.2 Collaborator Employee Inventions

Collaborator may retain title to any **Subject Invention** made solely by its employees. Collaborator agrees to file patent applications on such **Subject Invention** at its own expense and in a timely fashion. Collaborator agrees to grant to the U.S. Government a nonexclusive, nontransferable, irrevocable, paid-up license in the patents covering **Subject Inventions** developed by Collaborator’s employees to practice the invention or have the invention practiced, throughout the world by or on behalf of the U.S. Government. Such nonexclusive license shall be evidenced by a confirmatory license agreement prepared by Collaborator in a form satisfactory to NPS.

## 7.3 NPS Employee Inventions

NPS, on behalf of the U.S. Government, shall have the initial option to retain title to each **Subject Invention** made by its employees under this CRADA. If a **Subject Invention** is made jointly by personnel of both parties under this CRADA, it and all patent applications and patents issued thereon shall be jointly owned by the parties, subject to the obligations contained in paragraphs 7.4 and 7.6 herein. NPS may release the rights provided for by this paragraph to employee inventors or to Collaborator subject to a license in NPS.

## 7.4 Filing of Patent Applications

The party having the right to retain title and file patent applications on a specific **Subject Invention** may elect not to file patent applications thereon provided that it so advises the other party within ninety (90) days from the date it reports the **Subject Invention** to the other party. Thereafter, the other party may elect to file patent applications on the **Subject Invention** and the party initially reporting such **Subject Invention** agrees to assign its right, title, and interest in such **Subject Invention** to the other party and cooperate with such party in the preparation and filing of patent applications thereon. The assignment of the entire right, title, and interest to the party pursuant to this paragraph shall be subject to the retention by the party assigning title of a nonexclusive, irrevocable, paid-up license to practice, or have practiced, the **Subject Invention** throughout the world. In the event that none of the parties to this CRADA elect to file a patent application on a **Subject Invention**, either or both (if a joint invention) may, at their sole discretion and subject to reasonable conditions, release the right to file to the inventor(s) with a license in each party of the same scope as set forth in the immediate preceding sentence.

## 7.5 Patent Expenses

All of the expenses attendant to the filing of patent applications as specified in paragraph 7.4 above shall be borne by the party filing the patent application. Any post-filing and post-patent

fees also shall be borne by the same party. Each party shall provide the other party with copies of the patent applications it files on any **Subject Invention** at the time the application is filed at the U.S. Patent & Trademark Office or patent office of another country. Each party also will provide the other party with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office.

## 7.6 License Provisions

Collaborator, at any time, may license or sublicense in whole or in part, any rights and interests granted to Collaborator from NPS under the terms and conditions of this CRADA. Collaborator may exercise such right without obtaining additional authorization from NPS, but Collaborator expressly agrees that in so licensing or sublicensing, it will specifically reserve to NPS all rights and privileges provided in this agreement for NPS, including the provisions of Appendix B. In the event of a license or sublicense, Collaborator will notify NPS of each license and sublicense to enable NPS to call for the reports provided for in this agreement.

## 7.7 Enforcement of Jointly-Owned Patents

Collaborator must advise NPS of any events that cause Collaborator to suspect that a third party is or may be infringing on jointly owned patents resulting from research conducted under this CRADA (hereinafter referred to as “CRADA patents”). Collaborator must institute and diligently prosecute proper legal proceedings at Collaborator’s own expense in the event of infringement of CRADA patents. Should Collaborator fail to institute such proceedings within ninety (90) days from receipt of written request from NPS to institute such proceedings, NPS may take the following actions:

- 1) Institute a suit in its own name as subrogee of Collaborator’s rights to enforce the patent; or
- 2) Institute a suit against Collaborator for damages resulting from Collaborator’s failure to terminate or abate the infringement.

In the event of institution of a suit for infringement by NPS pursuant hereto, it is understood that Collaborator may participate and be represented by its own counsel; however, any recovery damages shall be equitably apportioned, less the U.S. Government litigation costs. Either party may make reasonable settlements with respect to any infringements. Collaborator agrees to join in any legal proceedings brought by NPS if joinder is required by law.

# Article 8. Copyrights

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***Article 8 contains the provisions relating to copyrighted material resulting from CRADA related research activities, and are consistent with the copyright provisions contained in CRADAs used by other Federal agencies.***

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8.1 Collaborator shall have the option to own the copyright in all software (including modifications and enhancement thereto), documentation, or other works created in whole

or in part by Collaborator under this CRADA, which is subject to being copyrighted under Title 17, United States Code. Collaborator shall mark any such works with a copyright notice showing Collaborator as the author or co-author and shall in its reasonable discretion determine whether to file applications for registration of copyright.

8.2 Collaborator agrees to grant to the U.S. Government, solely for its purposes, a nonexclusive, irrevocable, paid-up, worldwide license (hereinafter referred to as Government Purpose License) in all copyrighted software or other copyrighted works developed under this CRADA. The Government Purpose License (“GPL”) conveys to the U.S. Government the right to use, duplicate, or disclose the copyrighted software or other works in whole or in part, and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only. Government purposes include competitive procurement, but do not include the right to have or permit others to use the copyrighted software or other works for commercial purposes.

8.3 Collaborator will clearly mark all copyrighted software or other works subject to the GPL with its name and the words “GOVERNMENT PURPOSE LICENSE.”

8.4 Collaborator shall furnish to NPS, at no cost to NPS, at least one copy of each software, documentation or other work developed in whole or in part by Collaborator under this CRADA, subject to the terms and conditions of the GPL granted to NPS under paragraph 8.2.

## **Article 9. Copyright Royalties**

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*Article 9 contains provisions acknowledging Collaborator’s obligation to pay royalties on revenues earned from the licensing, assignment, sale, lease, or rental of any copyrighted work created under the CRADA.*

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9.1 Appendix B covers the obligations of Collaborator to compensate NPS from royalties produced from the sale or use of copyrighted materials. As provided in Appendix B, Collaborator shall pay to NPS royalties over the life of the copyright from the licensing, assignment, sale, lease, and rental (hereinafter referred to as “disposition”) of any copyrighted work created under this CRADA.

## **Article 10. Data and Publication**

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*Article 10 contains the provisions relating to the use of data resulting from research activities conducted under the CRADA, as well as the procedures relating to protection of proprietary information. The provisions of Article 10 are consistent with the data and publication provisions used in CRADAs by other Federal agencies.*

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## 10.1 Release Restrictions

NPS shall have the right to use all **Subject Data**, as defined in Article 2, for any Governmental purpose, but shall not release such **Subject Data** publicly except:

- 1) NPS, when reporting on the results of sponsored research, may publish **Subject Data**, subject to the provisions of paragraph 10.4 below; and
- 2) NPS may release such **Subject Data** where such release is required pursuant to a request under the Freedom of Information Act, as amended (5 USC § 552 *et seq.*); provided, however, that such data shall not be released to the public if a patent application is to be filed (35 USC § 205) until the party having the right to file the patent application has had a reasonable time to file.

## 10.2 Proprietary Information and Background Intellectual Property

### 10.2.1 Proprietary Information

Collaborator shall place a proprietary notice on all information it delivers to NPS under this CRADA that Collaborator asserts is **Proprietary Information**, as defined in Article 2. NPS agrees that it will use any information designated as proprietary that Collaborator furnishes to NPS under this CRADA, only for the purpose of carrying out this CRADA. NPS agrees not to disclose, copy, reproduce, or otherwise make available in any form whatsoever information designated as proprietary to any other person, firm, corporation, partnership, association, or other entity without the consent of Collaborator, except as such information may be subject to disclosure under the Freedom of Information Act, as amended (5 USC § 552, *et seq.*). NPS agrees to use its best efforts to protect information designated as proprietary from unauthorized disclosure. Collaborator agrees that NPS is not liable for the disclosure of information designated as proprietary that, after notice to and consultation with Collaborator, NPS determines may not lawfully be withheld or that a court of competent jurisdiction requires disclosure.

### 10.2.2 Background Intellectual Property

Both parties agree to identify in advance and during the course of the CRADA **Background Intellectual Property (BIP)**, as defined in Article 2, that has value for the joint research but which was developed with separate funds outside the CRADA. **BIP** does not qualify as a **Subject Invention** and is not subject to a government use license.

## 10.3 Protected CRADA Information

10.3.1 Each party may designate as **Protected CRADA Information**, as defined in Article 2, any **Generated Information** produced by its employees, and with the agreement of the other party, mark any **Generated Information** produced by the other party's employees. All such designated **Protected CRADA Information** shall be appropriately marked.

10.3.2 For a period of five (5) years from the date the **Protected CRADA Information** is produced, the parties agree not to further disclose such **Protected CRADA Information** except:

- 1) as necessary to perform this CRADA; and

2) as mutually agreed by the parties in writing in advance.

10.3.3 The obligation of 10.3.2 above shall end sooner for any **Protected CRADA Information** which shall become publicly known without fault of either party, shall come into a party's possession without breach by that party of the obligations of 10.3.2 above, or shall be independently developed by a party's employees who did not have access to the **Protected CRADA Information**, or as required by the Freedom of Information Act, as amended (5 USC § 552, *et seq.*).

## 10.4 Publication

10.4.1 NPS may submit for publication the results of the research work associated with this project. Depending on the extent of contribution made, employees of Collaborator may be cited as co-authors.

10.4.2 NPS and Collaborator agree to confer and consult at least thirty (30) days prior to either party's submission for publication of **Subject Data** to assure that no **Proprietary Information** or **Protected CRADA Information** is released and that patent rights are not jeopardized. The party receiving the document for review has thirty (30) days from receipt to object in writing detailing the objections to the proposed submissions.

# Article 11. Rights in Generated Information

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*Article 11 summarizes NPS's rights in data generated pursuant to research activities conducted under the CRADA.*

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11.1 The parties understand that the Government shall have unlimited rights in all **Generated Information** or information provided to the parties under this CRADA which is not marked as being copyrighted (subject to Article 8) or as **Proprietary Information** (subject to paragraph 10.2.1) or as **Protected CRADA Information** (subject to paragraph 10.3).

# Article 12. Termination

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*Article 12 describes the procedures for termination of the CRADA by the parties. Either party may terminate at any time by giving thirty (30) days written notice to the other party. Termination, however, does not affect the obligations of the parties pursuant to Article 5 (Collaborator's Benefits-Sharing Obligation), Article 7 (Patent Rights), Article 8 (Copyrights), Article 9 (Copyright Royalties), Article 10 (Data and Publication), Article 11 (Rights in Generated Information), and Article 14 (Liability); the parties' obligations pursuant to all of the Articles of the CRADA survive termination pursuant to Article 12 and remain enforceable.*

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12.1 Collaborator and NPS each have the right to terminate this CRADA upon thirty (30) days notice in writing to the other party. In the event of termination by [name of collaborating unit of the National Park System], [name of collaborating unit of the National Park System] shall repay Collaborator any prorated portion of payments previously made to [name of collaborating unit of the National Park System] pursuant to Article 5.1 of the CRADA in excess of actual costs incurred by [name of collaborating unit of the National Park System] in pursuing this project. A report on results to date of termination will be prepared by [name of collaborating unit of the National Park System] and the cost of the report will be deducted from any amounts due to Collaborators from [name of collaborating unit of the National Park System].

12.2 In-kind payments received by NPS as provided in Appendix B may be retained in support of the project.

12.3 A report on results to date of termination will be prepared by Collaborator and the cost of the report will be deducted from any amounts due to NPS.

12.4 Termination of this CRADA by either party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this CRADA. No termination or expiration of this CRADA, however effectuated, shall release the parties hereto from their rights, duties, and obligations under Articles 7, 8, 9, 10, 11, and 14, and payments due under Appendix B.

## **Article 13. Disputes**

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***Article 13 contains the provisions relating to procedures intended to resolve any disputes arising between the parties under the CRADA.***

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13.1 Any dispute arising under this CRADA which is not disposed of by agreement of the parties shall be submitted jointly to the signatories of this CRADA. A joint decision of the signatories or their designees shall be the disposition of such dispute.

13.2 If the signatories are unable to jointly resolve a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted to the Director of the NPS, or his or her designee, for resolution.

13.3 Pending the resolution of any dispute or claim pursuant to this Article, the parties agree that they will diligently pursue performance of all obligations in accordance with the direction of the NPS signatory.

# Article 14. Liability

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*Article 14 relates to the parties' liability for losses or damage incurred under the CRADA.*

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## 14.1 Property

The U.S. Government shall not be responsible for damages to any property of Collaborator provided to [*name of collaborating unit of the National Park System*] pursuant to this CRADA.

## 14.2 Collaborator's Employees

14.2.1 During any temporary assignment at [*name of collaborating unit of the National Park System*] facilities that may result from this CRADA, **Collaborator's Assigned Employees**, as defined in Article 2, shall pursue their activities on the work schedule mutually agreed upon between them, Collaborator, and NPS. **Collaborator's Assigned Employees** must agree to comply with Federal Government security and conduct regulations that apply to [*name of collaborating unit of the National Park System*] employees. **Collaborator's Assigned Employees** shall conform to the requirements of the Office of Government Ethics "Standards of Ethical Conduct for Employees of the Executive Branch" (5 CFR Parts 2635 and 2636) and Security Regulations, hereby made part of this CRADA, to the extent that these regulations prohibit private business activity or interest incompatible with the best interests of the U.S. Department of the Interior.

14.2.2 **Collaborator's Assigned Employees** shall comply with regulations that apply to [*name of collaborating unit of the National Park System*] employees with regard to disclosure of proprietary or procurement-sensitive information, refusal from any activities which may present a conflict of interest, including procurement or other actions in which Collaborator may have an interest. **Collaborator's Assigned Employees** may not represent Collaborator or work for Collaborator in competing for award from any other Federal agency during the term of the CRADA (*see* Article 16) or extension thereto.

14.2.3 **Collaborator's Assigned Employees** are permanently prohibited from representing or performing activities for Collaborator on any matters before NPS on which Collaborator's employees worked at [*name of collaborating unit of the National Park System*] while assigned to this project.

14.2.4 Collaborator's employees are prohibited from acting as Government employees, including making decisions on behalf of the Government or performing inherently Governmental functions while working at [*name of collaborating unit of the National Park System*].

## 14.3 No Warranty

Except as provided in Title 28, United States Code, Section 1498, the United States shall not be liable for the use or manufacture of any Invention made under this CRADA nor for the

infringement of any patent or copyright during the performance of this CRADA. NPS makes no express or implied warranty as to any matter whatsoever, including the conditions of the research or any **Invention** or **Product**, whether tangible or intangible, made or developed under this CRADA, or the ownership, merchantability, or fitness for a particular purpose of the research or any **Invention** or **Product**. These provisions shall survive termination of the CRADA.

## **14.4 Indemnification**

### **14.4.1 Collaborator's Employees**

Collaborator agrees to indemnify and hold harmless the U.S. Government for any loss, claim, damage, or liability of any kind involving an employee of Collaborator arising in connection with this CRADA, except to the extent that such loss, claim, damage or liability arises from the negligence of NPS or its employees acting within the scope of their employment. NPS shall be solely responsible for the payment of all claims for the loss of property, personal injury or death, or otherwise arising out of any negligent act or omission of its employees in connection with the performance of work under this CRADA as provided under the Federal Tort Claims Act. 28 USC § 2672.

### **14.4.2 Technical Developments and Products**

Collaborator holds the U.S. Government harmless and indemnifies the Government for all liabilities, demands, damages, expenses, and losses arising out of the use by Collaborator, or any party acting on its behalf or under its authorization, of NPS's research and technical developments or out of any use, sale, or other disposition by Collaborator, or others acting on its behalf or with its authorization, of any **Subject Invention** or **Product** made by Collaborator using NPS's technical developments. In respect to this Article, the Government shall not be considered an assignee or licensee of Collaborator. This provision shall survive termination of this CRADA.

### **14.4.3 Insurance**

Collaborator agrees to maintain insurance in amounts reasonably customary in the industry and to provide proof of liability insurance to NPS upon request.

## **14.5 Force Majeur**

Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this CRADA (and which it has been unable to overcome by the exercise of due diligence), including but not limited to flood, drought, earthquake, storm, fire, pestilence, lightening, and other natural catastrophes, epidemic, war, riot, civil disturbance or disobedience, strikes, labor dispute, or failure, threat of failure or sabotage of [*name of collaborating unit of the National Park System*] facilities, or any order or injunction made by a court or public agency. In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as result of the force majeure event.

# Article 15. Miscellaneous Terms and Conditions

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*Article 15 contains the miscellaneous terms and conditions relating to the parties' rights and obligations under the CRADA, and is consistent with similar provisions contained in CRADAs used by other Federal agencies. Article 15 also includes provisions relating to "successors," "severability," and "assignment" that require NPS written approval to assure ongoing compliance with the terms of the CRADA by other parties in the future.*

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## 15.1 Successors

Subject to the limitations stated in the *General Provisions*, this CRADA shall be a binding obligation to the successors and permitted assignees of all the right, title and interest of each party hereto. Any such successor or assignee of a party's interest shall expressly assume in writing the performance of all the terms and conditions of this CRADA to be performed by said party. Any such assignment shall not relieve the assignor of any of its obligations under this CRADA.

## 15.2 Severability

The provisions of this CRADA are severable and in the event any of provisions of this CRADA are determined to be invalid or unenforceable by a court of competent jurisdiction, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof, except that for so long as Collaborator is receiving financial benefit from the use of any **Progeny, Unmodified Derivatives, Modifications, Subject Invention, or Product** for any **Commercial Purpose** resulting from research involving **Research Specimens** acquired from [*name of collaborating unit of the National Park System*], Collaborator agrees to make the payments as provided in Appendix B.

## 15.3 Waiver

Neither party may waive or release any of its rights or interests in this CRADA except in writing. Failure by either party to assert any rights or interests arising from any breach or default of this CRADA shall not be regarded as a waiver of any existing or future rights, interests or claims.

## 15.4 Enforcement

Collaborator and NPS specifically acknowledge the right to pursue all legal and equitable remedies necessary to cure any breach of their obligations under this CRADA that are not satisfactorily resolved under this CRADA.

## 15.5 No Benefits

No member of, or delegate to the United States Congress, or resident commissioner,

shall be admitted to any share or part of this CRADA, nor to any benefit that may arise therefrom; but this provision shall not be construed to extend to this CRADA if made with a corporation for its general benefit.

## **15.6 Governing Law**

The construction validity, performance and effect of this CRADA for all purposes shall be governed by applicable Federal laws.

## **15.7 Entire Agreement**

This CRADA, consisting of the Statement of Work, Appendix A (research specimen collection permit(s) issued by NPS to Collaborator), and Appendix B, constitutes the entire agreement between the parties concerning the subject matter hereto and supersedes any prior understanding or written or oral agreement relative to said matter.

## **15.8 Headings**

Titles and headings of the Sections and Subsections of this CRADA are for the convenience of references only and do not form a part of this CRADA and shall in no way affect the interpretation thereof.

## **15.9 Amendments**

If either party desires a modification in this CRADA, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by all parties hereto by their representatives duly authorized to execute such amendment.

## **15.10 Assignment**

Neither this CRADA nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party, except that Collaborator may assign, subject to the provisions of paragraph 15.1, this CRADA to the successors or assignees of a substantial portion of Collaborator's business interests to which this CRADA directly pertains.

## **15.11 Notices**

All notices pertaining to or required by this CRADA shall be in writing and shall be directed to the signatory(s).

## **15.12 Independent Contractors**

The relationship of the parties to this CRADA is that of independent contractors and not as agents of each other or as joint venturers or partners. NPS shall maintain sole and exclusive control over its personnel and operations.

## 15.13 Use of Name or Endorsements

15.13.1 Collaborator shall not use the name of [*name of collaborating unit of the National Park System*], NPS or the Department of the Interior on any **Progeny, Unmodified Derivatives, Modifications, Subject Invention, or Product** or service which is directly or indirectly related to either this CRADA or any patent license or assignment agreement which implements this CRADA without the prior approval of [*name of collaborating unit of the National Park System*]. Collaborator shall not publicize, or otherwise circulate, promotional material (such as advertisements, sales brochures, press releases, speeches, still or motion pictures or video, articles, manuscripts or other publications) which states or implies Governmental, Departmental, Bureau, or U.S. Government employee endorsement of any **Progeny, Unmodified Derivatives, Modifications, Subject Invention, or Product**, service or position which Collaborator represents. No release of information relating to this CRADA may state or imply that the Government approves of Collaborator's work product, or considers Collaborator's work product to be superior to other products or services.

15.13.2 Collaborator must obtain prior U.S. Government approval from NPS for any public information releases which refer to the Department of the Interior, any bureau or employee (by name or title), or this CRADA. The specific text, layout, photographs, etc. of the proposed release must be submitted with the request for approval.

15.13.3 By entering into this CRADA, NPS does not directly or indirectly endorse any product or service provided or to be provided by Collaborator, its successors, assignees, or licensees.

15.14 The operations of Collaborator will be conducted in all material respects in accordance with all applicable laws, ratified treaties, international agreements and conventions, regulations, guidelines and other requirements of all governmental bodies having jurisdiction over Collaborator. Collaborator shall have all material licenses (including a radioactivity license), permits, orders or approvals from governmental bodies required for the conduct of its business. All such licenses, permits, approvals or other requirements shall be in full force and there shall exist no violations or breaches of any such domestic licenses, permits, approvals or other requirements. Collaborator shall be in compliance in all material respects with all limitations, restrictions, conditions, standards, prohibitions, requirements, obligations, schedules and timetables contained in any applicable law or in any plan, order, decree, judgment, notice or demand letter issued, entered, promulgated or approved thereunder.

## Article 16. Duration of Agreement and Effective Date

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*Article 16 provides that the CRADA will remain in effect for a term of five (5) years, unless terminated earlier pursuant to Article 12. Five years is believed to be a reasonable term for the conduct of important joint scientific research projects governed by the CRADA. The*

***CRADA can be renewed with the consent of the parties pursuant to the “amendment” provisions of paragraph 15.9.***

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## **16.1 Effective Date**

This CRADA shall enter into force as of the date of the last signature of the parties as shown on the signature page, and will terminate five (5) years from the effective date. In no case will this CRADA extend beyond the ending date specified herein, unless it is revised in accordance with paragraph 15.9 of this CRADA.

## **16.2 Review Period**

Notwithstanding paragraph 16.1 above, the NPS Director shall have the opportunity to disapprove or require the modification of this CRADA for a 30-day period beginning on the date the agreement is presented to the Director by the Superintendent of [*name of collaborating unit of the National Park System*], unless the agreement is signed by the Director.

***SIGNATURES BEGIN ON NEXT PAGE***

# Signature Page

## SIGNATURES

In Witness Whereof, the parties have executed this CRADA on the dates set forth below. This CRADA may be signed in counterparts, each of which will be deemed to be an original. All such counterparts shall together constitute a single, executed instrument when all parties have so signed. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

FOR NPS:

_____	_____
[name]	Date
Director	
National Park Service	

FOR *[name of collaborating unit of the National Park System]*:

_____	_____
[name]	Date
Superintendent	
<i>[name of collaborating unit of the National Park System]</i>	

Mailing Address for Notices: Office of the Superintendent  
*[name and address]*

FOR COLLABORATOR:

_____	_____
[signatory's name]	Date
[title]	
[name of collaborator (if different from signatory)]	

Mailing Address for Notices:  
  
*[name and address]*

# Statement of Work

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*Collaborator and the collaborating unit of the National Park System should work together to draft the Statement of Work that describes the CRADA effort and anticipated results. Each Statement of Work will describe the specific research activities to be undertaken by Collaborator with a collaborating unit of the National Park System. Whereas the CRADA General Provisions apply to all benefits-sharing CRADAs Service-wide, Statements of Work describe the specific facts and circumstances relating to specific CRADA research activities. Nonetheless, all activities described in a Statement of Work are subject to the controlling provisions of the CRADA General Provisions.*

*The Statement of Work should be a concise, technical document containing the kinds of information found in typical research proposals. It should consist of the following subsections:*

*Background - The history of the opportunity or problem; the scientific purpose, need, or potentially useful application of the idea or research activity; earlier attempts to solve the problem or address the need; projections of potential applications if successful.*

*Objective - The anticipated result(s) of current and planned research and development activities, including identification of the anticipated uses of possible discoveries.*

*Tasks - Each task or step necessary to reach the stated objective should be described in detail. This should include a list of the relative responsibilities of Collaborator as well as the collaborating unit of the National Park System.*

*Expected Results - Implications of the project; short-term generations of additional projects or research activities (if any); foreseeable longer-term applications of anticipated research results; estimates or related market data of expected economic value of discoveries or inventions resulting from the research activities (if known).*

*Constraints - Uncertainties in the future or estimates associated with the research project; assumptions about future events and the availability of resources, personnel, or equipment; questions of technical feasibility; deadlines, windows of opportunity, or other constraints.*

*Resources - A detailed list of all resources being supplied to the research project pursuant to the CRADA by the partners including financial contributions and an estimate of in-kind expenses and contributions.*

*Once approved, the Statement of Work becomes a key part of the completed CRADA.*

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# CRADA APPENDIX A

[COPY OF COLLABORATOR'S NPS SCIENTIFIC RESEARCH AND  
COLLECTING PERMIT(S)]

# CRADA APPENDIX B

[BENEFITS-SHARING TERMS]

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# **Appendix B**

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## **Example Material Transfer Agreement (MTA)**

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***Text that appears in bold italics and between double lines is provided as clarification to the reader. These explanatory text sections will be included in the Environmental Impact Statement, but they will not be included in any final (signed) MTA.***

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*The MTA begins by providing the substantive definitions that are used in the MTA. The definitions that appear in the MTA are consistent with the definitions used in the CRADA that appears in Appendix A of this EIS, which also reflect the definitional approach contained in the Uniform Biological Material Transfer Agreement developed and published by the National Institutes of Health/Public Health Service in March 1995 (see 60 Fed. Reg. 12771 (March 8, 1995)). Additional explanations concerning the meaning of certain definitions appear with the definitions used in the CRADA that appears in Appendix A of this FEIS.*

*Defined terms appear in bold-faced print throughout the MTA.*

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## **I. Definitions**

### **1.1 Provider**

The term “**Provider**” means the person(s) providing the **Material**. The name and address of Provider is:

\_\_\_\_\_

*(Name)*

\_\_\_\_\_

*(Address)*

### **1.2 Recipient**

The term “**Recipient**” means the person(s) receiving the **Material**. The name and address of Recipient is:

\_\_\_\_\_

*(Name)*

\_\_\_\_\_

*(Address)*

### **1.3 Transferred Material**

The term “**Transferred Material**” means the **Material** being transferred from **Provider** to **Recipient** that is described as follows: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## 1.4 Material

The term “**Material**” means **Research Specimens, Progeny, and Unmodified Derivatives**. The **Material** shall not include: (a) **Modifications** or (b) other substances created by **Provider** through use of the **Material** that are not **Modifications, Progeny, or Unmodified Derivatives**.

## 1.5 Research Specimens

The term “**Research Specimens**” means material in **Provider’s** possession that **Provider** has or had authority to collect under the collection permit or permits issued by [*name of authorizing unit of the National Park System*] to **Provider** (copy of permit(s) attached hereto), or that was otherwise originally and lawfully collected from [*name of authorizing unit of the National Park System*] and is now in **Provider’s** possession.

## 1.6 Progeny

The term “**Progeny**” means any unmodified descendant from **Material**, such as virus from virus, cell from cell, or organism from organism.

## 1.7 Unmodified Derivatives

The term “**Unmodified Derivatives**” means substances created by **Recipient** that constitute an unmodified functional subunit or product expressed by **Material**. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of **Material**, proteins expressed by DNA/RNA obtained from **Material**, or monoclonal antibodies secreted by a hybridoma cell line.

## 1.8 Modifications

The term “**Modifications**” means substances created by **Recipient** that contain/incorporate/are derived from **Research Specimens, Progeny, or Unmodified Derivatives**.

## 1.9 Invention

The term “**Invention**” means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 USC § 2321 *et seq.*).

## 1.10 Product

The term “**Product**” means any **Modifications, Inventions**, or any other commercially valuable or otherwise useful or potentially useful material, compound, or useful or potentially useful combination of compound, protein, or metabolite recovered, obtained, derived, resulting, or otherwise isolated by scientific research conducted on **Progeny, Unmodified Derivatives**, or a **Research Specimen** originally acquired from [*name of authorizing unit of the National Park System*], or any derivative or analog of such material, compound, protein, metabolite or other isolate, or any discovery that is or may be patentable or otherwise

protected under Title 35 of the United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 USC § 2321 *et seq.*) and developed from **Progeny, Unmodified Derivatives, or Research Specimens** originally acquired from [*name of authorizing unit of the National Park System*].

## 1.11 Commercial Purpose

The term “**Commercial Purpose**” means the sale, lease, license, or other transfer of any **Progeny, Unmodified Derivatives, Modifications, Invention, or Product** for value received, including but not limited to scientific research uses of any **Progeny, Unmodified Derivatives, Modifications, Invention, or Product** by any person (including but not limited to **Provider and Recipient**) in the performance of any contract research, screening compound libraries, or the conduct of research activities that result in any sale, lease, license, or other transfer of any **Progeny, Unmodified Derivatives, Modifications, Invention, or Product**.

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*The “Terms and Conditions” of the MTA are intended to document the Provider’s and Recipient’s understanding and compliance with the obligations of the parties pursuant to the National Park Service (NPS)’s research permit requirements, as re-stated in the MTA. The Provider is authorized to transfer Material to Recipient only upon approval of the MTA by the NPS. By executing the MTA, Recipient also specifically acknowledges and agrees to the same terms and conditions relating to use of Research Specimens that apply to all permitted researchers who collect research specimens directly from units of the National Park System. In this way, the NPS intends to promote equity among researchers who collect directly from national parks pursuant to a permit as well as researchers who obtain specimens indirectly from other authorized third-party Providers.*

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## II. Terms and Conditions of this Agreement and Authorization

2.1 **Provider and Recipient** hereby acknowledge that the NPS retains ownership of the **Research Specimens**. **Provider** is authorized to transfer to **Recipient** the specific **Transferred Material** described above in Section 1.3 upon execution of this Material Transfer Agreement (MTA) by **Provider, Recipient**, and [*name of authorizing unit of the National Park System*].

2.2. **Recipient** agrees that the **Transferred Material**:

(a) will be used in compliance with all applicable federal and state laws, governmental regulations, and guidelines (including but not limited to all applicable terms and conditions of the NPS’s standardized Scientific Research and Collecting Permit that governs collection, distribution, and use of **Research Specimens** collected from U.S. national parks; reference copy of Scientific Research and Collecting Permit General Conditions is attached);

(b) may be used for scientific or educational purposes only, and may not be used for any **Commercial Purpose** without the prior written authorization of the NPS; and

(c) may not be sold or otherwise transferred to any other person without the prior written authorization of the NPS.

2.3. **Recipient** understands and agrees that the NPS may seek damages to which the NPS may be entitled, including but not limited to injunctive relief for any unauthorized sale, transfer, or other use of **Transferred Material**.

2.4. **Recipient** agrees to provide to [*name of authorizing unit of the National Park System*] a copy of any interim reports, final reports, publications, and other materials resulting from use of **Transferred Material**. **Recipient** also agrees to identify in each such written report or other material the project study number (if any) of the NPS-permitted project that collected the original **Research Specimen** from which the **Transferred Material** is derived. In addition, **Recipient** agrees to provide notice in writing to [*name of authorizing unit of the National Park System*] not less than sixty (60) days before **Recipient** files an application for a patent or other intellectual property claim resulting from use of **Transferred Material**.

2.5. **RECIPIENT AGREES THAT THE TRANSFERRED MATERIAL IS EXPERIMENTAL IN NATURE AND IS BEING PROVIDED WITHOUT WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR FREEDOM FROM INFRINGEMENT OF ANY PATENT OR OTHER PROPRIETARY RIGHT OF A THIRD PARTY.**

2.6. **RECIPIENT AGREES TO HOLD HARMLESS AND INDEMNIFY THE U.S. DEPARTMENT OF THE INTERIOR, NATIONAL PARK SERVICE, AND ANY UNIT THEREOF, THE U.S. GOVERNMENT, AND PERSONS ACTING ON THEIR BEHALF, FOR ANY CLAIM ASSERTED BY A THIRD PARTY RELATED TO RECIPIENT'S POSSESSION, USE, STORAGE, OR DISPOSAL OF TRANSFERRED MATERIAL.**

### **III. Administration**

Any correspondence or other notice concerning this agreement should be addressed to: [*insert name and address of authorizing official and unit of the National Park System*].

***SIGNATURES BEGIN ON NEXT PAGE***

# Signature Page

## SIGNATURES

In Witness Whereof, the parties have executed this MATERIAL TRANSFER AGREEMENT (MTA) on the dates set forth below. This MTA may be signed in counterparts, each of which will be deemed to be an original. All such counterparts shall together constitute a single, executed instrument when all parties have so signed. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

### FOR NPS:

\_\_\_\_\_  
[Name] \_\_\_\_\_ Date  
Superintendent  
[Name of authorizing unit of the National Park System]

Mailing address for notices: Office of the Superintendent  
[name and address]

### FOR PROVIDER:

\_\_\_\_\_  
[Signatory's name] \_\_\_\_\_ Date  
[Title]  
[Name of Provider (if different from signatory)]

Mailing address for notices: [name and address]

### FOR RECIPIENT:

\_\_\_\_\_  
[Signatory's name] \_\_\_\_\_ Date  
[Title]  
[Name of Recipient (if different from signatory)]

Mailing address for notices: [name and address]

*NOTE: Both **Provider** and **Recipient** should sign this MTA, and then forward it to [name of authorizing unit of the National Park System] for approval. A fully executed copy of the completed MTA will be sent to **Provider** and **Recipient** upon approval. This agreement does not enter into force until signed by the NPS.*



## GENERAL CONDITIONS For SCIENTIFIC RESEARCH AND COLLECTING PERMIT

United States Department of the Interior  
National Park Service

1. **Authority** - The permittee is granted privileges covered under this permit subject to the supervision of the superintendent or a designee, and shall comply with all applicable laws and regulations of the National Park System area and other federal and state laws. A National Park Service (NPS) representative may accompany the permittee in the field to ensure compliance with regulations.
2. **Responsibility** - The permittee is responsible for ensuring that all persons working on the project adhere to permit conditions and applicable NPS regulations.
3. **False information** - The permittee is prohibited from giving false information that is used to issue this permit. To do so will be considered a breach of conditions and be grounds for revocation of this permit and other applicable penalties.
4. **Assignment** - This permit may not be transferred or assigned. Additional investigators and field assistants are to be coordinated by the person(s) named in the permit and should carry a copy of the permit while they are working in the park. The principal investigator shall notify the park's Research and Collecting Permit Office when there are desired changes in the approved study protocols or methods, changes in the affiliation or status of the principal investigator, or modification of the name of any project member.
5. **Revocation** - This permit may be terminated for breach of any condition. The permittee may consult with the appropriate NPS Regional Science Advisor to clarify issues resulting in a revoked permit and the potential for reinstatement by the park superintendent or a designee.
6. **Collection of specimens (including materials)** - No specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting permit.

The general conditions for specimen collections are:

- Collection of archeological materials without a valid Federal Archeology Permit is prohibited.
- Collection of federally listed threatened or endangered species without a valid U.S. Fish and Wildlife Service endangered species permit is prohibited.
- Collection methods shall not attract undue attention or cause unapproved damage, depletion, or disturbance to the environment and other park resources, such as historic sites.
- New specimens must be reported to the NPS annually or more frequently if required by the park issuing the permit. Minimum information for annual reporting includes specimen classification, number of specimens collected, location collected, specimen status (e.g., herbarium sheet, preserved in alcohol/formalin, tanned and mounted, dried and boxed, etc.), and current location.
- Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from

the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization.

- Each specimen (or groups of specimens labeled as a group) that is retained permanently must bear NPS labels and must be accessioned and cataloged in the NPS National Catalog. Unless exempted by additional park-specific stipulations, the permittee will complete the labels and catalog records and will provide accession information. It is the permittee's responsibility to contact the park for cataloging instructions and specimen labels as well as instructions on repository designation for the specimens.
- Collected specimens may be used for scientific or educational purposes only, and shall be dedicated to public benefit and be accessible to the public in accordance with NPS policies and procedures.
- Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a Cooperative Research And Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS. The sale of collected research specimens or other unauthorized transfers to third parties is prohibited. Furthermore, if the permittee sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without a CRADA or other approved benefit-sharing agreement with NPS, permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled including but not limited to injunctive relief against the permittee.

7. **Reports** - The permittee is required to submit an Investigator's Annual Report and copies of final reports, publications, and other materials resulting from the study. Instructions for how and when to submit an annual report will be provided by NPS staff. Park research coordinators will analyze study proposals to determine whether copies of field notes, databases, maps, photos, and/or other materials may also be requested. The permittee is responsible for the content of reports and data provided to the National Park Service.

8. **Confidentiality** - The permittee agrees to keep the specific location of sensitive park resources confidential. Sensitive resources include threatened species, endangered species, and rare species, archeological sites, caves, fossil sites, minerals, commercially valuable resources, and sacred ceremonial sites.

9. **Methods of travel** - Travel within the park is restricted to only those methods that are available to the general public unless otherwise specified in additional stipulations associated with this permit.

10. **Other permits** - The permittee must obtain all other required permit(s) to conduct the specified project.

11. **Insurance** - If liability insurance is required by the NPS for this project, then documentation must be provided that it has been obtained and is current in all respects before this permit is considered valid.

12. **Mechanized equipment** - No use of mechanized equipment in designated, proposed, or potential wilderness areas is allowed unless authorized by the superintendent or a designee in additional specific conditions associated with this permit.

13. **NPS participation** - The permittee should not anticipate assistance from the NPS unless specific arrangements are made and documented in either an additional stipulation attached to this permit or in other separate written agreements.

14. **Permanent markers and field equipment** - The permittee is required to remove all markers or equipment from the field after the completion of the study or prior to the expiration date of this permit. The superintendent or a designee may modify this requirement through additional park specific conditions that may be attached to this permit. Additional conditions regarding the positioning and identification of markers and field equipment may be issued by staff at individual parks.

15. **Access to park and restricted areas** - Approval for any activity is contingent on the park being open and staffed for required operations. No entry into restricted areas is allowed unless authorized in additional park specific stipulations attached to this permit.

16. **Notification** - The permittee is required to contact the park's Research and Collecting Permit Office (or other offices if indicated in the stipulations associated with this permit) prior to initiating any fieldwork authorized by this permit. Ideally this contact should occur at least one week prior to the initial visit to the park.

17. **Expiration date** - Permits expire on the date listed. Nothing in this permit shall be construed as granting any exclusive research privileges or automatic right to continue, extend, or renew this or any other line of research under new permit(s).

18. **Other stipulations** - This permit includes by reference all stipulations listed in the application materials or in additional attachments to this permit provided by the superintendent or a designee. Breach of any of the terms of this permit will be grounds for revocation of this permit and denial of future permits.

# **Appendix C**

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## **Estimating Potential Monetary Benefits Under Alternative B (Implement Benefits-Sharing)**

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## C.1 Introduction

Chapter 4’s analysis of the potential quantitative impacts of Alternative B on natural resource management is based on the possible monetary benefits that could be generated under benefits-sharing agreements (*see* Chapter 4, Section 4.2). This appendix describes and estimates potential monetary benefits resulting from implementation of Alternative B.

The National Park Service has reviewed the experience of federal laboratories and academic institutions related to the commercial use of research results as described in Appendix G (Background for Benefits-Sharing and Technology Transfer). Annual reports about income generated by licenses held by federal laboratories are compiled by the U.S. Department of Commerce (DOC).<sup>1</sup> The analysis below uses a five-year dataset, FY1999–FY2003, as reported in the DOC’s 2004 Summary Report on Federal Laboratory Technology Transfer. Annual reports about income generated by licenses held by academic institutions are compiled by the Association of University Technology Managers (AUTM).<sup>2</sup> A four-year dataset, FY1999–FY2002, from AUTM’s Licensing Survey Report for 2002, was analyzed and is presented below.<sup>3</sup>

## C.2 Monetary Benefits Types: Up-Front and Performance-Based

Two types of monetary benefits could occur under Alternative B: up-front payments and performance-based payments.

### C.2.1 Up-Front Payments

The Federal Technology Transfer Act of 1986 (FTTA) authorizes private-sector research partners to provide funds through CRADAs to be used to support the participating federal laboratory’s research activities consistent with its mission. This FEIS terms such payments “up-front payments.”

Not all benefits-sharing agreements would generate up-front payments. Some benefits-sharing agreements could provide up-front payments before any research result actually yielded income for the researcher’s institution.

### C.2.2 Performance-Based Payments

Performance-based payments would likely be due to the NPS whenever (and if) the researcher’s institution derived any kind of income from research results. The rate at which performance-based payments would be paid to the NPS would be established in the mutually agreed terms of a benefits-sharing agreement.

Income can be produced in a number of ways; one occurs when intermediate research results are licensed to another institution (license income). Licenses can generate income for the researcher’s institution through royalties based, for instance, on product sales (royalty income from licensing), or through other means such as license issue fees, annual minimum

payments, or milestone payments (payments based on successful completion of certain research and development stages, described in Chapter 3, Section 3.4.3).

Income can also be produced by the performance of contract research, such as when a researcher screens compounds for particular characteristics, or if research results are developed fully for the marketplace. For example, a researcher’s major source of income could be derived from performing research for others under contract using proprietary methods the researcher developed from study of NPS research specimens.

## C.3 Monetary Benefits Timing

A benefits-sharing agreement could generate monetary benefits during the immediate benefits period, the deferred benefits period, both periods, or neither period. These possibilities are summarized in Figure C.3. For this FEIS, immediate benefits are those that occur during the initial five-year term of an agreement. Deferred benefits are those that occur after the initial five-year term of an agreement.

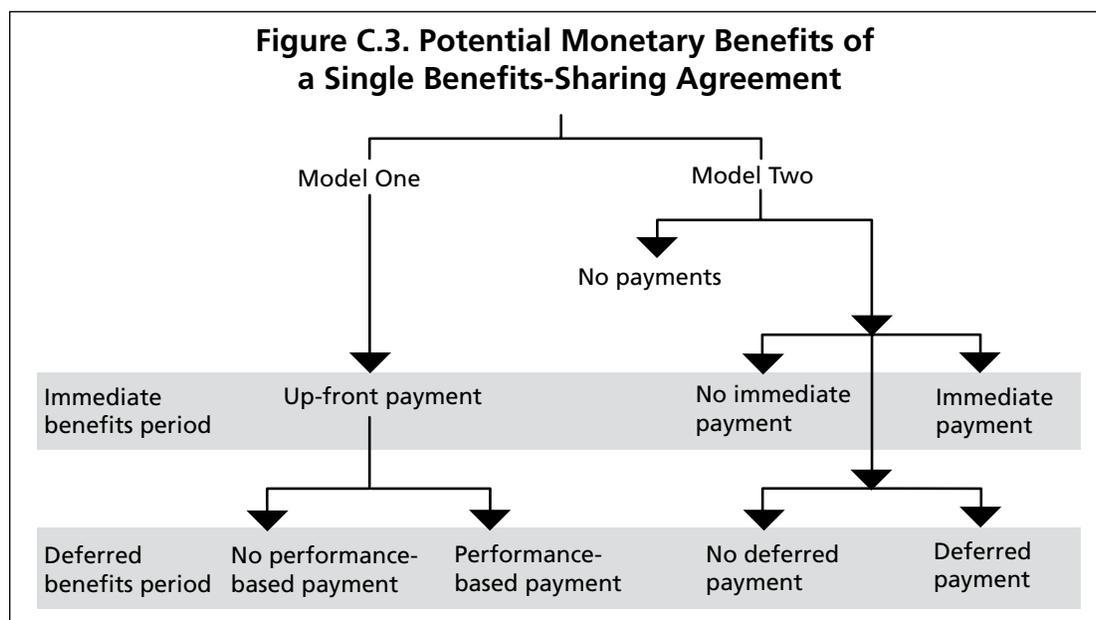


Figure C.3. A benefits-sharing agreement could generate monetary benefits during either the immediate benefits period, the deferred benefits period, both periods, or neither period.

### C.3.1 The Immediate Benefits Period

For purposes of analysis, each benefits-sharing agreement’s obligation to provide immediate benefits to the NPS was assumed to expire after five years. This estimate was based on examination of the average duration of CRADAs and academic technology transfer licenses. Although actual benefits-sharing agreements could be negotiated to provide immediate monetary benefits during longer or shorter periods, and could be extended for additional immediate benefits periods, a five-year average immediate benefits period was used in this FEIS for modeling potential monetary benefits.

Table C.3.1 displays information about the average duration of CRADAs (*see* Appendix G) and AUTM licenses (termed here “agreements”). The number of agreements active each year was divided by the number of new agreements executed each year to determine the average duration of agreements. On average, though the duration of CRADAs is less than the duration of AUTM licenses, 23% of all agreements were newly executed each year. Therefore, the average agreement duration is greater than four years.

**Table C.3.1. Average duration of CRADAs and AUTM licenses<sup>4</sup>**

	FY1999	FY2000	FY2001	FY2002	FY2003	Total CRADAs/ years 1999– 2003	Average duration of agreements
New CRADAs	1,023	904	926	2,582	2,748	8,183	
Active CRADAs	3,227	3,133	3,670	5,325	5,551	20,906	2.6 years
	FY1999	FY2000	FY2001	FY2002		Total licenses/ years 1999– 2002	Average duration of agreements
New AUTM licenses	3,914	4,362	4,058	4,673		17,007	
Active AUTM licenses	18,617	20,968	22,937	26,086		88,608	5.2 years
						Total agreements/ years 1999– 2002	
						New CRADAs and licenses	25,190
						Active CRADAs and licenses	109,514
							4.3 years

Table C.3.1. Federal laboratory CRADAs and AUTM licenses are active for an average of greater than four years.

The only example of a benefits-sharing agreement negotiated by an NPS unit is the Yellowstone–Diversa CRADA. The immediate benefits period in that CRADA was five years, with additional five-year periods possible, subject to agreement renewal. Accordingly, the analysis in this FEIS is based on a five-year immediate benefits period.

### C.3.2 The Deferred Benefits Period

Due to the lag time between discovery and each subsequent stage of research and development (R&D) (*see* Chapter 3, Section 3.4.3), most performance-based payments would generally not occur immediately upon entering into a benefits-sharing agreement. AUTM has concluded that the age of a program is a significant factor in evaluating performance because of several variables, including the time needed to develop and market products after discoveries have been made.<sup>5</sup>

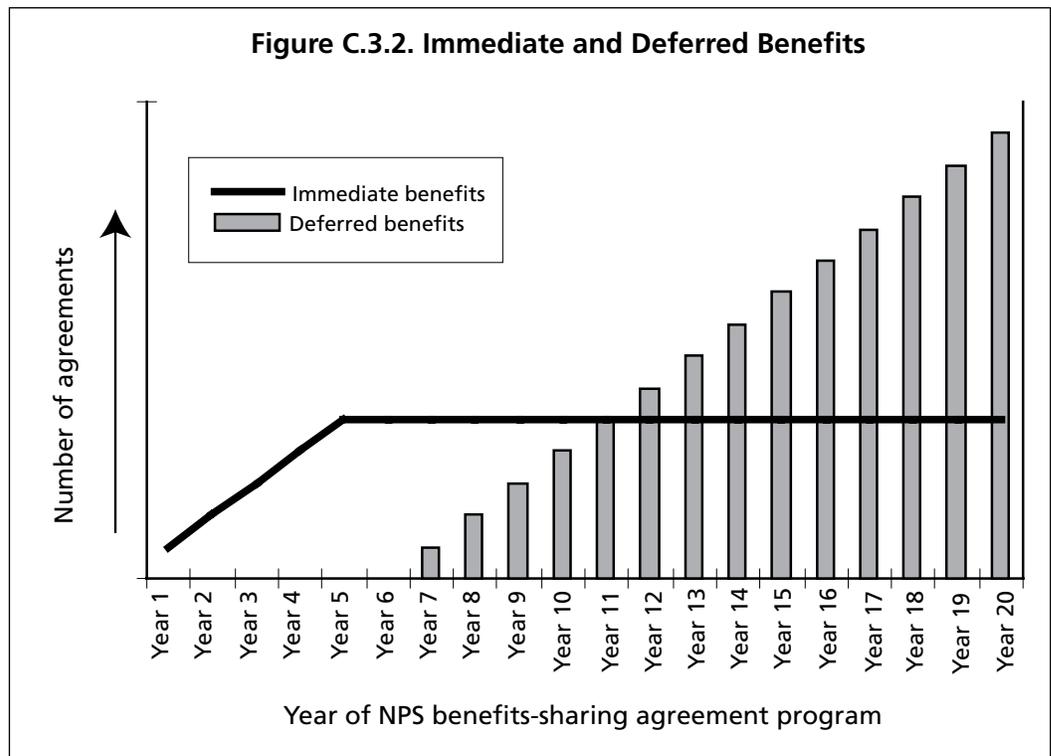


Figure C.3.2. Each agreement's obligation to provide immediate benefits would expire, but its obligation to provide performance-based payments through the 20-year FEIS analysis period would continue. As the years pass, more agreements each year might generate deferred benefits. (See Section C.7 and Table C.7.3 for a detailed presentation of the concepts illustrated in this figure.)

Performance is influenced by complex factors, including the irregular pace at which R&D yields new knowledge and inventions.<sup>6</sup> For example, development of new medicines can require 15 years or more between the discovery stage and the marketing stage.<sup>7</sup> Other commercial applications may require somewhat less time. Accordingly, for purposes of analysis, each benefits-sharing agreement's deferred payments (if any) were assumed to begin on average in the seventh year after execution of a benefits-sharing agreement.

As established in the example CRADA (*see* Appendix A), any obligation to make performance-based payments would survive termination of the agreement.<sup>8</sup> However, a practical estimate of the effective length of time when performance-based payments could occur is considered to be as long as the life of a U.S. patent, because the most common way to obtain legal protection for inventions is through patenting. U.S. patents are normally issued for a period of 20 years, within which only the inventor (and/or assignee) is authorized to make use of the invention. Accordingly, for purposes of analysis, each benefits-sharing agreement that paid deferred monetary benefits was also assumed to continue to do so for 20 years.<sup>9</sup>

If implemented, benefits-sharing would involve increasing numbers of agreements every year. As the years pass, more agreements each year might generate deferred benefits, as illustrated in Figure C.3.2.

## C.4 License Income Reported by Federal and Academic Research Institutions

Estimates of the potential amount of monetary benefits are based on license income reported by federal and academic research institutions. In general, federal and academic institutions do not themselves commercialize research results. Usually, intermediate research results (the intellectual property of the researcher and his or her institution) are licensed to another institution for further R&D and eventual commercialization (*see* Chapter 1, Section 1.6).

Federal laboratories and academic institutions report their annual total license income as well as the royalties that contributed to the total income generated by licenses.<sup>10</sup> Royalty income from licensing is related to performance—a licensee must make money before it owes royalties.

For purposes of analysis in this FEIS, the reported royalty income from licensing was used to represent all performance-based payments to academic and federal institutions from licensing of research results.<sup>11</sup> Both federal laboratories and academic institutions report that royalties provide a substantial proportion of license income (*see* Tables C.10.2-1 and C.10.3-1).

In this FEIS, total license income received by an institution relative to research results, minus royalty income from licensing, is termed “other license income.”<sup>12</sup> Possible components of other license income include, for example, up-front fees, annual minimum payments, and milestone payments. “Other license income” is not necessarily based on research results that have been completely developed and marketed; a license could yield “other license income” during the immediate benefits period of a benefits-sharing agreement.

Research projects are not always successful in producing a valuable new product or technology. The best available information for anticipating the proportion of benefits-sharing agreements that might generate payments to the NPS is discussed below. In addition, unavailable information, when known to the NPS, is described as required under NEPA.<sup>13</sup>

### C.4.1 Best Available Information

AUTM provides the best information known to the NPS about income generated by commercial use of a wide range of research results over time. From 1999–2002, 43% of licenses reported by AUTM yielded income, and 23% yielded royalties (*see* Tables C.4.1-1 and C.4.1-2). Although the proportion of NPS benefits-sharing agreements that could generate income might be higher or lower than the AUTM average, analysis of potential impacts in this FEIS used these proportions for modeling potential monetary benefits.

**Table C.4.1-1. Proportion of AUTM licenses that yielded income<sup>14</sup>**

Year	FY1999	FY2000	FY2001	FY2002	Total licenses/years
Number of active licenses	18,617	20,968	22,937	26,086	88,608
Number of licenses yielding income	8,308	9,059	9,707	10,866	37,940
Percentages of active licenses yielding income = number of income-yielding licenses divided by the number of active licenses	45%	43%	42%	42%	43%

Table C.4.3-1. On average, 43% of AUTM licenses yielded income each year.

**Table C.4.1-2. Proportion of AUTM licenses that yielded royalties<sup>15</sup>**

	FY1999	FY2000	FY2001	FY2002	Total licenses/years
Number of active licenses	18,617	20,968	22,937	26,086	88,608
Number of licenses that yielded royalties = number of licenses multiplied by the percent of licenses that paid royalties	4,654	5,242	5,046	5,739	20,681
Percentage of active licenses that paid royalties	25%	25%	22%	22%	23% (Average—total active license/years divided by total royalty-yielding license/years)

Table C.4.3-2. On average, 23% of AUTM licenses yielded royalties each year.

## C.4.2 Unavailable Information

The NPS does not have agency- or Department of the Interior-specific data with which to project the proportion of benefits-sharing agreements that could be likely to generate performance-based payments.<sup>16</sup> The only NPS-specific example of a benefits-sharing agreement is the Yellowstone–Diversa CRADA, under which a performance-based payment would be realized (for Pyrolase 200™; *see* Chapter 1, Section 1.2.4). No other NPS-specific data about the proportion of benefits-sharing agreements that could generate performance-based payments exists, because the NPS has not negotiated or entered into any additional benefits-sharing agreements.

Some limited information is available from federal laboratories about the number of licenses under which a research result becomes available for consumer or commercial use. For example, approximately 4% of the licenses held by the Department of Health and Human Services in 1999 and 2000 resulted in a research result becoming available for consumer or commercial use in those years. However, in making this report, the DOC explained that attributing year-specific cause and effect between licensing and consumer availability cannot be done, because “[d]ue to the inevitable time lags and activities by outside parties involved, there is normally no relationship between the level of activities [licensing] in a given FY [fiscal year] and the number of ‘outcomes’ [availability for consumer or commercial use] that can be itemized.”<sup>17</sup>

## **C.5 Research Result Income Received by Commercial Firms**

### **C.5.1 Best Available Information**

Market data for industrial sectors that engage in natural products research, including pharmaceuticals, agricultural crop protection, soil remediation, industrial enzymes (detergents, starch, textiles, baking, beverages, dairy), biocatalysts, and diagnostics, are presented in Section C.8.3.1.

### **C.5.2 Unavailable Information**

Information about income related to commercial use of research results by commercial firms is generally considered to be proprietary, and cannot be obtained to inform the analysis in this FEIS. The best information about the proportion of commercially related research projects that ultimately could trigger performance-based payments is similarly proprietary, and unavailable for analysis.

## **C.6 CRADA Income Received by Federal Agencies**

### **C.6.1 Best Available Information**

None (*see* Section C.6.2).

### **C.6.2 Unavailable Information**

There is no available information about funding of research under existing CRADAs, because the DOC does not collect or report such data.<sup>18</sup>

## **C.7 Potential Number of Agreements that Could Be Active Annually in the NPS**

The estimate of the range of total annual monetary benefits that could be generated if Alternative B is implemented is based on potential average monetary benefits per agreement, multiplied by the number of benefits-sharing agreements that could generate such payments each year. For purposes of analysis, the number of benefits-sharing agreements that could be active each year is estimated at three benchmark levels: entering into two, four, or nine new agreements per year. These benchmarks were selected for analysis based on three available datasets related to the study of specimens originating in the NPS, the number of patents issued, new patent applications filed, and the estimated number of inventions (*see* Sections C.7.1 and C.7.2).<sup>19</sup> The number of potential benefits-sharing agreements that could accumulate over the 20-year analysis period is estimated for each of the three benchmarks (*see* Section C.7.3).

### **C.7.1 NPS-related Patents and New Patent Applications**

Information about NPS-related patenting was obtained by searching the U.S. Patent and Trademark Office (USPTO) website. Not all patents or patent applications disclose the origin of the specimen studied, and only those that specifically disclose study of biological material originating as an NPS research specimen were counted. In this EIS, the term NPS-related patents refers to patents (and patent applications) that involved research results related to the study of biological material originating in U.S. national parks.

Between 1978 and 2007, the USPTO issued at least 55 NPS-related patents, 53 from Yellowstone National Park and 2 from Yosemite (*see* figure 1.2.4.1). Beginning in 2001, the USPTO began to post patent applications on its web site. Because patent applications may be re-filed, only new patent applications were examined instead of all patent applications in order to avoid double counting.<sup>20</sup> Between 2001 and 2007, at least 23 new NPS-related patent applications were filed, 22 from Yellowstone and 1 from Shenandoah National Park.

Since a benefits-sharing agreement could be based on research results that are the subject of a patent or a patent application, it is possible that on average, two or three benefits-sharing agreements could be established annually, which is consistent with the rate at which patents were granted and patent applications were filed (*see* Tables C.7.1-1 and C.7.1-2 and Chapter 1, Section 1.2.4).

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**Table C.7.1-1. NPS-related patents granted annually**

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<b>Grant year</b>	<b>No. of patents</b>	<b>Grant year</b>	<b>No. of patents</b>
1978	1	1993	1
1979	0	1994	4
1980	0	1995	1
1981	2	1996	3
1982	2	1997	0
1983	2	1998	5
1984	0	1999	6
1985	0	2000	3
1986	4	2001	0
1987	1	2002	2
1988	2	2003	1
1989	2	2004	1
1990	1	2005	1
1991	0	2006	3
1992	3	2007	4

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Total patents granted: 55

Average per year: 2

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Table C.7.1-1. An average of two patents related to study of NPS specimens are known to have been granted each year.

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**Table C.7.1-2. NPS-related new patent applications filed annually**

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<b>File year</b>	<b>No. of patent applications</b>	<b>File year</b>	<b>No. of patent applications</b>
2001	10	2005	6
2002	2	2006	0
2003	1	2007	3
2004	1		

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Total new patent applications filed: 23

Average per year: 3.3

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Table C.7.1-2. An average of 3.3 new patent applications related to study of NPS specimens are known to have been filed annually.

## **C.7.2 Potential Number of NPS-related Inventions**

A benefits-sharing agreement could be based on an invention or other commercial application that was not patented (*see* the definition of “commercial purpose” in Appendix A).<sup>21</sup> This FEIS estimates the possible number of inventions resulting from research involving NPS research specimens that could have occurred in the past by examining the comparative rates of new patent application filing and inventing in other institutions. Under Alternative B, inventions (without an associated patent) could trigger a benefits-sharing agreement.

Federal laboratories and academic institutions report the number of inventions disclosed as well as the number of new patent applications filed annually by researchers in their institutions. In every year, more inventions are recorded than new patent applications filed, and more patent applications are filed than patents granted. This is because patent applications are not filed on every new invention, and not all inventions that are the subject of patent applications satisfy the statutory standards for patentability. Each invention, whether patented or not, represents a potential commercial application for research results (*see* Appendix G, Figures G.3.1-3 and G.3.2-2).

### **C.7.2.1 Best available information**

In the time since the draft EIS (DEIS) was published, a new data set became available from the U.S. Patent and Trademark Office (USPTO) regarding new patent applications. The DEIS estimated the potential number of inventions related to study of NPS specimens per year based on the number of patents granted each year, the best data available for that analysis at the time. However, AUTM reports indicate that the number of new patent applications filed each year is more strongly correlated to the number of inventions disclosed. AUTM institutions report that from 1997 through 2006 (the most recent decade for which data is available), the ratio of new U.S. patent applications filed to invention disclosures received has ranged from 38% to 62% (*see* Table C.10.1). For purposes of analysis, these comparative rates were used to estimate the number of inventions that could have been generated by NPS-related research each year.

### **C.7.2.2 Estimating potential NPS-related inventions**

The average number of new patent applications known to have been filed each year relating to research involving NPS biological material was 3.3 (*see* Table C.7.1-2). If the range of comparative rates of inventing to patent application filing (38% to 62%) is calculated according to this average, then the annual number of inventions would have been between five and nine.

In addition, multiple discoveries, inventions, or patents could be made by a single researcher. However, this FEIS seeks primarily to characterize potential impacts of the alternatives, rather than to estimate the potential number of patents, inventions, or other commercial applications that would trigger a benefits-sharing agreement. In particular, any monetary benefits (income) resulting from an NPS benefits-sharing program would be related more to the number of commercially valuable discoveries than strictly to the number of benefits-sharing agreements. This is because multiple valuable discoveries could be subject to a single agreement (*see* Chapter 1, Section 1.2.4).

## **C.7.3 Estimated Number of NPS Benefits-Sharing Agreements**

For the purpose of analysis, three benchmark levels—entering into two, four, or nine new agreements per year—were selected based on three available datasets related to the study of specimens originating in the NPS (*see* Sections C.7.1 and C.7.2). The number of potential benefits-sharing agreements that could accumulate over the 20-year analysis period is then estimated for each of the three benchmarks. The benchmark levels were used to develop the range of potential monetary benefits described in Section C.9 and used in Chapter 4’s impact analysis.

Any obligation to provide monetary benefits during the immediate benefits period is estimated in this FEIS to occur for an average period of five years (*see* Section C.3.1). Accordingly, by the fifth year after adoption of Alternative B, the number of agreements that could affect natural resource management by generating payments during their immediate benefits period would likely remain steady.

Any obligation to make performance-based payments would survive termination of the agreement (*see* Appendix A). Accordingly, implementation of benefits-sharing would involve increasing numbers of agreements every year. As the years pass, more agreements each year might generate deferred benefits, as illustrated visually in figure C.3.2, and in numerical detail in Table C.7.3.

**Table C.7.3. Number of agreements that could generate benefits**

	2 new agreements annually		4 new agreements annually		9 new agreements annually	
	Immediate benefits obligated	Deferred benefits obligated	Immediate benefits obligated	Deferred benefits obligated	Immediate benefits obligated	Deferred benefits obligated
Year 1	2	0	4	0	9	0
Year 2	4	0	8	0	18	0
Year 3	6	0	12	0	27	0
Year 4	8	0	16	0	36	0
Year 5	10	0	20	0	45	0
Year 6	10	0	20	0	45	0
Year 7	10	2	20	4	45	9
Year 8	10	4	20	8	45	18
Year 9	10	6	20	12	45	27
Year 10	10	8	20	16	45	36
Year 11	10	10	20	20	45	45
Year 12	10	12	20	24	45	54
Year 13	10	14	20	28	45	63
Year 14	10	16	20	32	45	72
Year 15	10	18	20	36	45	81
Year 16	10	20	20	40	45	90
Year 17	10	22	20	44	45	99
Year 18	10	24	20	48	45	108
Year 19	10	26	20	52	45	117
Year 20	10	28	20	56	45	126

Table C.7.3. A steady number of agreements could obligate monetary benefits after Year 5 of the immediate benefits period, while increasing numbers of agreements could obligate monetary benefits starting in Year 7 of the deferred benefits period.

## C.8 Modeling Potential Monetary Benefits

Quantitative estimates of the potential monetary benefits to the NPS resulting from benefits-sharing were developed using two different models describing income generation, each of which could apply to some benefits-sharing agreements. These estimates vary widely, in large part because given the wide variety of processes, products, and services that could be developed, the profitability of each individual commercial application may vary widely (*see* Chapter 1, Section 1.2.4). Model One suggests a higher level of monetary benefits than Model Two; both account for a wide variation in possible monetary benefits. The potential number of benefits-sharing agreements that could be active each year was estimated in Section C.7.3. These preliminary estimates were combined to provide a range of potential estimated monetary benefits each year after implementation of Alternative B for purposes of evaluating potential quantitative impacts to natural resource management.

In addition to the wide variety of possible end products, the effort required to bring products to market varies widely. The development and regulatory approval processes are relatively short for chemical and industrial products, of intermediate length for agricultural products, and longer for pharmaceutical products. Accordingly, the amount of investment and effort needed to develop different types of products in different industrial sectors can affect the range of potential royalty rates or other performance-based payments that the NPS could reasonably expect to be generated by benefits-sharing agreements.

This section describes the models used for analysis and the estimated range of average payments that could accrue to the NPS under each model. Section C.10 contains data used in analysis and shows how these data led to the conclusions presented in Section C.9.

### C.8.1 Model One (Researcher's Institution Completes All Stages of Bioprospecting)

In Model One, a researcher affiliated with an institution that could complete R&D of a commercially valuable research result; produce a product or perform a research-related service; and offer the final result for sale, lease, license, or other transfer for value would enter into a benefits-sharing agreement with the NPS. Model One assumes that all benefits-sharing agreements would generate some income, and that payments to the NPS could be roughly similar to payments made to academic institutions through licensing of research results.

Because Model One assumes that all benefits-sharing agreements would generate some income for the NPS, potential monetary benefits under Model One are calculated based only on income generated by licenses that yield income. Licenses that yield no income were excluded from this analysis.

#### C.8.1.1 Best available information

Model One is based solely on publicly available license income information collected and reported by AUTM (for academic institutions), because AUTM reports both license income and the proportion of licenses that yield income, and so the average payment per income-yielding and royalty-yielding licenses can be calculated.

The NPS is aware that the AUTM data reflect diverse variables such as the types of technologies under license, the types of licenses, the value of various technologies, and other factors. However, it is the best available information about the average income per license related to commercial use of research results known to the NPS.

### **C.8.1.2 Unavailable information**

Because the information reported for federal laboratory license income does not identify the proportion of licenses that generate income, it cannot be used for Model One.

### **C.8.1.3 Immediate monetary benefits**

Model One assumes that potential immediate monetary benefits would consist of up-front payments equivalent to average “other license income” (meaning total license income minus royalty income from licensing as reported by AUTM for licenses that yield income). Although individual payments would likely be higher or lower than the average, Model One suggests that potential annual payments averaging approximately \$24,000 could accrue annually for an average period of five years, and would be part of the immediate benefits package associated with all benefits-sharing agreements. (Relevant data and calculations are presented in Section C.10.2.)

The NPS experience with immediate benefits negotiated under the Yellowstone–Diversa CRADA is consistent with this analysis, because under that CRADA, Diversa agreed to provide \$20,000 annually to support Yellowstone’s research activities consistent with the park’s mission.

Model One estimates that the proportion of benefits-sharing agreements that could potentially generate immediate monetary benefits is 100%.

### **C.8.1.4 Deferred monetary benefits**

For purposes of analysis in this FEIS, the estimated range of deferred monetary benefits, if any, under Model One was based on the average royalties received by academic institutions (AUTM) when royalties were generated. Although agreement-specific, performance-based payments would likely be higher or lower than the AUTM average, Model One suggests that potential payments averaging approximately \$155,000 could accrue annually beginning in the seventh year after an agreement was established. (Relevant data and calculations are presented in Section C.10.3.)

Model One estimates the proportion of benefits-sharing agreements that could potentially generate deferred monetary benefits to be 23% (consistent with the proportion of AUTM licenses that generate royalties).

### **C.8.1.5 Model One monetary benefits summary**

Table C.8.1.5. presents the benefits levels projected to occur under Model One (Researcher’s Institution Completes All Stages of Bioprospecting).

**Table C.8.1.5. Analysis of potential annual benefits per average benefits-sharing agreement based on data reported by AUTM (Model One)\***

Benefit timing	Potential non-monetary benefits**	Potential monetary benefits
Immediate (5-year period)	Probable obligation to provide knowledge and research relationships, training or education, research-related equipment, or special services.	Average of \$24,000 annually. All agreements would generate up-front payments.
Deferred (occurring after the end of the immediate benefits period)	Possible continuation of some or all non-monetary benefits.	Average of \$155,000 on 23% of all agreements annually, beginning on average in the seventh year after each agreement is established (overall average of \$36,000).

\*Researcher's Institution Completes All Stages of Bioprospecting

\*\*See Chapter 4 for a full description of potential non-monetary benefits

Table C.8.1.5. The average benefits-sharing agreement in Model One would include both non-monetary and monetary benefits.

## **C.8.2 Model Two (Researcher's Institution Develops Intellectual Property with Potential Commercial Uses)**

In Model Two, a researcher affiliated with an institution that licensed, or otherwise transferred for value, its intermediate research results to another institution for continuation into later R&D stages, such as product development, manufacturing, and marketing, would enter into a benefits-sharing agreement with the NPS. Model Two assumes that both immediate and deferred monetary payments would consist of performance-based payments related directly to the amounts and patterns of income (if any) received by the researcher's institution from licensing intellectual property.

### **C.8.2.1 Best available information**

Model Two is based on average license income generated by both academic and federal licenses. Estimated potential monetary benefits during the immediate benefits period are based on "other license income," and estimates for the deferred benefits period are based on royalty income (*see* Sections C.3.1 and C.3.2). Not all licenses generate income, and payments in Model Two would be part of only some of the benefits packages associated with benefits-sharing agreements: those for which the researcher's institution received income through licensing.

Model Two assumes that a researcher's institution could pay the NPS a portion of its income from licensing of research results. For purposes of analysis, an average performance-based payment rate of 3% was used to represent the proportion of its license income that a researcher's institution might obligate to the NPS under a benefits-sharing agreement. The average of the range of royalty rates reported in 1999 by ten Kate in *The Commercial Use of Biodiversity* for benefits-sharing agreements that related to raw samples or research specimens provided during the early stages of research was 3%.<sup>22</sup> Similarly, a study of the pharmaceutical industry reported that when an outside source provided research specimens during the early stages of research, royalty rates ranged between 1% and 5%.<sup>23</sup> Therefore,

potential immediate monetary benefits and potential deferred benefits were calculated at 3% of other license income and royalty license income received by the researcher's institution.

Estimates of monetary benefits in Model Two are based on income generated by AUTM licenses for 1999–2002, and by federal laboratory licenses for 1999–2003 (*see* Tables C.10.2-1 and C.10.3-1). This is the best information about income generated by commercial use of a wide range of research results over time known to the NPS.

### **C.8.2.2 Unavailable information**

The average amount of revenue generated solely by income-yielding licenses is not known, because the DOC does not report that average. However, because not all licenses generate income, the all-license average income used for Model Two is necessarily lower than the average generated solely by income-yielding licenses.

Exact royalty rates related to bioprospecting research and paid to the entity that provided the research specimens are ordinarily proprietary and unavailable for analysis.

### **C.8.2.3 Immediate monetary benefits**

Model Two estimates potential immediate monetary benefits as 3% of other license income received by researcher's institutions as reported by both AUTM and federal laboratories (meaning total license income minus royalty income from licensing as reported by AUTM and DOC for all licenses, whether or not they generate income). This all-license average (including both income-yielding and non-income-yielding agreements) is \$300 per benefits-sharing agreement (*see* Section C.10.3). For purposes of analysis in this FEIS, these annual payments are assumed to occur for a period of five years for each benefits-sharing agreement. (Relevant data and calculations are presented in Section C.10.)

Model Two estimates the proportion of benefits-sharing agreements that could potentially generate immediate monetary benefits to be 43%.

### **C.8.2.4 Deferred monetary benefits**

Model Two estimates potential deferred monetary benefits to be 3% of average royalty income received by researcher's institutions as reported by both AUTM and federal laboratories. Model Two suggests that potential annual payments averaging \$900 could accrue annually beginning in the seventh year after an agreement was established. (Relevant data and calculations are presented in Section C.10.)

Model Two estimates the proportion of benefits-sharing agreements that could potentially generate deferred monetary benefits to be 23% (consistent with the proportion of AUTM licenses that generate royalties).

### **C.8.2.5 Model Two monetary benefits summary**

Table C.8.2.5 presents the benefits levels projected to occur under Model Two (Researcher's Institution Develops Intellectual Property with Potential Commercial Uses).

**Table C.8.2.5. Analysis of potential annual benefits per benefits-sharing agreement based on data reported by federal laboratories and AUTM (Model Two)\***

Benefit timing	Potential non-monetary benefits**	Potential monetary benefits
Immediate (5-year period)	Probable obligation to provide knowledge and research relationships, training or education, research-related equipment, or special services.	Average of \$300 annually.
Deferred (occurring after the end of the immediate benefits period)	Possible continuation of some or all non-monetary benefits.	Average of \$900 annually, beginning on average in the seventh year after each agreement is established.

\**Researcher's Institution Develops Intellectual Property with Potential Commercial Uses*

\*\**Potential non-monetary benefits are described in detail in Chapter 4.*

Table C.8.2.5. The average benefits-sharing agreement in Model Two would include both non-monetary and monetary benefits.

### **C.8.3 Potential for High-Value Royalties**

The likelihood that a high-value, performance-based payment (defined as more than \$1 million annually) might result under Alternative B is analyzed here. Information is presented about markets in industrial sectors that engage in natural products research, license income data reported by federal laboratories and academic institutions, and income from the development of Taq polymerase.

Although markets indicate that the demand for research-related products is significant and growing, the likelihood of any particular research project resulting in a high-value product is very low. Federal and academic license income also indicates that royalty incomes of more than \$1 million annually occur at a low rate (*see* Table C.8.3.2). There is only one known case in which development of research results involving study of an NPS research specimen has generated millions of dollars in annual income.

Chapter 4's impact analysis includes a possibility that Alternative B could generate income of more than \$1 million annually. However, the number of NPS benefits-sharing agreements that might generate high-value royalties, if any, would likely be very low.

#### **C.8.3.1 Market estimates**

The high value of some of the most successful products resulting from biological research activities represent the high-end range of potential values resulting from biological research.

Some efforts to forecast the potential value of biological research results have been based on studies of the size of markets in industrial sectors that engage in natural products research. These industrial sectors include pharmaceuticals, agricultural crop protection, soil remediation, industrial enzymes (detergents, starch, textiles, baking, beverages, dairy), biocatalysts, and diagnostics.

Published estimates of the global markets for these industrial sectors indicate that they are robust and expanding. However, while these estimates indicate that the demand for and value

of such biological research results is substantial, the limited predictive value of such studies has been noted.<sup>24</sup> Thus, the following figures cannot be used to predict the potential value of any particular research result in any given field, and the demand for such research-related products varies widely between the total estimated value of pharmaceuticals compared with other sectors.

**Table C.8.3.1. Global markets**

<b>Industrial sector</b>	<b>Estimated market value (U.S. dollars)<sup>25</sup></b>
Pharmaceuticals	\$300 billion <sup>26</sup>
Agricultural crop protection	\$30 billion <sup>27</sup>
Soil remediation	\$10–25 billion <sup>28</sup>
Industrial enzymes <sup>29</sup>	
Detergents	\$0.7 billion
Starch	\$0.16 billion
Textiles	\$0.13 billion
Baking	\$0.09 billion
Beverages	\$0.09 billion
Dairy	\$0.06 billion
Other <sup>30</sup>	\$0.24 billion
Biocatalysts	\$0.02–0.1 billion <sup>31</sup>
Diagnostics	\$0.15–0.2 billion <sup>32</sup>

Table C.8.3.1. Estimated market values in industrial sectors that engage in natural products research activities range from \$20 million to \$300 billion.

The potential value of biological research results is sometimes estimated from the value of particular products resulting from such research. However, as with total market estimates, these figures provide only limited estimates, and vary widely both within and among various industrial sectors. For example, 1997 revenue figures for only the top six pharmaceutical products with natural origins ranged from \$941 million to \$3.56 billion.<sup>33</sup> These figures represented significant increases over the revenue figures reported in 1990 for the top four pharmaceuticals with natural origins, which ranged from \$665 million to \$837 million.<sup>34</sup> In the agricultural crop protection sector, annual revenues for certain specific products derived from genetic resources have been reported to range from \$100 million to \$1.2 billion.<sup>35</sup>

### **C.8.3.2 Federal and academic licensing**

The low probability of potential high-value royalty payments related to the commercial development of research results is illustrated by the license income data reported by federal laboratories and academic institutions.

The Department of Commerce reports that “earned royalty income” in FY2003 differed widely across federal agencies—from a license that yielded three dollars in FY2003 to one yielding \$1.5 million.<sup>36</sup> Median earned royalty income for the four agencies that reported such information ranged from a low of \$700 to a high of \$10,000 annually (*see* Table C.8.3.2, below).<sup>37</sup>

Income greater than \$1 million was reported by AUTM to occur for 0.6% of all licenses from 2000 through 2002. The potential for large license royalty payments also increased as an institution's license program aged. In 2001, AUTM reported that no technology transfer programs less than 11 years old generated more than \$1 million annually in license income from all licenses held by a single institution.<sup>38</sup>

Based on the data reported by the Department of Commerce and AUTM, licenses that generate income of more than \$1 million annually occur at a low rate, representing no more than 0.6% of licenses.

**Table C.8.3.2. Federal and academic license income greater than \$1 million<sup>39</sup>**

Department	License/years (1 license active in 1 year = 1 license/year)	License/years yielding more than \$1 million
Defense 2001 <sup>40</sup>	288	1 (0.3%)
Energy 2001–2003 <sup>41</sup>	9,151	≤ 2 (≤ 0.02%)
Agriculture 2001–2003, Commerce 2001–2003, Interior 2001, NASA 1999–2003, Transportation 1999–2003, Veterans Administration 2001	2,868	0 (0%)
Environmental Protection Agency and Health and Human Services, 1999–2003, Agriculture and Commerce 1999–2000, Interior 1999–2000, Veterans Administration 2002–2003	7,866	not reported
AUTM, 2000–2002	69,991	401 (0.6%)

Table C.8.3.2. Less than one percent of licenses reported recently by federal laboratories and academic institutions generated royalty payments of more than \$1 million.

### **C.8.3.3 Taq polymerase**

The most valuable product known to have resulted from research involving NPS research specimens was the Polymerase Chain Reaction (PCR), which involved the sale of patent rights estimated at \$300 million, with an additional estimated \$100 million in annual revenues for each of many years (*see* Chapter 1, Section 1.2.4).<sup>42</sup> The development of Taq polymerase is the only known development of research results involving study of an NPS research specimen that generated annual income of millions of dollars.

If research involving NPS research specimens resulted in another product with income equivalent to that reported for PCR, and if that product generated income for the NPS at a royalty rate of only 1%, the annual performance-based payment (royalty) to the NPS would be \$1 million. A higher royalty rate would generate correspondingly more income for the NPS.<sup>43</sup>

### C.8.3.4 Conclusion

In conclusion, the rate at which high-value royalties could be generated by NPS benefits-sharing agreements would likely be very low. To provide the full range of income estimates for analysis of the potential impacts of benefits-sharing agreements on parks, the possibility of generating royalties of more than \$1 million annually was included in Chapter 4's impact analysis for 0.6% of agreements.

## C.8.4 Modeling a Single Agreement

Individual parks other than Yellowstone could also negotiate and enter into benefits-sharing agreements. The historical record suggests that parks other than Yellowstone could be more likely to negotiate a single agreement than multiple agreements, because of the low numbers of bioprospectors working in NPS units other than Yellowstone. In 2001, although seven of the 12 research projects involving declared bioprospectors were conducted in NPS units other than Yellowstone, no park other than Yellowstone was host to more than one declared bioprospector. In addition, only two of the 55 known patents related to research involving NPS biological material did not involve material that originated in Yellowstone. For these reasons, and the fact that the effects of benefits-sharing would likely be most notable at the park level, this FEIS examined the potential impact of benefits that could be generated by a single agreement.

Actual annual income generated by a single license in both federal laboratories and academic institutions ranged from \$0 to more than \$1 million in recent years (see Tables C.4.1-1, C.8.3.2, and C.10.3.1). The following discussion uses Models One and Two to characterize potential monetary benefits of a single agreement in more detail.

### C.8.4.1 Model One and a single agreement

The conclusions of Model One are presented in Section C.8.1. Because Model One assumes that all benefits-sharing agreements would generate some income, these conclusions could apply to parks with a single agreement.

### C.8.4.2 Model Two and a single agreement

Model Two assumes that not all agreements would generate income. However, the conclusions presented for Model Two in Section C.8.2 were expressed as averages for all benefits-sharing agreements, including agreements without income. Accordingly, further interpretation is needed to characterize the potential monetary benefits of any single agreement under Model Two.

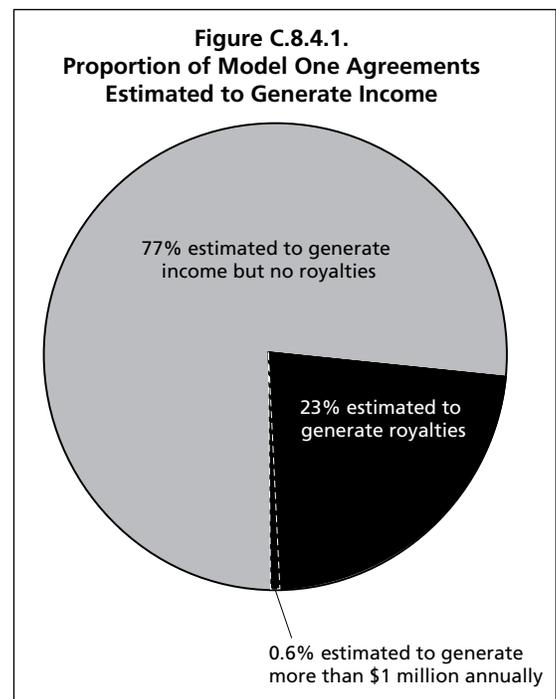


Figure C.8.4.1. Model One estimates that every benefits-sharing agreement could generate some income.

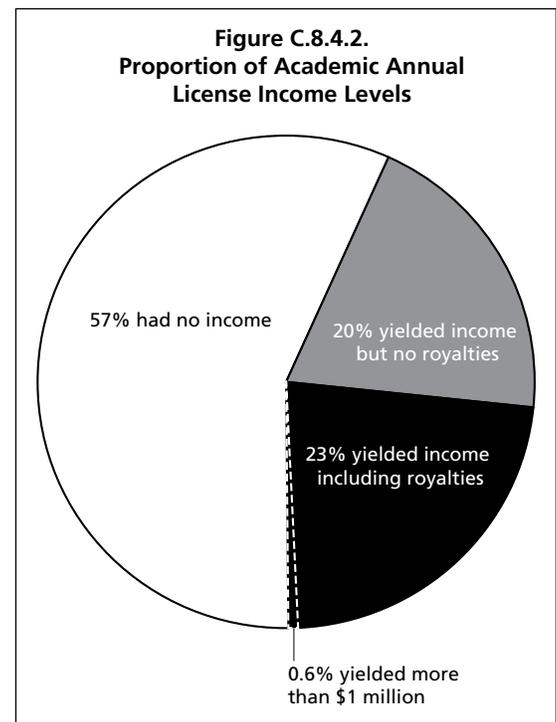


Figure C.8.4.2. Annual licensing income at academic institutions ranged from \$0 for more than half of all licenses to more than \$1 million for 0.6% of licenses in 1999–2002.

Potential monetary benefits in Model Two could be realized at similar frequencies to those reported by AUTM. From 1999–2002, AUTM reported that 57% of licenses generated no income, 20% yielded income but no royalties, and 23% generated royalty income as illustrated in Figure C.8.4.2.

Model Two’s estimated average annual monetary benefits were calculated per active agreement. However, only 43% of agreements would be likely to generate monetary benefits. An estimate of the average monetary benefits generated by a single, income-generating Model Two agreement is shown in Table C.8.4.2.

**Table C.8.4.2. Estimated potential average annual monetary benefits of Model Two applied to a single agreement**

If immediate benefits period payments for all Model Two agreements average \$300 annually, but only 43% of agreements generate those payments, what might a single income-generating agreement average annually during the immediate benefits period?	\$700
If deferred benefits period payments for all Model Two agreements average \$900 annually, but only 23% of agreements generate those payments, what might a single income-generating agreement average annually during the deferred benefits period?	\$4,000

Table C.8.4.2. Under Model Two, a benefits-sharing agreement is estimated to generate approximately \$700 when immediate benefits occur (43% of agreements) and approximately \$4,000 when deferred benefits occur (23% of agreements).

### **C.8.5 Fitting the Models Together: Preparing to Estimate the Range of Potential Monetary Benefits**

In this section, the proportion of agreements that could be more like Model One or Model Two is estimated.

The NPS expects that in general, commercial research firms could be more likely to complete all stages of bioprospecting (as described in Model One), and academic or federal institutions could be more likely to develop intellectual property that would be licensed to other institutions for further R&D (as described in Model Two). It is recognized that there are considerable variations from the norm described by these two models, and that the specific terms and conditions describing the benefits obligated by a benefits-sharing agreement would be negotiated individually in each case. The NPS is aware that commercial firms also license intermediate research results to other institutions.

The proportion of potential benefits-sharing agreements that could be entered into with either commercial research firms or academic institutions was characterized by examining the record of patents known to be related to the study of NPS research specimens. When a patent is granted, an “assignee” receives the rights associated with the patent. The rights to these patents were assigned to commercial firms, academic institutions, federal institutions, and non-U.S. institutions as shown in Table C.8.5.

**Table C.8.5. Patents and assignees known to be related to study of NPS specimens, 1978–2003**

	Number of patents	Number of assignees
U.S. commercial firms	20	12
U.S. government institutions	3	2
U.S. institutions fitting the description of AUTM members (whether or not actually included in AUTM surveys)	24	10
Non-U.S. institutions <sup>44</sup>	7	4
No assignee identified	1	-
<b>Total</b>	<b>45</b>	<b>25</b>

Table C.8.5. The rights to patents related to study of NPS research specimens were assigned to a variety of institutions.

Because patents were assigned to 12 commercial firms (Model One) and 12 government and academic institutions, monetary benefits like those described in Models One or Two are estimated to occur at nearly equal frequencies for purposes of analysis in this FEIS.

## C.9 Summary of Potential Monetary Benefits

This section provides an estimated range of potential monetary benefits in each context for this FEIS (servicewide, Yellowstone National Park, and individual parks) and summarizes how the estimates were developed. The estimated range of potential monetary benefits is used in Chapter 4 to analyze the quantitative impacts of Alternative B on natural resource management. Data and calculations for these estimates are in Section C.10, and the estimates are compared to impact thresholds in Section C.11.

The estimated average potential monetary benefits per benefits-sharing agreement (Table C.9) was based on the premise that Models One and Two could occur with equal frequency (*see* Section C.8.5). Immediate benefits were estimated to occur during the first five years of an agreement (*see* Section C.3.1). Deferred benefits were estimated to occur between the seventh and twentieth years of each agreement (*see* Section C.3.2).

**Table C.9. Average monetary benefits per benefits-sharing agreement**

	Model One	Model Two
Immediate benefits period accrued annually during years 1–5 of the agreement)	\$24,000	\$300
Deferred benefits period accrued annually during years 7–20 of the agreement)	\$36,000	\$900

## C.9.1 Servicewide Context

To estimate potential monetary benefits, three benchmarks were established: two, four, or nine new benefits-sharing agreements per year (*see* Section C.7). Chapter 4, Section 4.2, defines a short-term impact as any change that is evident for five years or less. Accordingly, the summary of the range of potential monetary benefits shown in Table 4.4.1.2-2 displays potential benefits in years one and five of an NPS benefits-sharing program. Chapter 4, Section 4.2, defines a long-term impact as any change that is evident after 20 years. Accordingly, Table 4.4.1.2-2 also displays potential benefits of years 10 and 20. The calculations that underlie this summary are presented in Section C.10.

The table below, summarizing the range of potential monetary benefits, appeared in Chapter 4 as Table 4.4.1.2-2. It is repeated here for reference. The calculations that underlie this summary are presented in Section C.10.4.1-2.

**Table 4.4.1.2-2. Range of potential cumulative monetary benefits used to analyze the potential impacts of a proposed NPS benefits-sharing program, servicewide and Yellowstone contexts**

Year	Low range estimated annual benefits	Mid-range estimated annual benefits	High range estimated annual benefits	High range with a high value annual royalty ( <i>see</i> Appendix C, Section C.8.3)
Year 1	\$24,313	\$48,626	\$97,252	no royalties expected this year
Year 5	\$121,565	\$243,130	\$486,260	no royalties expected this year
Year 10	\$268,178	\$536,357	\$1,206,803	\$2,206,803
Year 20	\$634,712	\$1,269,424	\$2,856,204	\$3,856,204

## C.9.2 Yellowstone National Park Context

Yellowstone National Park was selected for a park-specific analysis because the historical patent record suggests that multiple discoveries with commercial application could be based on research involving research material originating in Yellowstone (*see* Chapter 1, Section 1.2.4). For this reason, the potential impacts to Yellowstone were evaluated in the event that the majority of NPS benefits-sharing agreements were established between researchers and Yellowstone National Park.

Table 9.1, above, showing the range of potential monetary benefits servicewide, was also used to evaluate potential impacts in the Yellowstone context.

## C.9.3 Other Individual Parks Context

Based on the foregoing discussion, the estimated range of potential monetary benefits of a single benefits-sharing agreement can be summarized as follows.

### C.9.3.1 Immediate benefits period

Model One estimates an annual average immediate period payment of \$24,000 for 100%

of agreements. Because each agreement would have an equal chance to generate payments like Model One or like Model Two, 50% of agreements are estimated to generate an average \$24,000 annual payment during the immediate benefits period.

*Model One:  $100\% \div 2 = 50\%$*

Model Two estimates an annual average payment of \$700 when income is generated, but only 43% of agreements would generate immediate payments. Because 50% of agreements could be like Model Two, 21.5% (one half of 43%) of agreements are estimated to generate an average \$700 annual payment during the immediate benefits period. The remaining agreements would generate no immediate payment, meaning that 28.5% of all agreements would likely generate no immediate payment.

*Model Two (income-generating):  $100\% \div 2 = 50\% \times 43\% = 21.5\%$*

*Model Two (non-income-generating):  $100\% \div 2 = 50\% \times 57\% = 28.5\%$*

### **C.9.3.2 Deferred benefits period**

Because both Models One and Two estimate that only 23% of agreements would generate performance-based payments, 77% of agreements are estimated to generate no deferred monetary benefits (\$0). Model One estimates an average deferred period payment of \$155,000; because 50% of agreements could be like Model One, 11.5% of agreements are estimated to generate such a payment. Model Two estimates an average deferred payment of \$4,000 for a single agreement; because 50% of agreements could be like Model Two, 11.5% of agreements are estimated to generate such a payment. In addition, the impact analysis in this FEIS includes the possibility of an annual payment of more than \$1 million for an estimated 0.6% of agreements.

Chapter 4’s impact analysis was based on rounded numbers as displayed in Table 4.4.1.2-1, below. The calculations that underlie this summary are presented in Section C.10.

**Table 4.4.1.2-1. Estimated range of potential monetary benefits used to analyze the impacts of a proposed NPS benefits-sharing program on individual parks other than Yellowstone**

<b>Duration of potential impact</b>	<b>Potential annual payment</b>	<b>% of agreements likely to yield this average benefits level (see Appendix C, Section C.9.3)</b>	<b>See Appendix C (Sections referenced) for the derivation of this estimate</b>
Short-term impact analysis	0	29%	Model Two (Section C.8.2)
	\$700	22%	Model Two (Section C.8.2)
	\$24,000	50%	Model One (Section C.8.1)
Long-term impact analysis	0	77%	Both models
	\$4,000	12%	Model Two (Section C.8.2)
	\$155,000	12%	Model One (Section C.8.1)
	\$1,000,000	0.6%	High-value royalty analysis (Section C.8.3)

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## C.10 Data and Calculations

Section C.10 provides the information assembled by the NPS and used for estimating potential monetary benefits. These estimates are the basis for the quantitative analysis of the impacts of Alternative B to NPS natural resource management in Chapter 4.

### C.10.1 Comparative Rate of Patent Application Filing and Inventing

The following data and calculated ratios were used to develop the estimate presented in Section C.7.2.

**Table C.10.1. Ratio of patent application filings to invention disclosures as reported by AUTM 1997–2006**

	FY1997	FY1998	FY1999	FY2000	FY2001	FY2002	FY2003	FY2004	FY2005	FY2006
Inventions disclosed [AUTM 2002, page 10; AUTM 2006, page 24]	11,303	11,784	12,324	13,032	12,624	14,398	15,510	16,871	17,382	18,874
New patent applications filed [AUTM 2002, page 11; AUTM 2006, page 25]	4,267	4,808	5,545	6,375	6,397	7,319	7,921	10,517	10,270	11,622
Ratio of new patent applications to invention disclosures	38%	41%	45%	49%	51%	51%	51%	62%	59%	62%

## C.10.2 Potential Monetary Benefits of Model One Described in Section C.8.1

**Table C.10.2-1. Data reported by AUTM and used for development of Model One and Tables 10.2-2 and 10.2-3**

Data reported by AUTM	Data reference [year of AUTM report/page #]	FY1999	FY2000	FY2001	FY2002
New licenses	[2002/page 15]	3,914	4,362	4,058	4,673
Active licenses	[2002/page 15]	18,617	20,968	22,937	26,086
Licenses that yield income	[2002/ page 18]	8,308	9,059	9,707	10,866
Total "net" income (definition 2002/page 18 = not including money paid to other institutions, thus avoiding double counting)	[2002/page 18]	\$862,000,000	\$1,263,000,000	\$1,071,000,000	\$1,267,000,000
Percent of active licenses that paid royalties or had product sales this year	[1999/page i; 2000/page 1; 2001/page 1; 2002/ page 1]	25%	25%	22%	22%
Royalties are X% of income	[1999/page 15; 2000/page 12; 2001/page 12; 2002/page 19]	83%	57%	74%	79%
Cashed-in equity is X% of income	[1999/page 15; 2000/page 12; 2001/page 12; 2002/page 19]	3%	13%	10%	2%

**Table C.10.2-2. Calculations for Model One (estimated immediate monetary benefits)\***

	FY1999	FY2000	FY2001	FY2002	Total
Other license income = net income minus royalty income minus income from cashed-in equity	\$120,680,000	\$378,900,000	\$171,360,000	\$240,730,000	\$911,670,000
Licenses that yield income (number of income-yielding license/years, where 1 license/year equals 1 license active for 1 year)	8,308	9,059	9,707	10,866	37,940

Average annual other license income per income-yielding license = total other license income (\$911,670,000) divided by the number of income-yielding license/ years (37,940)	\$24,029
Model One average immediate monetary benefit used in this FEIS to estimate potential impacts of Alternative B	<b>\$24,029</b> <b>(rounded to \$24,000)</b>

\*Model One assumes that potential immediate monetary benefits would consist of up-front payments equivalent to average "other license income" (meaning total license income minus royalty income from licensing as reported by AUTM for licenses that yield income).

**Table C.10.2-3. Calculations for Model One (estimated deferred monetary benefits)\***

	FY1999	FY2000	FY2001	FY2002	Total
Royalty income = net income multiplied by the percent of income that is from royalties	\$715,460,000	\$719,910,000	\$792,540,000	\$1,000,930,000	\$3,228,840,000
Number of royalty-yielding licenses = number of active licenses multiplied by percent of active licenses yielding royalties	4,654	5,242	5,046	5,843	20,785
Average annual royalty payment per royalty-yielding license = royalty income divided by the number of royalty-yielding licenses	\$153,722	\$137,335	\$157,059	\$171,296	\$155,345

Four-year average annual royalty payment per royalty-yielding license = total royalty income divided by total number of royalty-yielding license/years	\$155,345
Model One average deferred monetary benefit for those agreements that generate deferred benefits	<b>\$155,345</b> <b>(rounded to \$155,000)</b>
% of agreements that could generate deferred monetary benefits = the % of AUTM licenses that yield royalties	23%
Model One average deferred monetary benefit per benefits-sharing agreement is used in this FEIS to estimate potential impacts of Alternative B	<b>\$35,729</b> <b>(rounded to \$36,000)</b>

\*Model One assumes that deferred monetary benefits (if any) would be equivalent to average royalties received by academic institutions when royalties are generated.

### C.10.3. Potential Monetary Benefits of Model Two Described in Section C.8.2

**Table C.10.3-1. Data reported by the Department of Commerce and used for development of Model Two and Tables 10.3-2 and 10.3-3**

Data reported by DOC	Agency	Page # DOC2004 Report	FY1999	FY2000	FY2001	FY2002	FY2003
Data highlighted in grey was removed from analysis because earned royalty income or total income was not reported.							
<b>Active licenses</b>	Agriculture	pages 30–32	218	225	255	267	270
	Commerce		43	43	40	41	101
	Defense		not reported	not reported	288	471	364
	Energy		1,922	2,070	2,005	3,459	3,687
	EPA		17	18	16	23	32
	HHS		1,364	1,608	1,367	1,357	1,380
	Interior		12	6	8	not reported	not reported
	NASA		288	305	328	357	521
	Transportation		0	0	1	0	0
	VA		not reported	not reported	86	81	88
	<b>Totals</b>		3,847	4,257	4,106	5,504	5,991
<b>Total license income</b>	Agriculture	page 37	\$2,377,000	\$2,555,000	\$2,622,000	\$2,571,378	\$2,290,903
	Commerce		\$405,469	\$186,368	\$268,568	\$164,622	\$127,566
	Defense		\$2,005,000	\$2,213,000	\$6,465,468	\$6,715,597	\$9,965,586
	Energy		\$11,764,000	\$15,840,000	\$21,403,362	\$23,476,716	\$25,805,498
	EPA		not reported	not reported	\$544,431	\$400,437	\$907,604
	HHS		\$44,821,000	\$52,547,000	\$46,722,000	\$52,882,331	\$55,198,722
	Interior		\$1,640,000	\$850,000	\$235,000	not reported	not reported
	NASA		\$1,360,061	\$1,756,796	\$1,970,739	\$2,498,167	\$2,852,985
	Transportation		\$0	\$0	\$5,500	\$0	\$0
	VA		not reported	not reported	\$38,000	\$18,000	\$153,000
	<b>Totals</b>		\$62,367,530	\$73,735,164	\$73,809,600	\$81,993,651	\$87,183,278
<b>Earned royalty income</b>	Agriculture	page 37	\$1,843,000	\$1,843,000	\$1,409,252	\$1,569,877	\$1,560,825
	Commerce		\$405,279	\$186,368	\$263,568	\$99,152	\$127,566
	Defense		not reported				
	Energy		\$1,975,000	\$2,228,000	\$7,832,481	\$5,604,774	\$6,611,568
	EPA		not reported	\$533,906	\$315,000	\$677,354	\$0
	HHS		\$34,599,000	\$43,892,000	\$36,612,000	\$36,012,005	\$38,338,328
	Interior		\$1,640,000	\$850,000	\$220,000	not reported	not reported
	NASA		\$183,294	\$116,490	\$521,164	\$554,769	\$814,624
	Transportation		\$0	\$0	not reported	\$0	\$0
	VA		not reported	not reported	\$17,000	not reported	not reported
	<b>Totals</b>		<b>\$40,645,573</b>	<b>\$49,115,858</b>	<b>\$47,190,465</b>	<b>\$44,517,931</b>	<b>\$47,452,911</b>

**Table C.10.3-2. Calculations for Model Two (estimated immediate monetary benefits)\***

	FY1999	FY2000	FY2001	FY2002	FY2003	Total
<b>Other license income, federal component</b>						
Total income for agencies that report both royalties and total income	\$62,367,530	\$73,735,164	\$73,809,600	\$81,993,651	\$87,183,278	\$379,089,223
Total earned royalty income	\$40,645,573	\$49,115,858	\$47,190,465	\$44,517,931	\$47,452,911	\$228,922,738
Other license income = total income minus royalty income	\$21,721,957	\$24,619,306	\$26,619,135	\$37,475,720	\$39,730,367	\$150,166,485
Other license income, AUTM component (see Table C.10.2-2)	\$120,680,000	\$378,900,000	\$171,360,000	\$240,730,000	N/A	\$911,670,000
					<b>Total</b>	<b>\$1,061,836,485</b>
<b>Active licenses</b>						
Federal laboratory active licenses for agencies that report both royalties and total income	3,847	4,257	4,106	5,504	5,991	23,705
AUTM active licenses [AUTM2002/page 15] (see Table 10.2-1)	18,617	20,968	22,937	26,086	N/A	88,608
					<b>Total</b>	<b>112,313</b>
All reported other license income, 1999–2003	\$1,061,836,485					
All reported license/years (where 1 license/year equals 1 license active for 1 year)	112,313					
Average annual other license income per active license = all other license income divided by the number of license/years	\$9,454					
Average benefits related to annual other license income per active license	3% (.03)					
Model Two average immediate monetary benefit used in this FEIS to estimate potential impacts of Alternative B	<b>\$284 (rounded to \$300)</b>					

\*Model Two estimates potential immediate monetary benefits as 3% of "other license income" received by researcher's institutions as reported by both AUTM and federal laboratories.

**Table C.10.3-3. Calculations for Model Two (estimated deferred monetary benefits)\***

	FY1999	FY2000	FY2001	FY2002	FY2003	Total
<b>Royalty income, federal component</b>						
Sum of royalty income for agencies that report both royalties and total income	\$40,645,573	\$49,115,858	\$47,190,465	\$44,517,931	\$47,452,911	\$228,922,738
<b>Royalty income, AUTM component</b>						
Sum of royalty income (see Table 10.2-3)	\$715,460,000	\$719,910,000	\$792,540,000	\$1,000,930,000	N/A	\$3,228,840,000
					<b>Total</b>	<b>\$3,457,762,738</b>
<b>Active licenses</b>						
Federal laboratory active licenses for agencies that report both royalties and total income	3,847	4,257	4,106	5,504	5,991	23,705
AUTM active licenses [AUTM2002/page 15] (see Table 10.2-1)	18,617	20,968	22,937	26,086	N/A	88,608
					<b>Total</b>	<b>112,313</b>
All reported royalty income 1999–2003	\$3,457,762,738					
All reported license/years (where 1 license/year equals 1 license active for 1 year)	112,313					
Average annual royalty per active license = all royalty income divided by the number of license/years	\$30,787					
Average benefits related to annual other license income per active license	3% (.03)					
Model Two average deferred monetary benefit used in this FEIS to estimate potential impacts of Alternative B	<b>\$924 (rounded to \$900)</b>					

\*Model Two estimates potential deferred monetary benefits as 3% of average royalty income received by researcher's institutions as reported by both AUTM and federal laboratories.

## C.10.4. Estimating the Range of Total Annual Monetary Benefits That Could Be Generated Under Alternative B

The basis for calculation of the range of potential monetary payments that could be generated for the NPS under Alternative B is described by three benchmarks: two, four or nine new agreements per year (see Section C.7.3.).

The calculation also uses three potential income levels: Model One, Model Two, and a potential high-value royalty payment of more than \$1 million annually. Models One and Two are included in these calculations at equal frequencies (see Section C.8.5). Because of the potential low frequency of high value royalties (see Section C.8.2), they are included in analysis only within the nine new agreements per year benchmark.

Section C.10.4 provides the data and calculations used to develop the conclusions shown in Chapter 4, Table 4.4.1.3-1, and is repeated below for reference.

**Table 4.4.1.2-1. Range of potential monetary benefits used to analyze the potential impacts of a proposed NPS benefits-sharing program: servicewide and Yellowstone contexts**

	2 new agreements annually	4 new agreements annually	9 new agreements annually	9 new agreements and at least one \$1 million performance-based payment annually
Year 1	\$24,300	\$48,600	\$109,350	no royalties expected this year
Year 5	\$121,500	\$243,000	\$546,750	no royalties expected this year
Year 10	\$269,100	\$538,200	\$1,210,950	\$2,210,950
Year 20	\$638,100	\$1,276,200	\$2,871,450	\$3,871,450

**C.10.4.1. Estimating the Range of Potential Total Income That Could Be Generated Under Alternative B**

The average estimated monetary benefits per agreement as developed in Sections C.8.1 and C.8.2 are displayed in Table C.10.4.1-1.

**Table C.10.4.1-1. Estimated annual average monetary benefits per agreement**

	Estimated average immediate annual monetary benefits per agreement	Estimated average deferred annual monetary benefits per agreement
Model One	\$24,029 (rounded to \$24,000)	\$35,729 (rounded to \$36,000)
Model Two	\$284 (rounded to \$300)	\$924 (rounded to \$900)

**Table C.10.4.1-2. Calculating estimated potential monetary benefits**

Immediate monetary benefits				Deferred monetary benefits			Total
	Number of agreements that could yield immediate benefits*	Model One (\$24,000 per agreement)	Model Two (\$300 per agreement)	Number of agreements that could yield deferred benefits*	Model One (\$36,000 per agreement)	Model Two (\$900 per agreement)	
<b>Low range, 2 new benefits-sharing agreements per year</b>							
Year 1	2	\$24,000 (1 agreement)	\$300 (1 agreement)	0	\$0	\$0	\$24,300
Year 5	10	\$120,000 (5 agreements)	\$1,500 (5 agreements)	0	\$0	\$0	\$121,500
Year 10	10	\$120,000	\$1,500	8	\$144,000 (4 agreements)	\$3,600 (4 agreements)	\$269,100
Year 20	10	\$120,000	\$1,500	28	\$504,000 (14 agreements)	\$12,600 (14 agreements)	\$638,100
<b>Mid-range, 4 new benefits-sharing agreements per year</b>							
Year 1	4	\$48,000 (2 agreements)	\$600 (2 agreements)	0	\$0	\$0	\$48,600
Year 5	20	\$240,000 (10 agreements)	\$3,000 (10 agreements)	0	\$0	\$0	\$243,000
Year 10	20	\$240,000	\$3,000	16	\$288,000 (8 agreements)	\$7,200 (8 agreements)	\$538,200
Year 20	20	\$240,000	\$3,000	56	\$1,008,000 (28 agreements)	\$25,200 (28 agreements)	\$1,276,200
<b>High range, 9 new benefits-sharing agreements per year</b>							
Year 1	9	\$108,000 (4.5 agreements)	\$1,350 (4.5 agreements)	0	\$0	\$0	\$109,350
Year 5	45	\$540,000 (22.5 agreements)	\$6,750 (22.5 agreements)	0	\$0	\$0	\$546,750
Year 10	45	\$540,000	\$6,750	36	\$648,000 (18 agreements)	\$16,200 (18 agreements)	\$1,210,950
Year 20	45	\$540,000	\$6,750	126	\$2,268,000 (63 agreements)	\$56,700 (63 agreements)	\$2,871,450
<b>High range plus an annual performance-based payment of at least \$1 million</b>							
Year 1							No royalties expected this year
Year 5							No royalties expected this year
Year 10							\$2,210,950
Year 20							\$3,871,450

\*see Table C.7.3

## C.11. Comparing Estimated Monetary Benefits to Impact Thresholds

**Table C.11-1. Comparison of potential SERVICEWIDE monetary benefits to FY2007 Natural Resource Challenge funding**

Impact definitions (see Chapter 4, Section 4.2)	
Major impact	15% of \$77,552,000
Moderate impact	10% of \$77,552,000
Minor impact	5% of \$77,552,000
Negligible impact	less than 5% of \$77,552,000

Impact determinations												
Year	Low range (2 new agreements)			Mid-range (4 new agreements)			High range (9 new agreements)			High range plus \$1 million annually		
	Total benefits	Percent	Impact	Total benefits	Percent	Impact	Total benefits	Percent	Impact	Total benefits	Percent	Impact
1	\$24,300	0.03%	Negligible	\$48,600	0.06%	Negligible	\$109,350	0.14%	Negligible			
5	\$121,500	0.16%	Negligible	\$243,000	0.31%	Negligible	\$546,750	0.71%	Negligible			
10	\$269,100	0.35%	Negligible	\$538,200	0.69%	Negligible	\$1,210,950	1.56%	Negligible	\$2,210,950	2.85%	Negligible
20	\$638,100	0.82%	Negligible	\$1,276,200	1.65%	Negligible	\$2,871,450	3.70%	Negligible	\$3,871,450	4.99%	Minor

**Table C.11-2. Comparison of potential YELLOWSTONE NATIONAL PARK monetary benefits to Yellowstone's identified natural resource management funding level (see Chapter 3, Section 3.2.2)\***

Impact definitions (see Chapter 4, Section 4.2)	
Major impact	35% of \$8,800,490 = \$3,080,172
Moderate impact	20% of \$8,800,490 = \$1,760,098
Minor impact	10% of \$8,800,490 = \$880,049
Negligible impact	<10% of \$8,800,490 = <\$880,049

Impact determinations												
Year	Low range (2 new agreements)			Mid-range (4 new agreements)			High range (9 new agreements)			High range plus \$1 million annually		
	Total benefits	Percent	Impact	Total benefits	Percent	Impact	Total benefits	Percent	Impact	Total benefits	Percent	Impact
1	\$24,300	0.3%	Negligible	\$48,600	0.6%	Negligible	\$109,350	1.2%	Negligible			
5	\$121,500	1.4%	Negligible	\$243,000	2.8%	Negligible	\$546,750	6.2%	Negligible			
10	\$269,100	3.1%	Negligible	\$538,200	6.1%	Negligible	\$1,210,950	13.8%	Minor	\$2,210,950	25.1%	Moderate
20	\$638,100	7.3%	Negligible	\$1,276,200	14.5%	Minor	\$2,871,450	32.6%	Moderate	\$3,871,450	44.0%	Major

\*CALCULATION: estimated monetary benefits (see Table 4.4.1.3-1) divided by \$8,800,490

**Table C.11-3. Comparison of potential INDIVIDUAL PARK monetary benefits to each park's natural resource management funding level**

Park code	Natural resource management funding level	Potential monetary benefit increments used for impact analysis					
		Model Two		Model One		\$1 million agreement	
		0	\$700 (immediate)	\$4,000 (deferred)	\$24,000 (immediate)	\$155,000 (deferred)	\$1,000,000
WWSA	\$21,701	0%	3%	18%	111%	714%	4608%
TIMU	\$54,783	0%	1%	7%	44%	283%	1825%
VICK	\$55,524	0%	1%	7%	43%	279%	1801%
SAGA	\$58,400	0%	1%	7%	41%	265%	1712%
VAFO	\$91,536	0%	0.8%	4%	26%	169%	1092%
GETT	\$120,020	0%	0.6%	3%	20%	129%	833%
NACC	\$127,925	0%	0.5%	3%	19%	121%	782%
MORU	\$133,387	0%	0.5%	3%	18%	116%	750%
BRCA	\$170,163	0%	0.4%	2%	14%	91%	588%
ISRO	\$184,571	0%	0.4%	2%	13%	84%	542%
APIS	\$239,376	0%	0.3%	2%	10%	65%	418%
GUMO	\$269,541	0%	0.3%	1%	9%	58%	371%
CHOH	\$310,544	0%	0.2%	1%	8%	50%	322%
VIIS	\$366,866	0%	0.2%	1%	7%	42%	273%
CAHA	\$389,709	0%	0.2%	1%	6%	40%	257%
LACL	\$415,024	0%	0.2%	1.0%	6%	37%	241%
GLCA	\$416,763	0%	0.2%	1.0%	6%	37%	240%
SAMO	\$454,922	0%	0.2%	0.9%	5%	34%	220%
KATM	\$464,346	0%	0.2%	0.9%	5%	33%	215%
OZAR	\$564,333	0%	0.1%	0.7%	4%	27%	177%
ACAD	\$597,155	0%	0.1%	0.7%	4%	26%	167%
VOYA	\$601,693	0%	0.1%	0.7%	4%	26%	166%
MORA	\$603,166	0%	0.1%	0.7%	4%	26%	166%
JOTR	\$627,336	0%	0.1%	0.6%	4%	25%	159%
BIBE	\$650,623	0%	0.1%	0.6%	4%	24%	154%
LAVO	\$798,816	0%	0.09%	0.5%	3%	19%	125%
BAND	\$866,385	0%	0.08%	0.5%	3%	18%	115%
BADL	\$872,988	0%	0.08%	0.5%	3%	18%	115%
INDU	\$915,831	0%	0.08%	0.4%	3%	17%	109%
WRST	\$1,013,200	0%	0.07%	0.4%	2%	15%	99%
CACO	\$1,046,270	0%	0.07%	0.4%	2%	15%	96%
PORE	\$1,134,550	0%	0.06%	0.4%	2%	14%	88%
LAME	\$1,178,921	0%	0.06%	0.3%	2%	13%	85%
ZION	\$1,313,382	0%	0.05%	0.3%	2%	12%	76%

Park code	Natural resource management funding level	Potential monetary benefit increments used for impact analysis					
		0	Model Two		Model One		\$1 million agreement
			\$700 (immediate)	\$4,000 (deferred)	\$24,000 (immediate)	\$155,000 (deferred)	\$1,000,000
ROMO	\$1,556,210	0%	0.04%	0.3%	2%	10%	64%
GRTE	\$1,616,934	0%	0.04%	0.2%	1%	10%	62%
DENA	\$1,803,935	0%	0.04%	0.2%	1%	9%	55%
REDW	\$1,954,456	0%	0.04%	0.2%	1%	8%	51%
SHEN	\$2,172,881	0%	0.03%	0.2%	1%	7%	46%
OLYM	\$3,673,140	0%	0.02%	0.1%	0.7%	4%	27%
GOGA	\$5,050,202	0%	0.01%	0.08%	0.5%	3%	20%
GRCA	\$5,385,078	0%	0.01%	0.07%	0.4%	3%	19%
EVER	\$7,763,353	0%	0.01%	0.05%	0.3%	2%	13%

\*CALCULATION: estimated monetary benefits (see Table C.9.3) divided by each park's natural resource management funding level

Table C.11-4 summarizes the conclusions presented in Table C.11-3, above. It shows how many of the 43 parks selected for impact analysis would experience beneficial impacts at each monetary benefits level (benefits levels are shown according to immediate or deferred benefits periods). Impacts could range from no impact to a major beneficial impact during both the immediate and the deferred benefits periods. However, beneficial impacts would be negligible for the majority of parks studied at either the \$700 or the \$24,000 benefits levels during the immediate benefits period.

**Table C.11-4. Number of study parks at each impact threshold (n = 43)**

Impact level	No impact (no payments)	Negligible (less than 10%)	Minor (10%)	Moderate (20%)	Major (35%)
Immediate benefits period					
\$0	43	-	-	-	-
\$700	-	43	-	-	-
\$24,000	-	32	5	2	4
Deferred benefits period					
\$0	43	-	-	-	-
\$4,000	-	42	1	-	-
\$155,000	-	7	11	8	17
\$1,000,000	-	3	1	1	38

# Notes

## Section C.1 Introduction

- <sup>1</sup> Licenses allow another institution to use the intellectual property (the ideas and knowledge) that was protected in the second stage of a bioprospecting research project (*see* Chapter 3, Section 3.4.3 of this document).
- <sup>2</sup> In the case of license income reported by academic institutions, income attributed to cashed-in equity was removed from analysis because the NPS does not expect to realize any similar income.
- <sup>3</sup> In addition, an alternative estimate of the potential monetary benefits of Alternative B was based instead on a two-year dataset, FY2002–FY2003, from the AUTM 2003 report. This analysis is on file at Yellowstone National Park. Data from both the 2003 and 2002 AUTM reports were analyzed separately because AUTM revised its reporting criteria between those years, reporting on academic institutions in both the U.S. and Canada up to 2002, and restricting their report to U.S. institutions in 2003. The conclusions regarding potential quantitative impacts of Alternative B on NPS Natural Resource Management in Chapter 4 remain unchanged under this alternative estimate except as noted in Chapter 4.

## Section C.3 Monetary Benefits Timing

- <sup>4</sup> U.S. Department of Commerce (DOC) Technology Transfer Report 2004, page 17, and Association of University Technology Managers (AUTM) Licensing Survey FY2002, 15.
- <sup>5</sup> AUTM Licensing Survey FY2002, 7.
- <sup>6</sup> DOC Technology Transfer Report 2002, 71.
- <sup>7</sup> A. Artuso, *Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing* (Binghamton, New York: The Haworth Press, 1997) 21.
- <sup>8</sup> *See* Appendix A, example CRADA, Article 12.4 of this document. The NPS expects that other forms of benefits-sharing agreements would also include a clause in which any obligation for performance-based payments to the NPS would survive termination of the agreement.
- <sup>9</sup> Although researchers can realize income related to their research results for a period of time longer than 20 years, this FEIS considers long-term impacts to be any change that is evident after 20 years. Therefore, using a deferred benefits period of 20 years is sufficient to analyze the potential impacts of Alternative B.

## Section C.4 License Income Reported by Federal and Academic Research Institutions

- <sup>10</sup> Annual reports about income generated by licenses held by federal laboratories are compiled by the DOC. Annual reports about income generated by licenses held by academic institutions are compiled by AUTM.
- <sup>11</sup> Neither federal nor academic research institutions report milestone payments or other non-royalty performance-based payments separately from total income, so actual performance-based payments generated under Alternative B may be larger than indicated in the analysis for this FEIS.
- <sup>12</sup> The AUTM survey “distinguishes between three sources of License Income: Running Royalties from sale of licensed products; Cashed-In Equity from sale of equity in the licensee received as part of the license consideration; and all other types of license income, such as upfront fees, annual minimum royalties, milestone payments and so forth,” (AUTM Licensing Survey 2002, 18). Income attributed to cashed-in equity was removed from analysis because the NPS does not expect to realize any similar income.
- <sup>13</sup> The NPS Conservation Planning, Environmental Impact Analysis, and Decision Making Handbook (7) states, “If information important to the decision between alternatives is incomplete or unavailable, you should state this in a NEPA document (CEQ 1502.22).” National Park Service, *DO-12 Director’s Order and Handbook*, 2001.
- <sup>14</sup> AUTM Licensing Survey 2002, 15, 18.
- <sup>15</sup> AUTM Licensing Survey 1999, i; AUTM Licensing Survey 2000, 1; AUTM Licensing Survey 2001, 1; AUTM Licensing Survey 2002, 1, 15.
- <sup>16</sup> From 1999 through 2001, the Department of Interior (DOI) reported between 6 and 11 active licenses annually, all of which were negotiated to obligate royalties. However, the number of licenses that actually yielded royalties was not reported. The DOI did not report any information for 2002–2003 (DOC Technology Transfer Report 2004, 115–117).
- <sup>17</sup> U.S. Department of Commerce, *Recent Trends in Federal Technology Transfer: FY1999–2000 Biennial Report*, 29.

## Section C.6 CRADA Income Received by Federal Agencies

<sup>18</sup> The terms of the Yellowstone–Diversa CRADA (described in Chapter 1, Section 1.8.1.1 of this document) included an up-front payment totaling \$100,000 over a five-year period.

## Section C.7 Potential Number of Agreements that Could Be Active Annually in the NPS

<sup>19</sup> Some benefits-sharing agreements could be based on commercial applications for research results (such as contract research, *see* Section C.2 and Appendix A of this document) that would not involve an invention.

<sup>20</sup> The number of total U.S. patent applications filed is often greater than the number of new U.S. patent applications. For example, AUTM institutions reported that approximately 16,000 patent applications were filed in 2006 of which only approximately 12,000 were new patent applications.

<sup>21</sup> The term “Commercial Purpose” means the sale, lease, license, or other transfer of any Progeny, Unmodified Derivatives, Modifications, Subject Invention or Product for value received, including but not limited to scientific research uses of any Progeny, Unmodified Derivatives, Modifications, Subject Invention or Product by Collaborator in the performance of any contract research, screening compound libraries, or the conduct of research activities that result in any sale, lease, license, or other transfer of any Progeny, Unmodified Derivatives, Modifications, Subject Invention or Product.

## Section C.8 Modeling Potential Monetary Benefits

<sup>22</sup> ten Kate (K. ten Kate and S. Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (London: Earthscan Publications LTD, 1999), 252) reports that royalty rates in agreements resulting from the collection of “raw samples” range from 0.05% to 5%, with rates increasing to as much as 8% when the agreement concerns research results such as “active strains/isolates,” “gene sequences,” and “purified enzymes/proteins.”

<sup>23</sup> W. Reid et al., *Biodiversity Prospecting* (Washington, D.C.: World Resources Institute, 1993), 111–112. *See also* E. Anderson, *INBio/Merck Agreement: Pioneers in Sustainable Development* (Cambridge, Mass: Harvard Business School, 1992), 10.

<sup>24</sup> *See, e.g.,* ten Kate and Laird, *The Commercial Use of Biodiversity*, 232: “Estimating the ‘market value’ or ‘global sales’ of biotechnology products is extremely difficult. To determine exactly which products have a strong biotechnology component would entail a company-by-company and product-by-product assessment. Not only would these figures be too fragmented and detailed to gather and analyze, but national statistics, figures from trade associations and reports by market analysts do not, as a rule, even estimate them, and may use different definitions when they do.”

<sup>25</sup> Global market estimates for 1998 unless otherwise noted.

<sup>26</sup> The global pharmaceutical market also was estimated to be expanding at a 6% annual rate through 2001 (ten Kate and Laird, *The Commercial Use of Biodiversity*, 34).

<sup>27</sup> *Ibid.*, 188, 27.

<sup>28</sup> *Ibid.*, 232.

<sup>29</sup> *Ibid.* the global market for “enzymes” was reported to be U.S.\$1 billion in 1989 (H. Zedan, “The Economic Value of Microbial Diversity,” *SIM News* 43(5) (September/October 1993), 182).

<sup>30</sup> “Other” specifically includes leather, tanning, metals, and oil fields.

<sup>31</sup> Zedan, “The Economic Value of Microbial Diversity,” 232.

<sup>32</sup> *Ibid.*, 232.

<sup>33</sup> *Ibid.*, 42.

<sup>34</sup> *Ibid.*, 183.

<sup>35</sup> ten Kate, *The Commercial Use of Biodiversity*, 194.

<sup>36</sup> DOC Technology Transfer Report, 2004, 74, 82 (Department of Defense, Department of Energy).

<sup>37</sup> DOC Technology Transfer Report 2004, 50, 60, 80, 122 (USDA, Department of Commerce, Department of Energy, NASA).

<sup>38</sup> AUTM Licensing Survey FY2001, 15.

<sup>39</sup> DOC Technology Transfer Report 2004, 50, 60, 74, 82, 102, 108, 116, 122, 130, 136; AUTM License Survey FY2000, 13; AUTM License Survey FY2001, 12; AUTM License Survey FY2002, 20. AUTM License Survey FY1999 did not report the number of licenses yielding royalties of more than \$1 million.

<sup>40</sup> The Department of Defense reported that in 2001, one license generated \$4.2 million, and that the top 29 revenue-generating licenses also generated \$4.2 million. Therefore, no more than one license could have generated more than \$1 million (DOC Technology Transfer Report 2002, 23). The Department of Defense had at least one license that yielded more than \$1 million in 2002 and 2003, but did not report any other information that could indicate whether more than one license yielded more than \$1 million (DOC Technology Transfer Report 2004, 74).

<sup>41</sup> The Department of Energy reported that in 2001, one license generated \$1.6 million, and that the top 100

revenue-generating licenses generated \$2.7 million. Therefore, no more than two licenses could have generated more than \$1 million. The Department of Energy reported that no licenses yielded more than \$1 million in 2002 or 2003 (DOC Technology Transfer Report 2004, 82).

<sup>42</sup> See, e.g., M. Milstein, "Firms Milk Park's 'Wildlife,'" *High Country News* 25(24) (December 27, 1993).

<sup>43</sup> Experts have reported that royalty rates associated with agreements resulting from the collection of "raw samples" range from 0.05% to 5%. Rates increase to as much as 8% when the agreement concerns research results such as "active strains/isolates," "gene sequences," and "purified enzymes/proteins" (ten Kate and Laird, *The Commercial Use of Biodiversity*, 252). Similarly, a study regarding the pharmaceutical industry reported that when an outside source provided research specimens during the early stages of research, the industry paid royalties of 1–5% (Reid et al., *Biodiversity Prospecting*, 111–112. See also Anderson, *INBio/Merck Agreement*, 10).

<sup>44</sup> These patents were assigned to government or private institutions.

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# **Appendix D**

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## **Public Involvement— Scoping**

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## D.1 Introduction

Scoping is an early and open process to determine the scope of environmental issues and alternatives to be addressed in an EIS. The public plays an integral role in the scoping process. The various points of view expressed in scoping comments were used by the National Park Service (NPS) to frame the issues to be resolved through the NEPA process and documented in this EIS.

During scoping, comments from the public were solicited in a variety of ways, outlined below. Scoping responses were analyzed to determine the full set of concerns expressed by the public, without regard to how often or from whom these opinions were expressed.

## D.2 Scoping Methodology

Scoping began with a variety of published requests for public input. More than 100 responses were received.

The NPS published a notice of intent to prepare an environmental assessment (EA) in the Federal Register on June 25, 2001.<sup>1</sup> An effort was made at that time to contact members of the public with an interest in providing input on potentially implementing benefits-sharing agreements in NPS units. More than 5,000 scoping newsletters were mailed to research scientists working in national park units servicewide, as well as to biotechnology associations, Native American tribes, organizations with an interest in national parks, NPS personnel, and others who expressed interest. A web site was established with background information and an invitation to comment via e-mail. A press release and fact sheet were distributed to national news media. Articles appeared in a variety of newspapers. Notices were posted in the nationwide NPS Morning Report and other NPS e-publications. Scoping comments were accepted between June 25 and August 27, 2001, for a total of 63 days.

The NPS received several comments suggesting that the EA should be an EIS. Subsequent to receiving comments that the EA should be an EIS, the NPS decided that the evaluation of benefits-sharing would be better served by the preparation of an EIS. The NPS published a notice of intent to prepare an EIS in the Federal Register on April 12, 2002.<sup>2</sup> Newsletters were once again mailed to more than 5,000 people, including all those who had submitted comments during the previous scoping period. Additional scoping comments were accepted between April 12 and May 31, 2002, for a total of 49 days. Accordingly, public comments were accepted for a total of 112 days during both scoping periods.

During the initial scoping period, 70 comment messages were received on a variety of items. A majority of messages (41) were received electronically. Messages were received from 21 states and one foreign country. During the second scoping period, 48 comment messages were received. A majority of messages (37) were received electronically. Messages were received from 17 states and several foreign countries.

Scoping comments were received from 93 individuals and from the following 25 organizations:<sup>3</sup>

Alliance for Wild Rockies  
American Wildlands  
Biotechnology Industry Organization  
Campaign for Responsible Transplantation  
Colorado Grizzly Project  
Costa Rica's National Biodiversity Institute (INBio)  
Defenders of Wildlife  
The Ecology Center  
EcoSystems Alert  
The Edmonds Institute  
Escalante Wilderness Project  
The Foundation for Sustainable Development (GAIA)  
Friends of the Escarpment  
Greater Yellowstone Coalition  
GreenBeing, Inc.  
International Center for Technology Assessment  
National Parks Conservation Association  
Native Forest Network  
Peace Habitat and Conservation Trust Society  
Public Employees for Environmental Responsibility  
The Sierra Club  
Wana Mandhira Foundation  
Washington Biotechnology Action Council  
Wilderness Watch  
The ZHABA Collective

## **D.3 Analysis Methodology**

Scoping responses were processed by extracting the specific points made by each respondent and then organizing these points under thematic headings. These themes, as articulated by scoping respondents, helped frame the issues to be resolved through the NEPA process and documented in this EIS.

All comments and concerns were considered, whether they were presented by a single person or by several people. Emphasis in this process was on the content of the comment, rather than the number of people who submitted it. All comments were treated individually and equally during processing. They were not weighted by number, organizational affiliation, or other status of respondents.

All messages were retained for future reference, including hard copies of electronic messages.

Most messages contained multiple separate comments related to separate specific points being made by the message writer (the respondent). The NPS identified 294 separate comments in 118 messages.

Comments from all respondents were organized thematically under headings called “Statements of Concern.” Each Statement of Concern presented, in a simple statement, a common theme found in the body of public comment. The Statements of Concern, accompanied by verbatim quotes from respondents, provided a summary of public comment. These Statements of Concern were available to the Interdisciplinary Team (IDT) and used in preparation of this EIS.

Every comment in every message was coded for entry into a database and double-checked with the primary purpose of ensuring that every comment in every message was identified for consideration by the IDT.<sup>4</sup> These codes allowed quick access to the full range of comments relating to specific themes. Neither the codes nor the Statements of Concern replaced consideration of the messages themselves; instead, they helped provide guidance and organization to comments on specific topics of interest.

## **D.4 How Scoping Comments Were Addressed**

All of the concerns expressed by the public were incorporated into the preparation of this EIS. The various points of view expressed in scoping comments were used by the NPS to frame the issues to be resolved through the NEPA process and documented in this EIS.

### **D.4.1 Issues Analyzed as Impact Topics in Chapter Four**

- NPS natural resource management
- NPS visitor experience and enjoyment
- Social resources: the research community
- Social resources: NPS administrative operations

### **D.4.2 Issues Addressed in the Alternatives in Chapter Two**

- Should benefits-sharing be implemented?
- Uses and distribution of potential benefits
- Criteria for requiring benefits-sharing
- Content of benefits-sharing agreements
- Potential confidentiality of benefits-sharing agreements
- Sale or commercial use (“commercialization”) of NPS resources
- Impacts of benefits-sharing on potential consumptive use (“harvesting”) of NPS biological resources
- Benefits-sharing and Native American rights
- Potential impacts of research on natural resources

### **D.4.3 Issues Not Evaluated Further in this FEIS**

- Genetic engineering
- Intellectual property rights
- Congressional appropriations
- Administration of scientific research activities in the NPS

## D.5 Initial Scoping Process and Public Participation

In this section, public comments are summarized in general terms and the way the NPS incorporated the comments into the FEIS is identified.

COMMENT: The NPS initially planned to prepare an EA. However, public comments resulted in the NPS decision to prepare an EIS. Early in scoping, several respondents insisted that an EA would be insufficient to properly evaluate the decision whether or not to implement benefits-sharing. Even when this opinion was based upon a misunderstanding of the decision to be made and the resources that might be at stake, it illustrated a sense of controversy regarding benefits-sharing. These commenters also argued that implementing an NPS policy that might inadvertently affect how specimen collection is authorized must be subject to a higher standard of review than an EA.

EIS: The NPS is preparing an EIS rather than an EA.

COMMENT: A number of respondents were under the misapprehension that benefits-sharing agreements would authorize an inappropriate commercial harvest or that that this programmatic EIS would try to evaluate the commercialization of NPS natural resources. They warned against such commercialization and against any programmatic authorization for any use of natural resources. There was also a concern that once an NPS resource was understood to be valuable, there might be pressure to harvest or poach that resource.

EIS: No alternative in the EIS proposes a new way to authorize collection of any natural resources. Every alternative in the EIS retains current policies and procedures that protect park resources (*see* Chapter 2).

COMMENT: Respondents gave contradictory advice concerning the potential impact of benefits-sharing on the meaning and value of the NPS—in other words, on the NPS mission. Some insisted that benefits-sharing would be good for the NPS, allowing more effective preservation of resources and serving as a source of pride to Americans. Others were equally adamant that benefits-sharing has no place in a national park, or that scientific research must not be allowed if its goal is to discover useful products or processes from the study of nature.

EIS: The alternatives provide a clear choice among these various opinions (*see* Chapter 2).

COMMENT: Research activities are closely related to benefits-sharing in the minds of many people. Commenters advised the NPS to ensure that the information uncovered during park research would be available to park managers. Some comments suggested that the scope of the EIS should be expanded to include an assessment of scientific research in general in the NPS.

EIS: The administration of scientific research in the NPS is outside the scope of this EIS (*see* Chapter 2).

COMMENT: Comments were received supporting scientific endeavors in parks and warning

against any action that might inhibit the search for a deeper understanding of park resources. A number of people suggested that the paperwork burden associated with a benefits-sharing requirement might discourage researchers from submitting or completing research proposals, thus effectively reducing the quantity of research performed in the NPS.

EIS: Alternative B (Implement Benefits-Sharing) would not require additional obligations from the vast majority of park researchers (*see* Chapter 4).

COMMENT: The public warned the NPS against allowing the evaluation of research proposals to be influenced by potential profitability. Some people suggested that scientific research projects should be subject to NEPA review, not realizing that every research proposal (almost 3,000 in 2001) is already required to undergo a separate, case-specific NEPA review.

EIS: The EIS proposes mitigation to prevent the research permitting process from being influenced by benefits-sharing considerations (*see* Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5).

COMMENT: Commenters suggested a number of conflicting criteria that should be used to determine who should be subject to benefits-sharing, or when that determination should be made. For instance, some suggested that the main criterion for requiring a benefits-sharing agreement should be the affiliation (corporate versus academic) of the researcher. Others suggested that the main criterion should be whether or not the research project had a chance of ever discovering a valuable application for research results. Others suggested excluding any project that is expected to recover a negligible financial return. A few respondents asserted that nobody should be required to submit to benefits-sharing.

EIS: Alternative B provides criteria for requiring benefits-sharing. Alternatives A and C would not require any benefits-sharing (*see* Chapter 2).

COMMENT: Terms and conditions of benefits-sharing agreements were the subject of concern for many respondents. There was virtual unanimity among these commenters that the NPS should receive “fair value,” but little specific guidance regarding how to achieve such a goal. Some respondents implied that “industry standards” exist to guide the negotiation of benefits. A few responders opined that all terms and conditions of benefits-sharing agreements should be a matter of public record. Some wanted to have each agreement subject to a public comment period prior to its execution. In addition, some respondents were concerned about the enforcement of the terms and conditions of benefits-sharing agreements, asserting that cheating would be easy for a disreputable biotech scientist.

EIS: Alternative B provides details that address these concerns (*see* Chapter 2).

COMMENT: The public presented many views of how best to use benefits. These commenters assumed that benefits would be required, and suggested appropriate uses for both financial and in-kind benefits. Suggestions for the use of benefits included support of conservation, restoration, preservation, research, and education projects. The public also made it clear that they were concerned that a perceived financial income from benefits-sharing might encourage Congress to reduce appropriations.

EIS: Alternative B dedicates all benefits to the conservation of park resources. Congressional appropriations are outside the scope of this EIS (*see* Chapter 2).

COMMENT: A number of people were concerned about topics that are outside the scope of this EIS, such as whether or not the NPS should support U.S. intellectual property laws. A form letter was received from several people opposed to research that might result in the invention of genetically modified organisms for potential use in agriculture, industry, or medicine.

EIS: These concerns are outside the scope of this EIS (*see* Chapter 1, Section 1.9.2).

COMMENT: Finally, some respondents had specific advice regarding laws, case law, regulations, and policies that should be kept in mind while preparing the EIS.

EIS: The legal framework for this FEIS is discussed in Chapter 1.

## Notes

### Section D.2 Scoping Methodology

<sup>1</sup> 66 Fed. Reg. 33712, 33713.

<sup>2</sup> 67 Fed. Reg. 18034, 18035.

<sup>3</sup> One hundred-eighteen messages were received, some of which were signed by more than one respondent. These included 93 individual respondents and 25 organizational respondents.

### Section D.3 Analysis Methodology

<sup>4</sup> Comments were entered as verbatim quotes into a database developed under NPS contract and used for the recent Bison Management EIS in Yellowstone National Park.

# **Appendix E**

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## **Research Trends Analysis**

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During scoping, several commenters suggested that selection of the benefits-sharing alternative (Alternative B) could affect the quantity of research activities in parks, either by attracting or discouraging scientific research activities undertaken by bioprospectors. These possibilities were analyzed, and the results are presented in this appendix. This analysis acknowledged that bioprospecting research has always been allowed in parks under the same regulations that control all types of scientific research activities, and that implementation of benefits-sharing as proposed in Alternative B would not change the criteria by which all scientific research permit applications are evaluated.

Four datasets were examined to determine whether there had been a measurable impact on the quantity of research in parks after the announcement of the Yellowstone–Diversa benefits-sharing agreement in 1997. Because the Yellowstone–Diversa agreement was entered into in 1997, the pre-benefits-sharing time period was defined as 1992–1997. The post-benefits-sharing time period was defined as 1998–2001. The four datasets included:

- The quantity of Scientific Research and Collecting Permits issued by Yellowstone, 1992–2001;
- The quantity of research reports (Investigator’s Annual Reports) submitted to Yellowstone, 1992–2001;
- The quantity of research reports submitted to the 38 parks that received at least one research report each year, 1992–2001 (these parks accounted for half (50.3%) of all the research reports received by the National Park Service during this period); and
- The quantity of research reports submitted to a total of 270 parks servicewide, 1992–2001.

For each dataset, the number of research reports submitted (or, in one case, Scientific Research and Collecting Permits issued) was determined for each year from 1992 through 2001. A chi-square test was performed to determine if the null hypothesis (“There was no change in the number of reports/permits after 1997 compared to before 1997”) could be rejected. This test detected no significant difference in the number of research projects conducted for any dataset between the pre-benefits-sharing and post-benefits-sharing time periods. Thus, the null hypothesis could not be rejected, that is, there is no evidence that the announcement or publicity surrounding the 1997 Yellowstone–Diversa agreement resulted in either an increase or decrease in National Park Service research reports or permits, and the fluctuations in the quantity of independent research activities in National Park Service units during the 10-year period 1992–2001 showed no significant trends.

***Tables begin next page***

**Table E-1. Number of Scientific Research and Collecting Permits issued by Yellowstone, 1992–2001**

Year	Number of permits
1992	308
1993	220
1994	223
1995	286
1996	271
1997	290
1998	240
1999	237
2000	259
2001	234

**Table E-2. Chi-square calculation, the number of Scientific Research and Collecting Permits issued by Yellowstone, 1992–2001, and 1992–1997 compared to 1998–2001**

Average permits 1998–2001 (after CRADA)	243
Average permits 1992–1997 (before CRADA)	266
Observed minus expected (“after minus before”)	-24
Squared	568
Divided by expected (chi-square value)	2.13277013

**Table E-3. Number of research reports (IAR) submitted to Yellowstone, 1992–2001**

Year	Number of reports
1992	227
1993	220
1994	208
1995	196
1996	191
1997	187
1998	190
1999	200
2000	171
2001	178

**Table E-4. Chi-square calculation, the number of research reports (IAR) submitted to Yellowstone, 1992–2001, and 1992–1997 compared to 1998–2001**

Average reports 1998–2001 (after CRADA)	185
Average reports 1992–1997 (before CRADA)	205
Observed minus expected (“after minus before”)	-20
Squared	403
Divided by expected (chi-square value)	1.9691145

**Table E-5. Number of research reports (IAR) submitted to 38 parks, 1992–2001**

Year	Number of reports
1992	1,024
1993	1,027
1994	1,016
1995	917
1996	1,140
1997	1,122
1998	1,032
1999	1,132
2000	1,023
2001	899

**Table E-6. Chi-square calculation, the number of research reports (IAR) submitted to 38 parks, 1992–2001, and 1992–1997 compared to 1998–2001**

Average reports 1998-2001 (after CRADA)	1,022
Average reports 1992-1997 (before CRADA)	1,041
Observed minus expected (“after minus before”)	-19
Squared	361
Divided by expected (chi-square value)	0.34678194

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**Table E-7. Number of research reports (IAR) submitted servicewide, 1992–2001**

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Year	Number of reports
1992	2,156
1993	2,108
1994	2,139
1995	1,692
1996	2,009
1997	2,075
1998	2,151
1999	2,362
2000	1,898
2001	1,947

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**Table E-8. Chi-square calculation, the number of research reports (IAR) submitted servicewide, 1992–2001, and 1992–1997 compared to 1998–2001**

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Average reports 1998–2001 (after CRADA)	2,090
Average reports 1992–1997 (before CRADA)	2,030
Observed minus expected (“after minus before”)	60
Squared	3,600
Divided by expected (chi-square value)	1.773399015

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# **Appendix F**

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## **An Informal Public- Private Partnership in Service to Yellowstone Natural Resources**

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The collaborative relationship between Diversa Corporation and Yellowstone National Park was developed under a Cooperative Research and Development Agreement (CRADA). An informal relationship survived the suspension of that CRADA. Diversa scientists provided two services to Yellowstone through this informal relationship—genetic analyses of the Yellowstone wolf population and of the microbes associated with a hydrothermal geologic feature.

In the late 1990s, Yellowstone National Park entered into a benefits-sharing agreement with Diversa Corporation (see Chapter One, 1.8). Despite the suspension of the Yellowstone–Diversa CRADA by a federal court in 2000, the collaborative research relationship developed by Yellowstone and Diversa during CRADA negotiations has remained somewhat intact.

When Yellowstone recognized a need for genomic (DNA) expertise to solve two separate resource management problems, it turned first to its former CRADA partner, Diversa. Diversa was well positioned to assist Yellowstone with two projects that would have been impossible for park employees to accomplish and prohibitively expensive to outsource. For Diversa, these problems were neither difficult nor expensive. The collaborative relationship between this private corporation and a national park encouraged the corporation to materially assist the park at little burden to itself.

The natural resource studies undertaken by Diversa for Yellowstone concerned wolves and hydrothermal geology, two seemingly unrelated disciplines. Starting in 1995, wolves were restored to Yellowstone National Park after more than half a century of absence. Thirty-two wolves were relocated to Yellowstone from Canada. Growing a much larger population from so few founders had the potential to result in genetic problems, and resource managers worried over this disturbing future possibility. Yellowstone needed the DNA “fingerprints” of the park’s wolves to prepare to assess the health of the park’s wolf population.

Park managers had saved blood samples from all wolves captured in the course of research, and Diversa offered to extract DNA and do the genetic fingerprinting tasks. The discoveries that were confirmed by this analysis were unprecedented. For instance, managers could immediately determine the origin of wolves killed on nearby roads or by illegal means, because DNA tests identified whether each wolf was part of the Yellowstone reintroduced population. Biologists were most pleased, however, because for the first time they were able to confirm the parentage of each wolf. A century from now, they will be able to track inbreeding depression or other genetic maladies, if they occur.

Yellowstone is also a fertile area for the study of geology, because it sits atop one of the world’s largest active volcanoes. In 1996, a research team exploring the depths of Yellowstone Lake discovered a large rock formation built by mineral-rich hot water entering the lake from below. When the park allowed part of this novel and rare geological specimen to be retrieved for scientific study, it required that all possible data be extracted, including a description of the microbes living in it. After two years, research on the physical and chemical nature of the specimen was progressing, but study of the biological element was not. When the park discovered this problem, managers hoped that there might still be enough microorganismal DNA on the specimen to describe the microbes that lived on and helped form the rock specimen.

Using its database on world biodiversity, Diversa was able to characterize many species of microorganisms living in the specimen, including six new species of Archaea and four new species of Bacteria. The gasses bubbling up into the lake from hot springs underneath were expected to nourish a thriving community of microbes, but the identification of 10 species new to science was remarkable.

These two examples could only have occurred because of the working collaboration between park scientists and private scientists. This level of collaboration was not routine; it had been fostered and required by the Yellowstone–Diversa CRADA. The examples also demonstrate that tasks that are hard for the National Park Service to accomplish on its own, because of either the expense or the expertise they require, are sometimes relatively easy for a biotechnology company to achieve.

# **Appendix G**

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## **Background for Benefits-Sharing and Technology Transfer**

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Although this FEIS has been prepared due to the precedent-setting nature of implementing benefits-sharing in the National Park Service (NPS), benefits-sharing has already been implemented by various other organizations in the U.S. and around the world. For purposes of this FEIS, the term “benefits-sharing” refers to the equitable and efficient sharing of benefits between researchers, their institutions, and a land management agency that result from research involving research specimens originating from the lands under that agency’s jurisdiction.

Appendix G provides an overview of existing benefits-sharing arrangements. Depending on the facts and circumstances, the research results subject to a benefits-sharing agreement may generate either monetary or non-monetary benefits (or both). Existing benefits-sharing arrangements were examined by the NPS in preparation for proposing to implement benefits-sharing.

## **G.1 Benefits-Sharing by the U.S. Government**

A U.S. Government agency (the National Cancer Institute) initiated the earliest known benefits-sharing agreements in 1988.<sup>1</sup> Two examples of benefits-sharing agreements that were developed in the 1990s by U.S. Government agencies are described in this section: the Yellowstone–Diversa Cooperative Research and Development Agreement (CRADA) and the International Cooperative Biodiversity Groups program.

### **G.1.1 Benefits-Sharing in the NPS: The Yellowstone–Diversa CRADA**

Despite the phenomenal success of the discoveries relating to *Thermus aquaticus* by private-sector researchers, Yellowstone National Park did not share any of the resulting benefits. As a consequence, the large economic gains resulting from the successful research activities involving samples of *T. aquaticus* first acquired from Yellowstone has prompted headlines such as “Industries Exploit First Park.”<sup>2</sup>

In the mid-1990s, prior to enactment of the National Parks Omnibus Management Act of 1998, the NPS evaluated the potential use of CRADAs as a “benefits-sharing” mechanism in circumstances involving joint research projects between units of the National Park System and visiting scientific researchers.

In August 1997, Yellowstone announced that it had negotiated a draft CRADA with the Diversa Corporation of San Diego, California, a biotechnology research firm that already had an NPS research permit to conduct research and collect microbial research specimens at the park, and whose scientists had been conducting research at Yellowstone for many years. Although the mechanisms and mandates authorizing and implementing CRADAs had been in place government-wide for more than a decade, the Yellowstone–Diversa CRADA was the first benefits-sharing agreement ever negotiated between a private-sector research firm and a U.S. national park.

The Yellowstone–Diversa benefits-sharing agreement provided that a portion of the economic and scientific benefits from discoveries made during Diversa’s ongoing laboratory research involving research specimens collected at Yellowstone would be provided directly to the park for resource conservation purposes.<sup>3</sup> The benefits to be shared included payment of royalties and other monetary benefits, scientific training, and technology transfer to Yellowstone.

The CRADA negotiated by Yellowstone was designed to operate in addition to the terms and conditions of Diversa’s existing research permit. The agreement did not expand the scope of authorized research specimen collection activities at the park.<sup>4</sup>

The Yellowstone–Diversa agreement was revised and finalized in May 1998, after review by the NPS Office of the Solicitor and the NPS director and receipt and consideration of comments from the public.

In early 1998, the Yellowstone–Diversa CRADA was challenged in the U.S. District Court for the District of Columbia. The plaintiffs alleged that the CRADA violated the NPS Organic Act (16 USC § 1), Yellowstone National Park Organic Act (16 USC § 21), Federal Technology Transfer Act of 1986 (FTTA) (15 USC §§ 3710a–3710d), NPS regulations (36 CFR §§ 2.1 and 2.5), the Administrative Procedure Act (5 USC §§ 702, 706), and the so-called “public trust doctrine.” The plaintiffs also alleged that the NPS failed to comply with the National Environmental Policy Act before negotiating the CRADA with Diversa. This FEIS is being prepared to comply with the court’s decision.

The court dismissed the plaintiffs’ case with prejudice and upheld the Yellowstone–Diversa CRADA as consistent with the NPS Organic Act, Yellowstone National Park Organic Act, FTTA, NPS regulations, and the public trust doctrine.<sup>5</sup> The court also required the NPS to “suspend implementation of the Yellowstone–Diversa CRADA pending the completion of any and all review mandated by the National Environmental Policy Act”<sup>6</sup> due to the precedent-setting nature of the Yellowstone–Diversa agreement within the NPS.<sup>7</sup>

The court’s analysis concluded that units of the National Park System (such as Yellowstone) that satisfy the definition of a federal “laboratory” provided in the FTTA are eligible to negotiate CRADAs with qualified researchers. The FTTA defines “laboratory” as “a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.”<sup>8</sup> The statute also gives federal agencies broad discretion in making laboratory determinations.<sup>9</sup> The legislative history explains that “[t]his is a broad definition which is intended to include the widest possible range of research institutions operated by the Federal Government.”<sup>10</sup>

The plaintiffs appealed the court’s decision upholding the Yellowstone–Diversa CRADA under the NPS Organic Act, the Yellowstone National Park Organic Act, the FTTA, and NPS regulations in the U.S. Court of Appeals for the District of Columbia Circuit. After the NPS filed a brief in support of the U.S. District Court’s ruling upholding the Yellowstone–Diversa CRADA, the plaintiffs asked the federal appeals court to dismiss their own appeal. The appeal was dismissed on December 22, 2000.

In 2002, the Diversa Corporation introduced an enzyme product for sale to the petroleum industry that was developed from research involving microbes first collected from Yellowstone. Although the discovery that led to development of the product involved research on microbial research specimens Diversa had collected at Yellowstone, the product (“Pyrolase 200™”) was synthesized in Diversa’s laboratories in San Diego. Diversa reports that Pyrolase 200™ can assist with the extraction of oil from underground reservoirs as well as with textile processing.<sup>11</sup> Diversa’s revenues from Pyrolase 200™ are not known.<sup>12</sup> Because the Yellowstone–Diversa benefits-sharing agreement is currently suspended, Yellowstone National Park is realizing no benefits from Diversa’s successful development of Pyrolase 200™.

## **G.1.2 International Cooperative Biodiversity Groups**

In 1992, four federal agencies combined efforts to launch the International Cooperative Biodiversity Groups (ICBG) Program, which provides grants to fund research projects. The ICBG Program aims to promote conservation, discover new drugs, and “ensure that equitable economic benefits from these discoveries accrue to the country of origin.”<sup>13</sup>

The agencies sponsoring the program are the National Institutes of Health (NIH), the National Institute of Mental Health (which subsequently became part of the NIH), the National Science Foundation, and the U.S. Agency for International Development (USAID). Acting together, the agencies sought to respond to scientific and public concern about three interdependent issues: (1) conservation of biodiversity among the world’s plant and animal resources, (2) sustained economic growth for developing countries, and (3) discovery and development of pharmaceuticals from natural products to improve human health.

In 1997, a panel of six experts reviewed the five ICBG projects that were conducted between 1992 and 1996. The panel’s findings and recommendations relating to the “benefits-sharing” aspects of the projects are included in the report.<sup>14</sup> The report identified the types of benefits (both monetary and non-monetary) that could be generated from a project, and some of the related factors relevant for directing benefits to achieving the conservation goals of the ICBG Program.<sup>15</sup>

Monetary benefits included in the terms of these cooperative agreements include, for example:

- Up-front payments based on the potential commercialization of products as well as royalty and milestone payments;
- Contributions by participating industries and local governments;
- Venture capital, risk funds, and trust funds obtained from interested parties; and
- Additional support from USAID, The World Bank, foundations, and other donor organizations.

Non-monetary benefits realized from ICBG projects as of 2002 include:

- More than 250 novel bioactive compounds discovered;
- 25 lead therapeutic compounds for malaria, leishmaniasis, tuberculosis, HIV, various bacterial infections, cancer, and crop protection identified and isolated;

- New species of plants, fungi and insects identified;
- Increased laboratory and field capacity developed in 12 countries;
- 3,000 people trained in multiple scientific disciplines;
- New and enhanced local databases on biodiversity distribution in participating countries;
- New publications in chemistry, biodiversity, and related policy matters; and
- Initiated creation of at least one new biodiversity reserve.

## **G.2 Benefits-Sharing Around the World**

Benefits-sharing related to research results has been implemented or is under development in many countries around the world. The benefits-sharing program in Costa Rica began in 1991, and is described below. The United Nations guidelines for collecting research specimens and establishing benefits-sharing agreements are also described.

### **G.2.1 Costa Rica: Benefits-Sharing Since 1991**

Costa Rica has an extensive system of national parks and conservation areas. When researchers propose study of specimens from those areas that could result in commercial applications, the National Biodiversity Institute (INBio) of Costa Rica develops research agreements that include benefits-sharing terms. INBio is a non-governmental, non-profit, public interest organization that supports efforts to develop scientific information about the country's biological diversity and to promote its sustainable use.<sup>16</sup>

Since 1991, INBio has acted as an intermediary for a variety of national (Costa Rican) and international research organizations wishing to study biological materials collected from Costa Rica's extensive system of national parks and conservation areas, and Costa Rica's Ministry of Natural Resources, Energy and Mines (MINAE), which manages them. In projects that involve biological research activities that could produce results with some valuable commercial application, INBio negotiates and develops collaborative research agreements that include benefits-sharing terms.<sup>17</sup> The terms of every benefits-sharing agreement are different based on differing facts and circumstances, and specific royalty payment totals are treated as confidential business information.<sup>18</sup> In 2001 and 2002, INBio reported that the total revenues generated from these agreements were almost \$2 million each year. INBio provides a portion of that revenue to the government agency that manages national parks.

An underlying long-term cooperative agreement between INBio and MINAE provides for two types of research-related payments from INBio to MINAE; ten percent (10%), up-front, of the total annual budget for each respective research project's work in Costa Rica; and fifty percent (50%) of any future royalties or other economic benefits (if any) subsequently earned by INBio if a revenue-generating product results from the collaborative research project.<sup>19</sup>

In 1991, the earliest of these agreements was announced between INBio and Merck &

Company.<sup>20</sup> In that agreement, Merck agreed to an initial two-year research and biological sampling budget of \$1,135,000, royalties on any resulting products, and technical assistance and training to help build pharmaceutical research capacity in Costa Rica.<sup>21</sup>

Since 1991, INBio has negotiated many additional agreements with other research firms.<sup>22</sup> While INBio has not published the total revenue earned from all such agreements,<sup>23</sup> a study published in 2001 identified 18 agreements negotiated between September 1991 and February 1998, and noted that INBio had contributed \$2,947,911 to research and conservation programs in Costa Rica from the resulting revenues.<sup>24</sup> Information reported by INBio indicates that this sum is approximately 10% of the total revenues received by INBio from such agreements during that period.

## G.2.2 The Bonn Guidelines

The United Nations has promulgated the Bonn Guidelines, which make recommendations for permitting access to research specimens and for establishing fair and equitable benefits-sharing agreements.<sup>25</sup> The Bonn Guidelines were developed as a result of a series of meetings organized under the United Nations Convention on Biological Diversity (CBD) between 1999 and 2001 that examined available case studies and best practices for access and benefits-sharing issues. The Bonn Guidelines identify ways that governments and other biological resource managers could implement benefits-sharing programs, and include examples of the wide variety of both monetary and non-monetary benefits that could be part of a benefits-sharing agreement (see Chapter 4, Section 4.4.1).<sup>26</sup> The importance of non-monetary benefits can often be expected to exceed the importance of monetary benefits.<sup>27</sup>

The Bonn Guidelines provide recommendations for establishing fair and equitable benefits-sharing agreements with mutually agreed terms that are intended to achieve:

- (a) Legal certainty and clarity;
- (b) Minimization of transaction costs;
- (c) Inclusion of provisions on user and provider obligations;
- (d) Development of model agreements;
- (e) Different uses may include, among others, taxonomy, collection, research, and commercialization;
- (f) Timeliness and efficiency (mutually agreed terms should be negotiated efficiently and within a reasonable period of time);
- (g) Mutually agreed terms should be set out in a written instrument.

Although not a party to the CBD, the U.S. actively participated in and contributed to the process that resulted in the Bonn Guidelines.<sup>28</sup> In addition, at the September 2002 World Summit for Sustainable Development in Johannesburg, South Africa, the U.S. supported adoption of the Johannesburg Plan of Implementation as it relates to the Bonn Guidelines.

Additional information about ongoing development and implementation of benefits-sharing concepts and management approaches can be found through the CBD Secretariat's website, <<http://biodiv.org>>.<sup>29</sup>

## **G.3 Commercial Use of Research Results Discovered by Federal or Academic Scientists**

In general, federal and academic institutions do not themselves commercialize research results. Usually, intermediate research results (the intellectual property of the researcher and his institution) are offered for sale, lease, license, or other transfer for value to another institution for further research and development and eventual commercialization. The term “technology transfer” is used when such intellectual property is sold, leased, licensed, or otherwise transferred for value.

### **G.3.1 Federal Technology Transfer**

The experience of other federal agencies related to the commercial use of research results is reported in the Department of Commerce (DOC)’s annual Technology Transfer Reports.<sup>30</sup> Because the NPS has identified CRADAs as the agreement type for implementing benefits-sharing under Alternative B (see Chapter 2, Section 2.4.2.1), CRADA use by other agencies is reviewed first, followed by information about research results with commercial applications (termed “inventions”) and income from technology transfer.

It is the policy of the U.S. Government to improve the economic, environmental, and social well-being of the United States by encouraging cooperative research and development projects involving federal and non-federal entities. Congress has stated, “Cooperation among academia, Federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchange, joint research projects, and others, should be renewed, expanded, and strengthened.”<sup>31</sup>

Federal laboratories have used CRADAs since 1987. Department of the Interior bureaus have increased their use of CRADAs from 10 or fewer per year in the early 1990s to 50 active CRADAs in FY2001 (*see* Figure G.3.1-1).<sup>32</sup>

Researchers at federal laboratories reported research results with commercial applications (termed “inventions” in DOC reports) at an average of approximately 3,900 annually from FY1999–FY2003. Federal laboratories disclosed almost twice as many inventions as patent applications (*see* Figure G.3.1-3).

Federal agencies derive income from the licensing of inventions (whether patented or not) to other research institutions for further research, development and commercialization. Income from licensing, including royalties and other payments, was \$97 million across all federal laboratories in FY2003, averaging approximately \$16,000 annually per license from FY1999 to FY2003.<sup>35</sup>

In the NPS, benefits-sharing likely would be related to biological research (*see* Section 1.2.4). Virtually all current licensing of biological materials for research is managed by the Department of Health and Human Services (HHS).<sup>36</sup> HHS’s income from licensing was approximately \$55 million in FY2003, accounting for 56% of all federal laboratory licensing

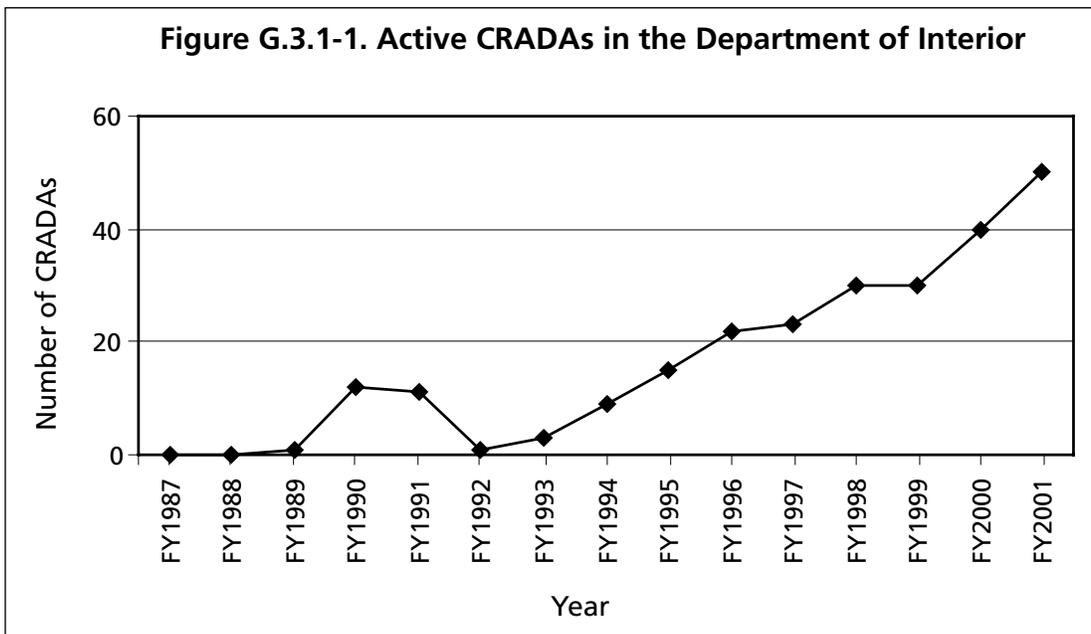


Figure G.3.1-1. The number of active CRADAs managed by the Department of the Interior is increasing.

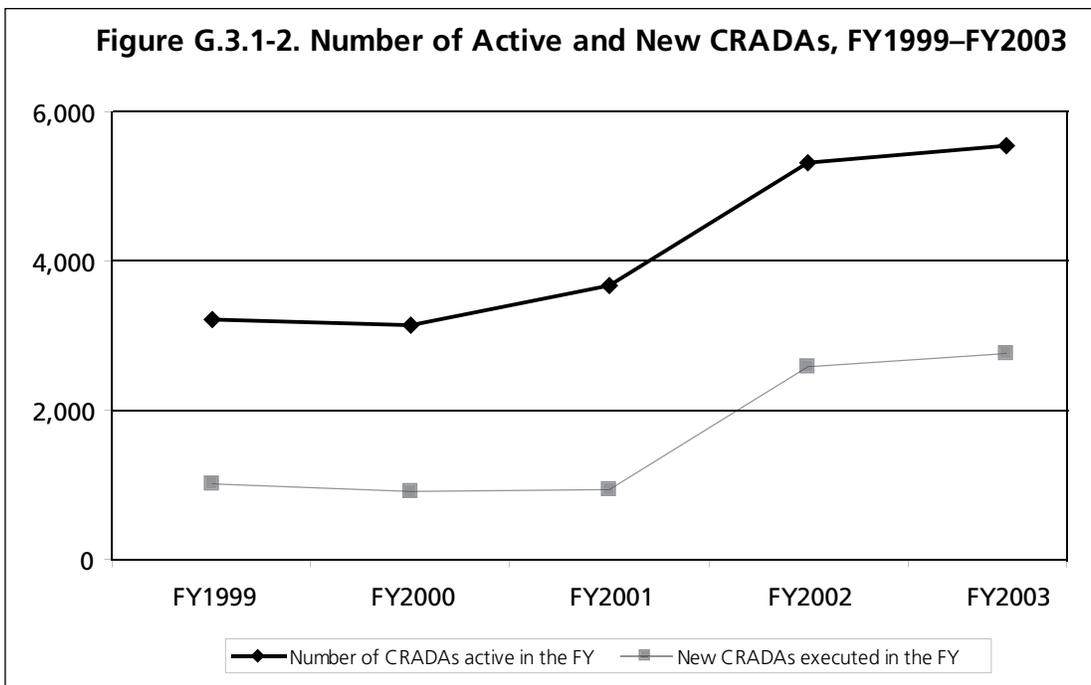


Figure G.3.1-2. Several thousand CRADAs were active annually from 1999 through 2003.

income. In 2004, the DOC concluded that the high proportion of federal laboratory license income generated by HHS licenses is “no doubt reflecting the competitively high economic value and strong commercialization opportunities associated with new technologies in the biosciences realm.”<sup>37</sup>

Royalties (when obligated) are earned by federal agencies based on the licensee’s income from commercial activities. Royalty income from licensing in FY2003 ranged from individual

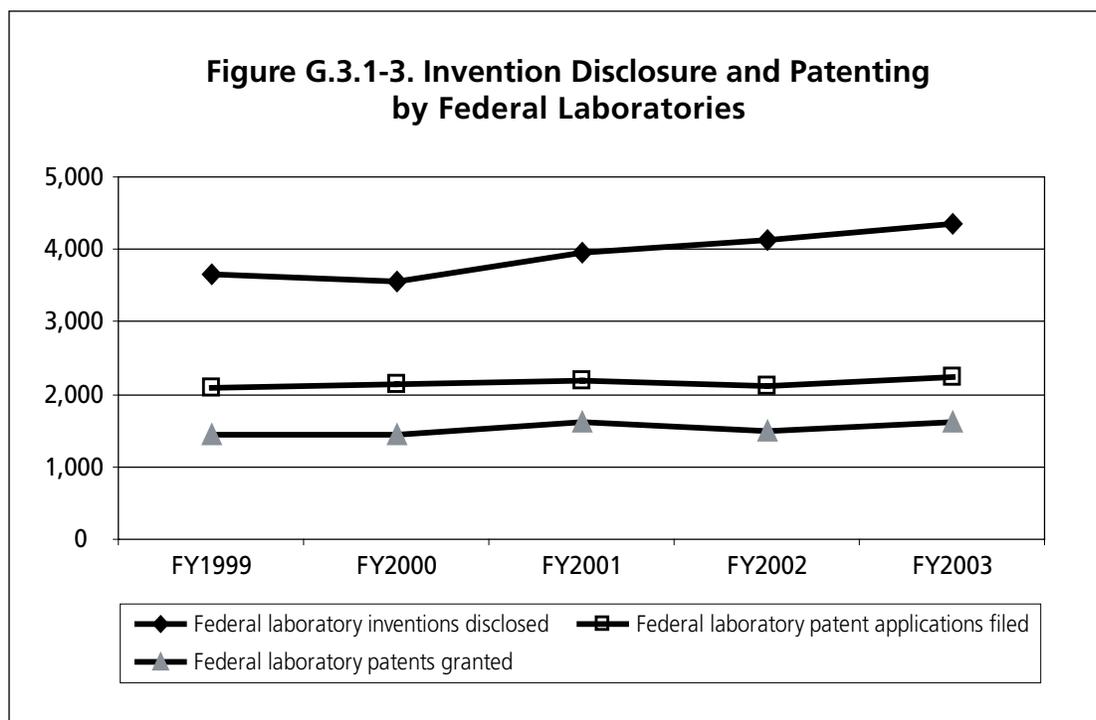


Figure G.3.1-3. During the five-year period FY1999–FY2003, federal researchers reported discovering approximately 3,900 inventions (commercial applications for research results) annually.

license agreements yielding only several dollars to one yielding \$1.5 million. Median royalty income per reported royalty-bearing license ranged from a low of approximately \$700 to a high of approximately \$9,500 annually.<sup>38</sup>

### G.3.2 Academic Technology Transfer

The Association of University Technology Managers (AUTM) surveys academic institutions in the U.S. and Canada each year, including most (92%) of the top 100 universities (by total research expenditures) to assemble and report information about their commercial use of research results. Each annual report focuses on how AUTM members manage intellectual property to make the results of academic research available to the public as commercial products, and includes information on technology transfer licensing, research results with commercial applications (termed “inventions” in the AUTM reports), income from technology transfer, and the effort needed to administer a technology transfer program.<sup>39</sup>

During 1999–2002, AUTM survey respondents reported that 19,000–26,000 technology transfer licenses were active annually, and 3,900–4,700 new licenses were executed each year.

### What have CRADAs done?

The DOC has found that it is often difficult to analytically demonstrate direct connections between cooperative public–private research activities and the eventual development of any discoveries or inventions into commercially valuable products or processes. This is because there may be many additional actors, actions, and other variables involved in the development process after the initial cooperative public–private research activities are undertaken. In addition, because the actual development and commercialization of an idea or discovery often takes many years, tangible results may not be immediately apparent.<sup>33</sup> Nonetheless, the DOC has identified and reported many case studies of successful downstream results from cooperative public–private research and development projects, including:

- Environmentally friendly mosquito and fly traps that provide an alternative to chemical pesticides and have been reported by the Department of Agriculture to support increasing public interest in less-toxic pest management practices;
- The world’s first approved, licensed, and manufactured live fish vaccine that prevents enteric septicemia (a major catfish disease caused by *Edwardsiella*). The Department of Agriculture reports that this disease costs catfish farmers as much as \$60 million a year in losses;
- Testing of new antimalarial drug and transdermal delivery approaches that eliminate the need to use hypodermic needles (Department of Defense);
- New technologies that the Environmental Protection Agency reports improve tests providing both enumeration of total coliforms and *E. coli* and presence/absence determinations;
- A new system, based on the PCR method, reported by the Environmental Protection Agency to detect and quantify more than 100 species or groups of species of potentially problematic fungi, including black mold; and
- Water treatment and reclamation technologies (Department of the Interior/Bureau of Reclamation).<sup>34</sup>

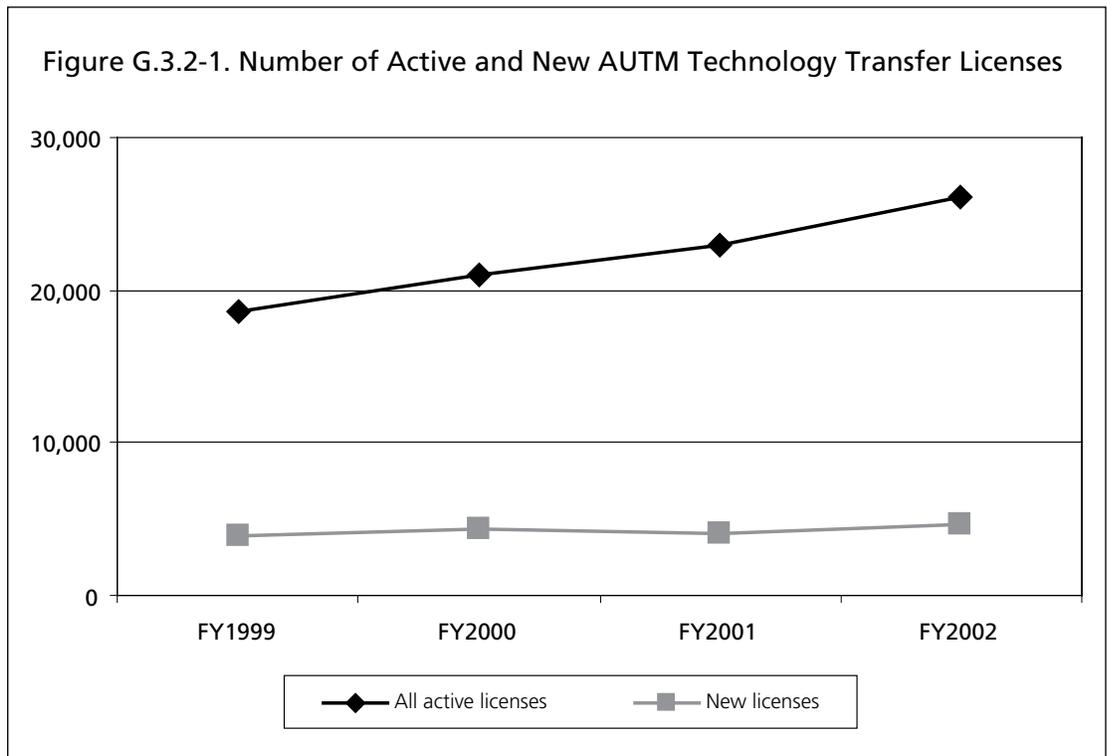


Figure G.3.2-1 On average, more than 22,000 technology transfer licenses were active annually from FY1999–FY2002.

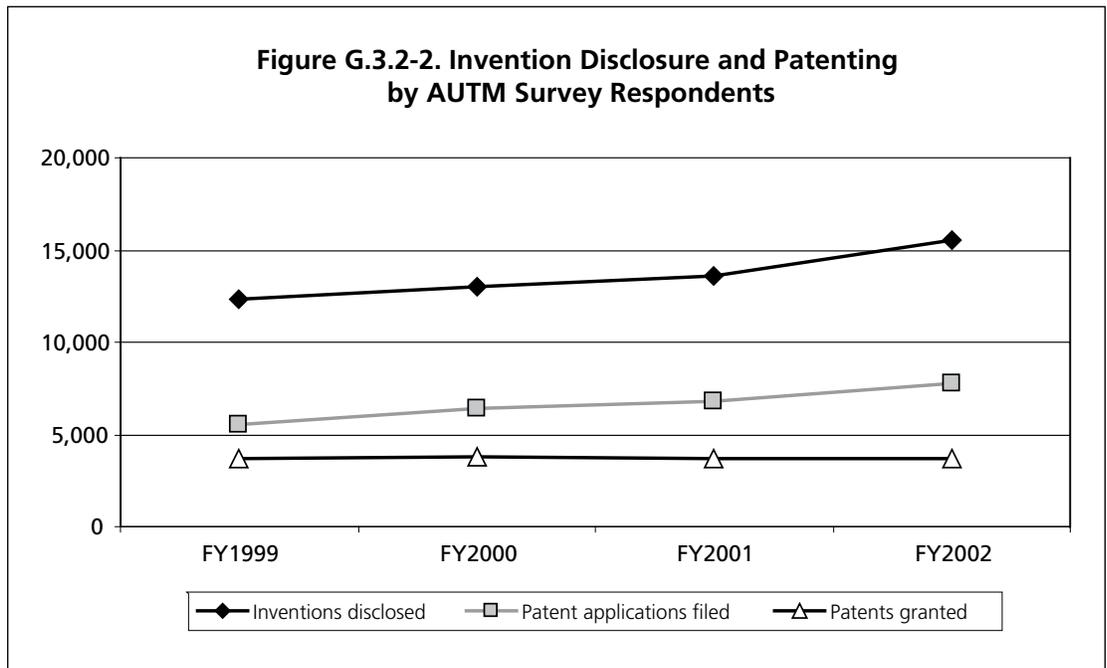


Figure G.3.2-2. During 1999–2002, academic researchers disclosed an average of more than 13,000 inventions (commercial applications for research results) annually.

Researchers at academic institutions reported an average of 13,000 research results with commercial applications (“inventions”) annually from FY1999 to FY2001. Patent applications were filed for 46% of these inventions (Figure G.3.2-1).

Academic institutions derive income from the licensing of inventions (whether patented or not) to other research institutions, including for-profit institutions, for further research, development, and commercialization. Income from licensing, including royalties and other payments, was more than \$1 billion total for all reporting institutions in FY2002. The average income per active license from FY1999 to FY2002 was \$49,000.

Royalties (when obligated) are earned by academic institutions based on the licensee’s income from product sales. From FY1999 to FY2002, AUTM reported that 23% of licenses generated royalty income, and that such income accounted for 73% of all license income (*see* Appendix C, Table C.3).

There is a workload cost associated with licensing that AUTM reports in terms of “full time equivalents” (FTE), or the amount of time one full-time employee works in one year. In 2006, reporting institutions required a total of 910.7 FTEs for activities associated with licensing and patenting including licensee solicitation, technology valuation, marketing of technology, license agreement drafting and negotiation, and start-up activity efforts (starting a new company based on an academic discovery).<sup>40</sup> AUTM cautions that administration of licenses does not happen all at once. Rather, “as is appreciated by technology transfer practitioners, negotiating license agreements is a process which takes days and weeks over a period of months and sometimes years.”<sup>41</sup>

## Notes

### Section G.1 Benefits-Sharing by the U.S. Government

<sup>1</sup> In 1988, the U.S. National Cancer Institute (NCI) initiated the earliest-known benefits-sharing policy and agreements relating to the collection of biological specimens for use in drug discovery research. The earliest agreements were styled as “Letters of Intent,” which provided very generally for the future sharing of royalties resulting from any commercialization of research results involving research specimens subject to the terms of the agreement. The first such “Letter of Intent” actually used by NCI was reportedly negotiated with Madagascar in 1990. For a history of the development of NCI’s early benefits-sharing approach, see K. ten Kate and A. Wells, “The Access and Benefit-Sharing Policies of the United States National Cancer Institute: A Comparative Account of the Discovery and Development of the Drugs Calanolide and Topotecan,” in *Submission to the Executive Secretary of the Convention on Biological Diversity by the Royal Botanic Gardens, Kew*, 9–14.

<sup>2</sup> See *Gazette Opinion*, “Industries Exploit First Park,” *Billings Gazette*, (December 6, 1994).

<sup>3</sup> See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, at 65-66 (DDC 2000) (“Prior to the CRADA, Diversa or other researchers were free to remove any specimen within the purview of their permit and develop it as they wished. If such development led to commercial uses, the Park Service never saw any proceeds from the derivative products. Thus, recognizing that resources yielding potentially valuable properties were being removed from Yellowstone with no remuneration to Yellowstone or the American people, officials at Interior began to consider a resource management scheme, patterned on the successes of Costa Rica and other nations, which would use bioprospecting to provide funds and incentives for the conservation of biological diversity.”)

<sup>4</sup> Diversa remained subject to all of the restrictions designed to protect NPS resources contained in its pre-existing Scientific Research and Collecting Permits and other underlying NPS regulations. The agreement prohibited the sale or commercial use of research specimens collected in compliance with 36 CFR 2.1.

- <sup>5</sup> The court specifically upheld the Yellowstone–Diversa CRADA as consistent with the conservation mandate of the NPS, and ruled that the NPS had not acted arbitrarily or capriciously in terms of compliance with any of its regulations relating to access to and use of research specimens collected from NPS units. The court specifically noted that Congress had authorized “negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements” in Section 5935 of NPOMA (16 USC § 5935). See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).
- <sup>6</sup> 93 F. Supp. 2d 63, at 72.
- <sup>7</sup> See *Edmonds Institute, et al. v. Babbitt, et al.*, 42 F. Supp. 2d 1 (DDC 1999); 42 F. Supp. 2d 1, at 38; 42 F. Supp. 2d 1, at 37, citing 516 DM 2, App. 2, Section 2.5. The court stated that “there can be no debate that the Yellowstone–Diversa CRADA is a precedent-setting agreement within the National Park System and the DOI in general” (42 F. Supp. 2d 1, at 38). The court also noted that DOI’s NEPA compliance manual provides that actions that “establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects” require NEPA review (42 F. Supp. 2d 1, at 37, citing 516 DM 2, App. 2, Section 2.5).
- <sup>8</sup> 15 USC 3710a(d).
- <sup>9</sup> 15 USC 3710a.
- <sup>10</sup> S.Rep. No. 283, 99th Cong., 2d Sess. (1986), at 11.
- <sup>11</sup> See <<http://www.diversa.com>>. Last accessed April 19, 2006.
- <sup>12</sup> Under the terms of the CRADA that Diversa negotiated with Yellowstone in 1997–1998, Diversa would have been required to report this type of revenue information to Yellowstone on an annual basis. In addition, under the terms of the Yellowstone–Diversa CRADA, this reporting obligation would survive termination of the CRADA. However, because the Yellowstone–Diversa CRADA has been suspended since early 1999, this information is not available to the NPS.
- <sup>13</sup> Report of a special panel of experts on the International Cooperative Biodiversity Groups, 1997, <<http://www.fic.nih.gov/programs/finalreport.html>>, last accessed April 19, 2006.
- <sup>14</sup> *Ibid.*, 14–17.

## Section G.2 Benefit-Sharing Around the World

- <sup>15</sup> See also *Pharmaceutical Biology* 37 (supplement) (1999) (special edition of case studies resulting from multiple ICBG projects).
- <sup>16</sup> See <<http://www.inbio.ac.cr>>, last accessed April 19, 2006.
- <sup>17</sup> INBio’s website identifies 18 separate governmental, academic, and philanthropic institutions and 19 private-sector institutions participating in agreements during the period 1991–2001. Participating research partners include private-sector corporations, academic institutions, philanthropic organizations, and publicly-supported research institutions. See <<http://www.inbio.ac.cr>>.
- <sup>18</sup> See A. Sittenfeld and A. Lovejoy, “INBio’s Biodiversity Prospecting Program: Generating Economic Returns For Biodiversity Conservation,” *Final Compendium for a Practical Workshop on Biodiversity Prospecting for Cameroon, Madagascar and Ghana* (Santo Domingo de Heredia, Costa Rica: Instituto Nacional de Biodiversidad (National Biodiversity Institute), 1995).
- <sup>19</sup> It should be noted that these percentage figures are *not* royalty rates. Rather, they are the percentages INBio is obligated to pay to MINAE under INBio’s underlying cooperative agreement with MINAE from the two different types of monetary benefits INBio has negotiated as part of the benefits-sharing terms of its collaborative biological research agreements. These percentages regard sums INBio is obligated to share with MINAE from revenues generated from collaborative research projects coordinated by INBio that involve Costa Rica’s conservation areas.
- <sup>20</sup> For more information about the Merck–INBio agreement, see, e.g., W. Reid et al., eds., *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development* (Washington, D.C.: World Resources Institute, 1993). Information about access and benefits-sharing regimes and case studies from around the world is provided by a variety of international organizations, governments, the private sector, and NGOs. The World Intellectual Property Organization’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has developed a pilot database of contractual practices and clauses relating to intellectual property, access to genetic resources, and benefits-sharing as a practical tool in the provision of information in this area. Also, the United Nations Convention on Biological Diversity (CBD) makes information about access and benefits-sharing regimes and case studies available through its “Clearing-House Mechanism.” See, e.g., *Synthesis of Case Studies on Benefit-Sharing*, Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity, U.N. Doc. UNEP/CBD/COP/4/Inf/7 (May 4, 1998), available online at <<http://www.biodiv.org/doc/documents.aspx>>, last accessed April 19, 2006. Moreover, the U.N.’s Food and Agriculture Organization’s (FAO) Commission on Genetic Resources for Food and Agriculture handles and reports on access and benefits-sharing with respect to plant and animal genetic resources for food and agriculture. In April 2002, the Sixth Conference of the Parties to the CBD adopted a set of

voluntary guidelines specifically concerning access and benefits-sharing issues. See U.N. Doc. UNEP/CBD/COP/6/20 (April 7–19, 2002) (Decision VI/24, available online at <<http://www.biodiv.org/doc/documents.aspx>>, last accessed April 19, 2006, (“Bonn guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization”). The United States has signed but not ratified the CBD. In 1993, the FAO established the International Code of Conduct for Plant Germplasm Collecting and Transfer. The main concepts underlying the NPS approach and the general principles embodied in the CBD’s Bonn Guidelines and the FAO’s Code of Conduct appear to be in harmony. Finally, at the World Summit for Sustainable Development in Johannesburg, South Africa, in September 2002, the U.S. supported adoption of the Johannesburg Plan of Implementation. Paragraph 44 of that plan reads, in pertinent part, as follows: “A more efficient and coherent implementation of the three objectives of the Convention [on Biological Diversity] and the achievement by 2010 of a significant reduction in the current rate of loss of biological diversity will require the provision of new and additional financial and technical resources to developing countries, and includes actions at all levels to: . . . (n) Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization of the Convention, as an input to assist Parties to the Convention when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contract and other arrangements under mutually agreed terms for access and benefit-sharing.”

- <sup>21</sup> See, e.g., Reid et al., *Biodiversity Prospecting*, 1; A. Sittenfeld and A. Lovejoy, “Biodiversity Prospecting,” in *Our Planet* (Nairobi: U.N. Environment Programme, 1997), 20–21; E. Anderson, *INBio/Merck Agreement: Pioneers in Sustainable Development* (Cambridge: Harvard Business School, 1992), 9. See also Instituto Nacional de Biodiversidad, *Summary of Terms: Collaboration Agreement, INBio-Merck & Co., Inc.* (Santo Domingo de Heredia, Costa Rica: Instituto Nacional de Biodiversidad, 1991).
- <sup>22</sup> According to Sittenfeld and Lovejoy (“INBio’s Biodiversity Prospecting Program,” 11), “INBio enjoys other agreements with a variety of industries reflecting the conviction that one collaboration, or many of the same type of collaboration are unable to effectively fulfill all institutional goals and provide solutions to diverse national problems. Each biodiversity prospecting agreement is different, arising from a separate set of circumstances and responding to varying national, institutional and private enterprise needs.”
- <sup>23</sup> One notable exception relates to the multi-party research project coordinated by INBio between 1993 and 1998 and funded by the International Cooperative Biodiversity Groups program of the National Institutes of Health. A report about this project was prepared by INBio and published in 1999. See *Pharmaceutical Biology* 37 (supplement) (1999), 55–68. According to the report, this project generated research-related funds totaling \$1,650,975 allocated to Costa Rica during the project period (*ibid.*, 67). Of this sum, the report states that \$500,643 was allocated directly to the Guanacaste Conservation Area, and that an additional 10% of the total research budget was allocated to MINAE in accordance with INBio’s pre-existing agreement with MINAE noted in the text.
- <sup>24</sup> N. Mateo, W. Nader, and G. Tamayo. “Bioprospecting,” in *Encyclopedia of Biodiversity, Volume I* (Philadelphia: Academic Press, 2001), 485–486.
- <sup>25</sup> In April 2002, the Sixth Conference of the Parties to the United Nations Convention on Biological Diversity (CBD) adopted a set of voluntary guidelines specifically concerning access and benefits-sharing issues. See U.N. Doc. UNEP/CBD/COP/6/20 (April 7–19, 2002) (Decision VI/24 (“Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization”). Note that although the guidelines are concerned with both access and benefits-sharing, this FEIS is about benefits-sharing only.
- <sup>26</sup> Bonn Guidelines, Appendix II (“Monetary and Non-Monetary Benefits”); *Ibid.*, para. 49.
- <sup>27</sup> According to K. ten Kate and S. A. Laird, “It is relatively common for biotechnology companies to share non-monetary forms of benefit. Companies share information and research results, transfer technology, train their collaborators and contribute to capacity building in the institutions from which they obtain supplies, although this often grows informally during a relationship with a supplier, rather than being prescribed up-front. Companies are prepared to share data and information, provided they can protect confidentiality and the opportunity to patent discoveries” (K. ten Kate and S.A. Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (London: Earthscan Publications Ltd., 1999). See also Mateo, Nader, and Tamayo (“Bioprospecting,” 481): “The experiences of the last few years indicate that monetary benefits (unless royalties would materialize) to host countries, although significant, are limited in comparison to other less tangible benefits such as technology transfer, increased scientific expertise, improvements in legal frameworks, and enhanced negotiating capacities. These less tangible benefits may be poorly understood or underappreciated by some segments of society, who quite rightly are interested in achieving a direct flow of resources and economic benefits to the local communities living near conservation areas.”
- <sup>28</sup> The recommendations outlined in the Bonn Guidelines are noted because they reflect widespread consensus concerning alternative benefits-sharing management approaches notwithstanding the fact that they are voluntary and require adaptation to local legal and administrative circumstances and

needs. For many years, some observers, particularly in the media, have noted similarities between the issues relating to benefits-sharing that have arisen within the context of the National Park Service and in ongoing developments abroad (see, e.g., R. Wolf, “Yellowstone discovery: Should U.S. get the profits?” *San Jose Mercury News* (July 25, 1994): 1F; see also C. Macilwain, “When Rhetoric Hits Reality in Debate on Bioprospecting,” *Nature* (April 9, 1998):535–540).

<sup>29</sup> See <<http://www.biodiv.org>>. Information about access and benefits-sharing case studies from around the world has been collected by a variety of international organizations, governments, the private sector, and NGOs. The CBD Secretariat also makes information about access and benefits-sharing case studies available through its “Clearing-House Mechanism” (See, e.g., Synthesis of Case Studies on Benefit-Sharing, Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity, U.N. Doc.UNEP/CBD/COP/4/Inf/7 (4 May 1998). See also the benefits-sharing case studies reported by the CBD Secretariat at <<http://www.biodiv.org>>). The case studies collected and reported by the CBD Secretariat represent a very wide range of context-specific experiences and approaches from many different parts of the world. For example, in many cases, “benefits” also are part of the negotiation for “access.” Also, the number and interests of the parties to different agreements in different parts of the world also are very different. For example, in some cases there are several intermediaries between the provider(s) of biological materials and the user(s); in other cases, the relationship is direct.

### Section G.3 Commercial Use of Research Results Discovered By Federal or Academic Scientists

<sup>30</sup> See U.S. Department of Commerce, “Summary Report on Federal Laboratory Technology Transfer (FY 2003 Activity Metrics and Outcomes),” *2004 Report to the President and the Congress under the Technology Transfer and Commercialization Act* (hereinafter referred to as “DOC 2004 Technology Transfer Report”).

<sup>31</sup> 15 USC 3701(3). See also 15 USC 3702. This policy has been implemented throughout the federal government via a series of legislative initiatives, including, most notably, the Technology Innovation Act of 1980, often referred to as the Stevenson-Wydler Act (15 USC 3701–3714); the University and Small Business Patent Procedures Act of 1980, often referred to as the Bayh-Dole Act (35 USC 200–211); and the FTTA (15 USC 3710a *et seq.*).

<sup>32</sup> *DOC 2004 Technology Transfer Report*, 17. This report does not contain information regarding DOI CRADAs for FY2002 or FY 2003. The Department of the Interior’s CRADA policy was outlined in May 1996 in the Department’s handbook, *Technology Transfer: Marketing Our Products and Technologies (A Training Handbook for the U.S. Department of the Interior*. The guidelines were revised in 1998.

<sup>33</sup> U.S. Department of Commerce, “Summary Report on Federal Laboratory Technology Transfer (Agency Approaches; FY 2001 Activity Metrics and Outcomes),” *2002 Report to the President and the Congress under the Technology Transfer and Commercialization Act* (September 2002), 88. See also *ibid.*, Chapter 2 (specific agency reports).

<sup>34</sup> *Ibid.*, 12, 24, 38, 50.

<sup>35</sup> *DOC 2004 Technology Transfer Report*, 37.

<sup>36</sup> The proposal under evaluation in this FEIS similarly concerns research results related to the study of (mostly) biological materials.

<sup>37</sup> *DOC 2004 Technology Transfer Report*, 11.

<sup>38</sup> *Ibid.*, 60, 122.

<sup>39</sup> Association of University Technology Managers, Inc., *AUTM Licensing Survey, FY 2002: A Survey Summary of Technology Licensing (and Related) Performance for U.S. And Canadian Academic and Nonprofit Institutions, and Patent Management Firms* (2003), available online at <<http://www.autm.org/surveys/dsp.surveyDetail.cfm?pid=16>>, last accessed April 12, 2006.

<sup>40</sup> *AUTM Licensing Survey, FY2002*, 18, 43.

<sup>41</sup> Association of University Technology Managers, Inc. *AUTM Licensing Survey, FY 2001: A Survey Summary of Technology Licensing (and Related) Performance for U.S. And Canadian Academic and Nonprofit Institutions, and Patent Management Firms* (2002), 16, available online at <<http://www.autm.org/surveys/dsp.surveyDetail.cfm?pid=17>>, last accessed April 12, 2006.

# **Appendix H**

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## **Supplemental Information about NPS Research Permitting**

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This appendix contains the procedures and requirements for applying for an NPS scientific research and collecting permit and a sample NPS research permit. The first two documents are posted on the Research Permit and Reporting System (RPRS) website (<http://rprs.nps.gov/research/>). Prospective and current researchers use the RPRS website to apply for or renew NPS research permits. The documents provide instructions to researchers who want to apply for an NPS research permit. None of the actions proposed in this EIS would change the policies or procedures that protect park resources embodied in or illustrated by the documents in this appendix.

***Documents begin next page***

# APPLICATION PROCEDURES AND REQUIREMENTS FOR SCIENTIFIC RESEARCH AND COLLECTING PERMITS



## United States Department of the Interior National Park Service

### **POLICY AND GENERAL REQUIREMENTS**

The National Park Service (NPS) welcomes your interest in considering national parks for your research site. The NPS is responsible for protecting in perpetuity and regulating use of our National Park areas (parks, monuments, battlefields, seashores, recreation areas, etc.). Preserving park resources unimpaired and providing appropriate visitor uses of parks require a full understanding of park natural resource components, their interrelationships and processes, and visitor interests that can be obtained only by the long term accumulation and analysis of information produced by science. The NPS has a research mandate to provide management with that understanding, using the highest quality science and information. Superintendents increasingly recognize that timely and reliable scientific information is essential for sound decisions and interpretive programming. NPS welcomes proposals for scientific studies designed to increase understanding of the human and ecological processes and resources in parks and proposals that seek to use the unique values of parks to develop scientific understanding for public benefit.

#### **When is a permit required?**

A Scientific Research and Collecting Permit is required for most scientific activities pertaining to natural resources or social science studies in National Park System areas that involve fieldwork, specimen collection, and/or have the potential to disturb resources or visitors. When permits are required for scientific activities pertaining solely to cultural resources, including archeology, ethnography, history, cultural museum objects, cultural landscapes, and historic and prehistoric structures, other permit procedures apply. The park's Research and Collecting Permit Office or Headquarters can provide copies of NPS research-related permit applications and information regarding other permits. Federally funded collection of information from the public, such as when formal surveys are used, may require approval from the Office of Management and Budget.

NPS superintendents may authorize their staff to carry out official duties without requiring an NPS research and collecting permit. NPS staff must comply appropriately with professional standards and with all conditions normally associated with scientific research and collecting permits issued by the park. All other natural and social science research and data collection in a park requires a Scientific Research and Collecting Permit and will be allowed only pursuant to the terms and conditions of the permit.

#### **Additional required permits, approvals, and agreements**

In some cases, other federal or state agency permits or approvals may be required before NPS staff can process an application for a Scientific Research and Collecting Permit. Examples include U.S. Fish and Wildlife Service threatened and endangered species permits and migratory bird permits and approvals by an Institutional Animal Care and Use Committee. It is the responsibility of the principal investigator to provide NPS with copies of such permits when they submit an application. Applicants are encouraged to contact park staff to determine if additional permits may be required in conjunction with a proposed study.

Separate agreements between the investigator and NPS are required when proposed studies or collected specimens are intended to support commercial research activities.

### **Who may apply?**

Any individual may apply if he/she has qualifications and experience to conduct scientific studies or represents a reputable scientific or educational institution or a federal, tribal, or state agency.

### **When to apply?**

We recommend that you apply at least 90 days in advance of your first planned field activities. Projects requiring access to restricted locations or proposing activities with sensitive resources, such as endangered species or cultural sites, usually require extensive review and can require 90 days or longer for a permitting decision. Simple applications can often be approved more quickly.

### **How and where to apply?**

An individual may obtain application materials via the Internet (find “Research Permit and Reporting System” at <http://science.nature.nps.gov/research> or through [www.nps.gov](http://www.nps.gov)) or by contacting the park in which the work will be conducted. Addresses for NPS areas are listed on the NPS Internet web site ([www.nps.gov](http://www.nps.gov)) or may be obtained by contacting the NPS Public Affairs Office via telephone number 202-208-4747. All application materials must be submitted to the NPS area in which you plan to work. You may submit this information via Internet or traditional postal service.

### **Study proposals**

Applications for Research and Collecting Permits must include a research proposal. Proposals must include, as appropriate, all elements outlined in the separate document *Guidelines to Researchers for Study Proposals*.

### **Review of proposals**

Each proposal will be reviewed for compliance with National Environmental Policy Act (NEPA) requirements and other laws, regulations, and policies. The superintendent may also require internal and/or external scientific review, depending on the complexity and sensitivity of the

work being proposed and other factors. You can expedite review of your proposal by providing photocopies of existing peer reviews, or by providing names, mailing addresses, and email addresses of persons that you wish to recommend to review your proposal. Specific details about the review process may be included with the application materials provided by that park.

### **Facilitating a favorable decision**

The superintendent makes a decision to approve a research and collecting permit based on an evaluation of favorable and unfavorable factors (see examples, below), and on an assessment of perceived risks and benefits. While park managers will work with applicants to arrive at a mutually acceptable research design, there may be activities where no acceptable mitigating measures are possible and the application may be denied.

The time and effort required to review the permit application and accompanying study proposal will be proportional to the type and magnitude of the proposed research. For example, a single visit for a non-manipulative research project will often require a relatively simple proposal and the permitting decision should be relatively fast. A highly manipulative or intrusive investigation, however, with the potential to affect non-renewable, rare, or delicate resources, needing detailed planning or logistics, would receive more extensive review. Some of the predisposing factors that influence permitting decisions are outlined below.

### **Favorable factors**

The proposed research:

- contributes information useful to an increased understanding of park resources, and thereby contributes to effective management and/or interpretation of park resources; provides for scheduled sharing of information with park staff, including any manuscripts, publications, maps, databases, etc., which the researcher is willing to share;
- addresses problems or questions of importance to science or society and shows promise of making an important contribution to humankind's knowledge of the subject matter;
- involves a principal investigator and support team with a record of accomplishments in the proposed field of investigation and with a demonstrated ability to work cooperatively and safely, and to accomplish the desired tasks within a reasonable time frame;
- provides for the investigator(s) to prepare occasional summaries of findings for public use, such as seminars and brochures;
- minimizes disruption to the park's natural and cultural resources, to park operations, and to visitors;
- discusses plans for the cataloging and care of collected specimens;
- clearly anticipates logistical needs and provides detail about provisions for meeting those needs; and
- is supported academically and financially, making it highly likely that all fieldwork, analyses, and reporting will be completed within a reasonable time frame.

### **Unfavorable factors**

The proposed research:

- involves activities that adversely affect the experiences of park visitors;

- shows potential for adverse impact on the park's natural, cultural, or scenic resources, and particularly to non-renewable resources such as archeological and fossil sites or special-status species (the entire range of adverse impacts that will be considered also includes construction and support activities, trash disposal, trail conditions, and mechanized equipment use in sensitive areas);
- shows potential for creating high risk of hazard to the researchers, other park visitors, or environments adjacent to the park;
- involves extensive collecting of natural materials or unnecessary replication of existing voucher collections; requires substantial logistical, administrative, curatorial, or project monitoring support by park staff; or provides insufficient lead time to allow necessary review and consultation;
- is to be conducted by a principal investigator lacking scientific institutional affiliation and/or recognized experience conducting scientific research; and
- lacks adequate scientific detail and justification to support the study objectives and methods.

### **Park response**

The principal investigator should receive notice of the approval or rejection of the application by written correspondence via mail, electronic mail, or facsimile. If modifications or changes in a study proposal initially deemed unacceptable would make the proposal acceptable, the park may suggest them at this time. If the application is rejected, the applicant may consult with the appropriate NPS Regional Science Advisor to clarify issues and assess the potential for reconsideration by the park.

### **Permittee response**

If your permit request is approved by the park, you will receive a copy of the permit that you must sign and return to the park via mail or fax. Once the park receives a copy of the permit that you have signed, appropriate NPS officials will validate it and return an approved copy to you. You must carry a copy of the approved permit at all times while performing your research or collecting in the park.

### **Permit stipulations**

*General Conditions* (requirements and restrictions) will be attached to all Research and Collecting Permits issued. These conditions must be adhered to by permit recipients. Additional Park-specific Conditions may also be included that address unique park resources or activities. An NPS permit is valid only for the activities authorized in the permit. The principal investigator must notify the NPS in writing of any proposed changes. Requests for significant changes may necessitate re-evaluation of the permit conditions or development of a revised proposal.

### **Access permit requirements**

Some NPS areas require access permits for off-road travel, camping, and other activities. Access to many areas is limited and popular destinations can be booked several months in advance.

Please contact the park's Research and Collecting Permit Office to obtain information on any needed access permits.

### **Research products and deliverables**

Researchers working in NPS areas are required to complete an NPS Investigator's Annual Report form for each year of the permit, including the final year. The NPS maintains a system enabling researchers to use the Internet to complete and submit the Investigator's Annual Report. NPS staff will contact permit holders near the beginning of each calendar year to request the prior year's report and explain how to access and use the system. Investigator's Annual Reports are used to consistently document accomplishments of research conducted in parks. Principal investigators are responsible for the content of their reports. NPS staff will not modify reports received unless requested to do so by the principal investigator responsible for the report.

Park research coordinators may request copies of field notes, data, reports, publications and/or other materials resulting from studies conducted in NPS areas. Additional deliverables may be required of studies involving NPS funding or participation.

### **Privacy Act and Paperwork Reduction Act**

NPS regulations (36 CFR 2.1) prohibit possessing, destroying, injuring, defacing, removing, digging, or disturbing from their natural state in any form animals, plants, paleontological, or mineral resources. NPS regulations (36 CFR 2.5) require researchers wishing to conduct research involving acts prohibited by other regulations, such as CFR 2.1, to obtain a specimen collection permit. The National Parks Omnibus Management Act of 1998 (Public Law 105-391) encourages use of parks for science, encourages publication of the results of research conducted in parks, and requires that research conducted in parks be consistent with park laws and management policies. This law also requires that research be conducted in a manner that poses no threat to park resources or public enjoyment. National Park Service Management Policies state that research activities that might disturb resources or visitors, that require the waiver of any regulation, or that involve the collection of specimens may be allowed only pursuant to terms and conditions of an appropriate permit.

The information you submit in your Application for a Scientific Research and Collecting Permit will be used by park managers to determine whether or not to issue you a Scientific Research and Collecting Permit. The information you submit in your Investigator's Annual Report will be used by park managers to inform resource management decision-makers, park visitors, the public, and other researchers about the objectives and progress results of your research.

Parks and park records are public assets. The information you submit in your Application and in your Investigator's Annual Report is not confidential and will be in the public record and available to the public. If you want to receive and maintain a Scientific Research and Collecting Permit, you must respond to both the Application and Investigator's Annual Report collections of information. If you do not respond to the request for information in the Application, you will not be considered for a Scientific Research and Collecting Permit. If you have received a Scientific Research and Collecting Permit and do not respond to the request for information in

the Investigator's Annual Report, your permit may be revoked and you may be denied future permits.

The Application for a Scientific Research and Collecting Permit and the Investigator's Annual Report are two parts of one complete process dealing with conducting scientific research and collecting in a unit of the National Park System. The total public reporting burden involved in electronically completing the collection of information process for a single scientific research and collecting activity in a unit of the National Park System includes the burden of reading the informational documents associated with these two information collection forms plus completing and submitting one Application form (approximately 45 minutes), plus the burden of signing and mailing an issued permit back to the park (approximately 15 minutes), plus the burden of completing one associated Investigator's Annual Report form (approximately 15 minutes). Some applicants will experience an additional burden of photocopying and mailing attachments (approximately 15 minutes). Other applicants will experience an additional burden of coordinating with a specimen repository (approximately 30 minutes). The total public reporting burden experienced by a successful permittee for electronically completing this process for a single scientific research and collecting activity in a unit of the National Park System thus is estimated to range between 1.25 and 2.0 hours per year. The total public reporting burden experienced by an unsuccessful applicant for electronically completing this process is estimated to be about 45 minutes per year because the unsuccessful applicant will not be required to complete the Investigator's Annual Report, mail a signed permit, or respond to other portions of the process. The few applicants who complete these forms manually are expected to experience a somewhat larger annual reporting burden. Direct any comments you may have regarding this burden estimate or any other aspect of this information collection process or of its two forms to the Office of Information and Regulatory Affairs of OMB, Attention Desk Officer for the Interior Department, Office of Management and Budget, Washington, DC 20503; and to the Information Collection Clearance Officer, WASO Administrative Program Center, National Park Service, 1849 C Street, N.W., Washington, DC 20240.

# GUIDELINES TO RESEARCHERS FOR STUDY PROPOSALS



## United States Department of the Interior National Park Service

Your proposal should include each of the required information items listed below, in enough detail that an educated non-specialist can understand exactly what you plan to do. If you have already prepared a relevant proposal for a funding application, work plan, formal agreement, or similar document, then your original proposal likely will satisfy National Park Service (NPS) proposal requirements. The primary area where new information may be necessary concerns the ability of the park to assess what, if any, impacts your research may have on park resources. You should compare your original proposal to these guidelines to be certain that you have provided all the required information. If additional information is required, you can provide it in a cover letter or supplement to your proposal, as appropriate. If a required topic does not apply to your proposed study, simply list the topic and write “not applicable.”

The length of your proposal depends primarily on the complexity of the work planned. In some cases, a proposal may consist of a couple of pages for a study expected to have no significant impact on park resources or visitor experiences. However, proposals for lengthy or complex research problems, for extensive collecting, and for work with special status species or sensitive cultural resources are typically longer, more detailed, and well-organized. Incomplete, disorganized, or illegible proposals may be returned for revision.

### I. INTRODUCTION

A. **Title**

B. **Date of proposal**

C. **Investigators** - Provide the name, title, address, telephone number, FAX number, email address, and institutional affiliation of the principal investigator and the name and affiliation of all additional investigators listed in the proposal.

D. **Table of contents** - Recommended for long or complicated proposals.

E. **Abstract** - Provide a brief summary description of the proposed project. Include up to five keywords that can be used by the NPS to quickly identify the proposal subject (for example, microbiology, geology, ecology).

II. **OVERVIEW** - Summarize the proposed project by describing in general the problem or issue being investigated as well as any previous pertinent research.

- A. **Statement of issue** - Describe the issue to be investigated and its importance and relevance to science and to the park. Provide relevant background information that clarifies the need for the project and why it is valuable for the research and/or collecting to be conducted in the park.
  - B. **Literature summary** - Summarize the relevant literature regarding the issue, problem, or questions that will be investigated.
  - C. **Scope of study** - Describe the overall geographic and scientific scope of the project.
  - D. **Intended use of results** - Describe how the products will be used, including any anticipated commercial use.
- III. **OBJECTIVES/HYPOTHESES TO BE TESTED** - Describe the specific objectives of the proposed project. Where appropriate, the objectives should be stated as specific hypotheses to be tested.
- IV. **METHODS** - Describe how the proposed methods and analytical techniques will achieve the study objectives or test the stated hypothesis/question. Provide pertinent literature citations.
- A. **Description of study area** – Clearly describe the study area in terms of park name(s), geographic location(s), and place names. Provide maps, park names, or geographic coordinates as appropriate. Indicate whether your work will take place in an area designated or managed as “wilderness” by the NPS.
  - B. **Procedures** - Describe the proposed study design that addresses the stated objectives and hypotheses. Explain the methods and protocols to be employed in the field and laboratory.
  - C. **Collections** - Describe the type, size, and quantity of specimens or materials to be collected, sampled, or captured, and your plans to remove them from the collecting site. If you are aware specimens of the proposed types already exist in a repository, explain why additional collecting is necessary. Provide scientific nomenclature where possible. Provide information on all other applicable federal or state permits where required.
  - D. **Analysis** - Explain how the data from the study will be analyzed to meet the stated objectives or test the hypotheses. Include any statistical techniques or mathematical models necessary to the understanding of the analysis.
  - E. **Schedule** - Provide a schedule that includes start of project, approximate dates or seasons of fieldwork, analysis, reporting, and completion dates.

- F. **Budget** - Briefly outline the expenses associated with this project and identify your expected funding source(s). Include the anticipated costs pertaining to the cataloging of collected and permanently retained specimens or materials.

## V. **PRODUCTS**

- A. **Publications and reports** - Describe the expected publications or reports that will be generated as part of this study.
- B. **Collections** – Describe the proposed disposition of collected specimens or materials. If you propose that the NPS lend the specimens or samples to a non-NPS institution for long-term storage, identify that institution and give a brief justification for this proposal.
- C. **Data and other materials** - Describe any other products to be generated as part of the project, such as, photographs, maps, models, handouts, exhibits, software presentations, raw data, GIS coverages, or videos, and the proposed disposition of these materials. If data are to be collected from the public as part of this study, provide a copy of the data collection instrument (survey, questionnaire, interview protocol, etc.).

- VI. **LITERATURE CITED** - Include full bibliographic citations for all reports and publications referenced in the proposal.

- VII. **QUALIFICATIONS** - Provide a background summary or curriculum vitae for the principal investigator and other investigators listed in the proposal. Identify their training and qualifications relevant to the proposed project and their ability to conduct field activities in the environment of the proposed study area. Describe previous research and collecting in NPS areas, including study and permit numbers if available.

- VIII. **SUPPORTING DOCUMENTATION AND SPECIAL CONCERNS** - Provide information on the following topics where applicable. Attach copies of any supporting documentation that will facilitate processing of your application, such as other required federal and state permits, copies of peer reviews, letters of support and funding commitments, and certifications. Collection of information from the public when federal funds are used may require approval from the Office of Management and Budget (OMB). Upon your request, the NPS Social Science Program will advise you on steps needed to obtain this OMB approval.

- A. **Safety** - Describe any known potentially hazardous activities, such as electrofishing, rock climbing, scuba diving, whitewater boating, aircraft use, wilderness travel, wildlife capture, handling or immobilization, use of explosives, etc.

- B. **Access to study sites** - Describe the proposed method and frequency of travel to and within the study site(s). Explain any need to enter restricted areas. Describe duration, location, and number of participants for planned backcountry camping.
- C. **Use of mechanized and other equipment** - Describe any field equipment, markers, or supply caches by type, number, and location. You should explain how long they are to be left in the field. Explain the need to use these materials in restricted areas and the alternatives that were considered.
- D. **Chemical use** - Identify any chemicals and hazardous material that you propose using within the park. Indicate the purpose, method of application, and amount to be used. Describe plans for storage, transfer, and disposal of these materials and describe steps to remediate accidental releases into the environment. Attach copies of Material Safety Data Sheets.
- E. **Ground disturbance** - Describe the type, location, area, depth, number, and distribution of expected ground-disturbing activities, such as soil pits, cores, stakes, or latrines. Describe plans for site restoration of significantly affected areas.

Proposals that entail ground disturbance may require an archeological survey and special clearance prior to approval of the study. You can help reduce the extra time that may be required to process such a proposal by including identification of each ground disturbance area on a USGS 7.5-minute topographic map.

- F. **Animal welfare** - For vertebrate species that require review by your Institutional Animal Care and Use Committee (IACUC) according to the Animal Welfare Act, please include a photocopy of the study protocol, and IACUC review form and approval.

For vertebrate species not requiring IACUC review, describe your protocol for any capture, holding, marking, tagging, tissue sampling, or other handling of these animals (including the training and qualifications of personnel relevant to animal handling and care). Please discuss alternative techniques considered and outline any procedures to alleviate pain or distress. Include contingency plans to be implemented in the event of accidental injury to or death of the animal.

- G. **NPS assistance** - Describe any NPS field assistance you would like to receive to complete the proposed study, such as use of equipment or facilities or assistance from staff.
- H. **Wilderness “minimum requirement” protocols** - If some or all of your activities will be conducted within a location administered by the NPS as a designated, proposed, or potential wilderness area, your proposal should describe how the project adheres to wilderness “minimum requirement” and “minimum tool” concepts. Refer to the park’s wilderness management plan for further information.

SCIENTIFIC RESEARCH AND COLLECTING PERMIT		<b>Study#:</b> XXXX-000000
Grants permission in accordance with the attached general and special conditions		<b>Permit#:</b> YELL-2007-SCI-0000
	<b>United States Department of the Interior National Park Service</b>	<b>Start Date:</b> XX/XX/XXXX
	Name of Park Unit	<b>Expiration Date:</b> XX/XX/XXXX
		<b>Coop Agreement#:</b>
		<b>Optional Park Code:</b>

**Name of principal investigator:**

**Name:** SAMPLE    **Phone:** 000-000-0000    **email:** sample@university.edu

**Name of institution represented:**

Sample University

**Additional investigator(s):**

Full Name	Phone	Email
sample	000-000-0000	sample@university.edu

**Project title:**

Do species matter in microbial communities?

**Purpose of study:**

The researcher's explanation of the purpose of the study appears here.

**Subject/Discipline:**

Subject identified here.

**Locations authorized:**

Exact locations for research activities are specified here.

**Transportation method to research site(s):**

For example, Vehicle and foot/skis.

**Collection of the following specimens or materials, quantities, and any limitations on collecting:**

The exact locations for specimen collection are identified here.  
The precise kinds of specimens (species, type, etc.) are specified.  
The maximum allowable quantity of collections are specified.

**Name of repository for specimens or sample materials if applicable:**

**Repository Type:** For example, a museum.

**Objects Collected:**

See above collections.

**Specific conditions or restrictions (also see attached conditions):**

EXAMPLES OF CONDITIONS SUBJECT TO THIS SPECIFIC PERMIT

1. A permittee may be required to provide somebody in his team to talk to visitors and explain the research activities that the visitors can observe.
2. A permittee may be required to take a certain route to access their research site for resource protection or safety reasons.

EXAMPLES OF CONDITIONS SUBJECT TO ALL PERMITS FOR THIS PARK

1. You are responsible for the research-related activities of your staff. Please ensure that all field staff adhere to all conditions of your permit. Field staff must possess a copy of your permit at all times while in the field.
2. When working in this park, you **MUST** notify in advance the ranger in charge of your work area/s. A contact list and map will be provided to you. Please make a good faith effort to call at least one week prior to your arrival at the park. This contact is especially important if you will be parked along the road for extensive periods, if you are staying overnight in the backcountry, or if you are working off-trail. If after several attempts you are still unable to reach the ranger, please call the Research Permit Office and we will assist you with reaching the area ranger/s. If you have an emergency and are trying to reach a ranger, CALL 911.
3. Unless otherwise authorized on your permit, you must carry out all of your activities out of public view. If you have obtained special permission to collect in front-country areas, you may be required to arrange for a uniformed escort.
4. If you collect specimens that are to be permanently retained, regardless of where they are kept, they must be accessioned and cataloged into the National Park Service's Automated National Catalog System, and must bear National Park Service accession and catalog numbers. For assistance, contact the Curator's office at (123) 123-1234.
5. All equipment left in the field including plot markers must be specifically authorized in advance. Label all equipment with your name, date of installation, phone number, and the words "Research Study #XXXX." If you are authorized to place equipment or plot markers in this park, you will be required to GPS their locations.
6. All VHF and GPS collars on wildlife must be camouflaged to blend in with the animal. The antennas on the collars must also be as invisible as possible. All collars must be removed at the completion of the study by either blow-off capabilities or cotton (rot-away) spacers.
7. Specific authorization must be obtained in advance before using chemicals or hazardous materials in this park. For specific information regarding the transport, use, and disposal of chemicals or hazardous materials, please contact the Research Permit Office.
8. Your research permit does not authorize you to enter closed or restricted areas in this park. Examples of restricted areas include most service roads, bear management areas, some thermal areas, some bird nesting areas, wolf den sites, and trout spawning areas.
9. Cultural resources must not be adversely impacted by your research activities. Any ground disturbances must be specifically authorized in advance. Report any findings of artifacts such as lithic scatters or historical trash to the Research Permit Office.
10. If your research requires flying in the park, you must request authorization in advance. You must also comply with FAA and Park flight regulations. Please contact the

Research Permit Office for details.

11. Your permit does not authorize the bearer or those that accompany them to conduct commercial filming activities. Commercial film permits must be obtained from the Public Affairs Office (123-123-1234).

#### CONDITIONS SUBJECT TO ALL NATIONAL PARK SERVICE RESEARCH PERMITS

1. Authority - The permittee is granted privileges covered under this permit subject to the supervision of the superintendent or a designee, and shall comply with all applicable laws and regulations of the National Park System area and other federal and state laws. A National Park Service (NPS) representative may accompany the permittee in the field to ensure compliance with regulations.

2. Responsibility - The permittee is responsible for ensuring that all persons working on the project adhere to permit conditions and applicable NPS regulations.

3. False information - The permittee is prohibited from giving false information that is used to issue this permit. To do so will be considered a breach of conditions and be grounds for revocation of this permit and other applicable penalties.

4. Assignment - This permit may not be transferred or assigned. Additional investigators and field assistants are to be coordinated by the person(s) named in the permit and should carry a copy of the permit while they are working in the park. The principal investigator shall notify the park's Research and Collecting Permit Office when there are desired changes in the approved study protocols or methods, changes in the affiliation or status of the principal investigator, or modification of the name of any project member.

5. Revocation - This permit may be terminated for breach of any condition. The permittee may consult with the appropriate NPS Regional Science Advisor to clarify issues resulting in a revoked permit and the potential for reinstatement by the park superintendent or a designee.

6. Collection of specimens (including materials) - No specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting permit. The general conditions for specimen collections are:

- Collection of archeological materials without a valid Federal Archeology Permit is prohibited.
- Collection of federally listed threatened or endangered species without a valid U.S. Fish and Wildlife Service endangered species permit is prohibited.
- Collection methods shall not attract undue attention or cause unapproved damage, depletion, or disturbance to the environment and other park resources, such as historic sites.
- New specimens must be reported to the NPS annually or more frequently if required by the park issuing the permit. Minimum information for annual reporting includes specimen classification, number of specimens collected, location collected, specimen status (e.g., herbarium sheet, preserved in alcohol/formalin, tanned and mounted, dried and boxed, etc.), and current location.
- Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization.
- Each specimen (or groups of specimens labeled as a group) that is retained permanently must bear NPS labels and must be accessioned and cataloged in the NPS National Catalog. Unless exempted by additional park-specific stipulations, the permittee will complete the labels and catalog records and will provide accession information. It is the permittee's responsibility to contact the park for cataloging

instructions and specimen labels as well as instructions on repository designation for the specimens.

- Collected specimens may be used for scientific or educational purposes only, and shall be dedicated to public benefit and be accessible to the public in accordance with NPS policies and procedures.

- Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a Cooperative Research And Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS. The sale of collected research specimens or other unauthorized transfers to third parties is prohibited. Furthermore, if the permittee sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without a CRADA or other approved benefit-sharing agreement with NPS, permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled including but not limited to injunctive relief against the permittee.

7.Reports - The permittee is required to submit an Investigator's Annual Report and copies of final reports, publications, and other materials resulting from the study. Instructions for how and when to submit an annual report will be provided by NPS staff. Park research coordinators will analyze study proposals to determine whether copies of field notes, databases, maps, photos, and/or other materials may also be requested. The permittee is responsible for the content of reports and data provided to the National Park Service.

8.Confidentiality - The permittee agrees to keep the specific location of sensitive park resources confidential. Sensitive resources include threatened species, endangered species, and rare species, archeological sites, caves, fossil sites, minerals, commercially valuable resources, and sacred ceremonial sites.

9.Methods of travel - Travel within the park is restricted to only those methods that are available to the general public unless otherwise specified in additional stipulations associated with this permit.

10.Other permits - The permittee must obtain all other required permit(s) to conduct the specified project.

11.Insurance - If liability insurance is required by the NPS for this project, then documentation must be provided that it has been obtained and is current in all respects before this permit is considered valid.

12.Mechanized equipment - No use of mechanized equipment in designated, proposed, or potential wilderness areas is allowed unless authorized by the superintendent or a designee in additional specific conditions associated with this permit.

13.NPS participation - The permittee should not anticipate assistance from the NPS unless specific arrangements are made and documented in either an additional stipulation attached to this permit or in other separate written agreements.

14.Permanent markers and field equipment - The permittee is required to remove all markers or equipment from the field after the completion of the study or prior to the expiration date of this permit. The superintendent or a designee may modify this requirement through additional park specific conditions that may be attached to this permit. Additional conditions regarding the positioning and identification of markers and field equipment may be issued by staff at individual parks.

15.Access to park and restricted areas - Approval for any activity is contingent on the park being open and staffed for required operations. No entry into restricted areas is

allowed unless authorized in additional park specific stipulations attached to this permit.

16. Notification - The permittee is required to contact the park's Research and Collecting Permit Office (or other offices if indicated in the stipulations associated with this permit) prior to initiating any fieldwork authorized by this permit. Ideally this contact should occur at least one week prior to the initial visit to the park.

17. Expiration date - Permits expire on the date listed. Nothing in this permit shall be construed as granting any exclusive research privileges or automatic right to continue, extend, or renew this or any other line of research under new permit(s).

18. Other stipulations - This permit includes by reference all stipulations listed in the application materials or in additional attachments to this permit provided by the superintendent or a designee. Breach of any of the terms of this permit will be grounds for revocation of this permit and denial of future permits.

THIS PERMIT SERVES AS YOUR GATE PASS THROUGH 12/31/07.

**Recommended by park staff (name and title):**

\_\_\_\_\_

**Approved by park official:**

\_\_\_\_\_

**Title:**

\_\_\_\_\_

**Reviewed by Collections Manager:**

Yes \_\_\_ No \_\_\_

**Date Approved:**

\_\_\_\_\_

**I Agree To All Conditions And Restrictions Of this Permit As Specified**

(Not valid unless signed and dated by the principal investigator)

\_\_\_\_\_  
**(Principal investigator's signature)**

\_\_\_\_\_  
**(Date)**

**THIS PERMIT AND ATTACHED CONDITIONS AND RESTRICTIONS MUST BE CARRIED AT ALL TIMES WHILE CONDUCTING RESEARCH ACTIVITIES IN THE DESIGNATED PARK(S)**

# **Appendix I**

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## **Key Judicial Decisions**

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## **I.1 Introduction**

This appendix provides the text of two judicial decisions by the U. S. District Court in the District of Columbia, that reviewed issues directly related to the Yellowstone–Diversa CRADA. The decisions (issued in March 1999 and April 2000) addressed different parts of the plaintiffs’ claims against the NPS. (*See also* Chapter 1, Section 1.7 for a brief overview of relevant laws (Sections 1.7.1 and 1.7.2), regulations (Section 1.7.3), policies (Sections 1.7.4 and 1.7.5), and additional judicial decisions (Section 1.7.6) applicable to this EIS).

## **I.2 What Happened in Court?**

### **I.2.1 Edmonds Institute, et al. v. Babbitt, et al., 42 F. Supp. 2d 1 (D.D.C. 1999)**

Plaintiffs filed an action alleging that the Yellowstone–Diversa CRADA violated the Federal Technology Transfer Act of 1986, the National Park Service Organic Act, the Yellowstone National Park Organic Act, the National Environmental Policy Act, the Administrative Procedure Act and the so-called public trust doctrine. In the first (March 1999) decision, the court dismissed the plaintiffs’ claim that the National Park Service (NPS) had violated the public trust doctrine and ruled that the NPS had failed to demonstrate compliance with NEPA. The court ordered the NPS to conduct “any and all review mandated by [NEPA].” The court also explained that “[t]he Court is concerned here solely with enforcing the procedural requirements of NEPA” (March 1999 decision, footnote 12); and, that the court’s role is “to ensure that the agencies act through the process mandated by Congress in reaching their substantive determination.”

### **I.2.2 Edmonds Institute, et al. v. Babbitt, et al., 93 F. Supp. 2d 63 (D.D.C. 2000)**

In its final (April 2000) decision, the court dismissed with prejudice all of the plaintiffs’ remaining claims. Specifically, the court ruled that the Yellowstone–Diversa CRADA was consistent with the mandates of the NPS and Yellowstone Organic Acts, NPS regulations and the Federal Technology Transfer Act of 1986; does not authorize an impermissible “consumptive use” of park resources as alleged by plaintiffs; does not conflict with the conservation mandate of the NPS and Yellowstone Organic Acts as alleged by plaintiffs; does not involve the “sale or commercial use” of park resources as alleged by the plaintiffs; and, noted “in certain respects the CRADA may impose restrictions on Diversa’s research activities over and above those provided in a permit.”

The court noted that Congress specifically authorized the NPS to negotiate “equitable, efficient benefits-sharing arrangements” with researchers who study NPS resources (quoting the National Parks Omnibus Management Act of 1998, 16 U.S.C. § 5935(d)).

## **I.3 What Was the Effect of the Court Case?**

To comply with the District Court's order and NEPA, the NPS published the Benefits-Sharing DEIS for public review on September 22, 2006, and accepted comments on the DEIS through January 29, 2007. The NPS developed the alternatives presented in the draft EIS in response to earlier public scoping comments, received during June–August 2001 and April–May 2002.

The NPS suspended the Yellowstone–Diversa CRADA while the EIS process is being completed. With the CRADA suspended, neither Diversa nor Verenum Corporation (in June 2007, Diversa merged with Celunol Corporation to form Verenum) has had any obligation to Yellowstone from its marketing of at least one new product developed from research first started at Yellowstone.

The NPS has not and will not enter into any other benefits-sharing agreements unless the EIS process ends with a decision to implement benefits-sharing. Research that might yield valuable new discoveries and inventions has continued in the national parks in compliance with current regulations and policies.

***Documents begin next page***

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

EDMONDS INSTITUTE, et al., )

Plaintiffs, )

v. )

BRUCE BABBITT, in his )  
official capacity as Secretary )  
of the Department of the )  
Interior, et al., )

Defendants. )

Civil Action 98-561 (RCL)

MAR 24 1999

NANCY MAYER WHITE  
U.S. DISTRICT COURT

ORDER

Upon consideration of defendants' motion to dismiss, defendants' motion for summary judgment, and plaintiffs' cross-motion for summary judgment, the various oppositions thereto, and the record in this case, and for the reasons set forth in the memorandum opinion issued this date, it is hereby

ORDERED that defendants' motion to dismiss is GRANTED in part and DENIED in part, and that Count V of the first amended complaint is hereby DISMISSED with prejudice; and it is further

ORDERED that defendants' motion for summary judgment is hereby DENIED; and it is further

ORDERED that plaintiffs' motion for summary judgment is hereby GRANTED; and it is further

ORDERED that summary judgment is hereby entered on Count IV and that defendants suspend implementation of the Yellowstone-Diversa CRADA pending the completion of any and all review mandated by the National Environmental Policy Act, including but not limited to the preparation of an Environmental Assessment.

SO ORDERED.

  
\_\_\_\_\_  
Royce C. Lamberth  
United States District Judge

DATE: 3-24-99

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

EDMONDS INSTITUTE, et al., )

Plaintiffs, )

v. )

BRUCE BABBITT, in his )  
official capacity as Secretary )  
of the Department of the )  
Interior, et al., )

Defendants. )

Civil Action 98-561 (RCL)

**FILED**

MAR 24 1999

NANCY WALKER WASHINGTON CLERK  
U.S. DISTRICT COURT

MEMORANDUM OPINION

This matter comes before the Court on defendants' motions to dismiss several counts of plaintiffs' first amended complaint and for summary judgment on plaintiffs' NEPA claim, as well as plaintiffs' cross-motion for summary judgment on the NEPA claim. The underlying issue is the legality of the Department of the Interior's decision to enter into a novel agreement that allows a private biotechnology company to "bioprospect" microbial organisms from geysers and other thermal features in Yellowstone National Park. Upon consideration of the three motions, the oppositions thereto, and the relevant record in this case, the Court will GRANT the defendants' motion to dismiss Count V of the complaint and DENY the remainder of the defendants' motions; the Court will GRANT the plaintiffs' motion for summary judgment on the NEPA claim and enter summary judgment in plaintiffs' favor.

## I. FACTS

### A. Introduction: The Yellowstone-Diversa CRADA

On August 17, 1997, the defendants held a ceremony to commemorate the 125<sup>th</sup> anniversary of the nation's oldest national park, Yellowstone National Park. The ceremony was attended by top environmental policymakers including Vice President Al Gore, Secretary of the Interior Bruce Babbitt, National Park Service Director Robert Stanton, and Yellowstone Superintendent Mike Finley, who announced that the federal government had entered into a novel contract with San Diego-based Diversa Corporation by which Diversa would obtain a nonexclusive right to "bioprospect" microbial organisms in Yellowstone, in exchange for an agreement to share potential financial returns with the Park. The agreement, officially called a Cooperative Research and Development Agreement (CRADA), was the first of its kind to involve a national park. As explained in the Statement of Work incorporated in the CRADA, Yellowstone and Diversa will cooperate to research and catalog the Park's biological diversity, primarily in the Park's thermal features such as geysers, hot springs, fumaroles, and mud pots, but also in the Park's "alpine tundra ecosystems, subalpine forests; riparian habitats, sedge marshes, bogs, swamps, streams and lakes." Statement of Work at 2. Based on this initial survey, the sites will be "prioritized and systematically sampled by [Diversa] scientists," using techniques to be "jointly selected by YNP and [Diversa] to ensure that there is no significant impact to park resources or other

appropriate park uses." Id. The samples

will consist of raw samples taken directly from the environment; for example, sample types will include raw environmental samples (biological tissues, soils, sediments, water and rock) located at YNP. Nucleic acids will be isolated directly from these environmental samples or they will be used as inocula for laboratory enrichment [to produce a microbial community large enough to harvest nucleic acids]....

...After the [nucleic acids] are isolated from the environmental matrix, it will undergo one or more steps to render it clonable. Once the total [nucleic acids] have been purified, it will be used to construct [a library of genetic information]....

The gene libraries are used by [Diversa] as starting material for the discovery and cloning of biocatalysts, bioactive, and other compounds.... Following subcloning and overexpression into a suitable industrial host, the resulting gene products, consisting of enzymes and bioactive molecules, will undergo biochemical characterization and be evaluated by [Diversa] for potential commercial application.

Id. at 2-3. The libraries of genetic information will also be available to Park scientists for their own research. The CRADA and Statement of Work explicitly state that all activity carried on under the agreement will be in accordance with applicable law, including Park management policy.<sup>1</sup>

Despite the impressive scientific aspects of the agreement,

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<sup>1</sup>Pursuant to the CRADA, a Research Authorization/Collection Permit was issued to Diversa in 1998 authorizing the collection of biological tissues, soils, sediments, water, and rock from Yellowstone.

the most innovative feature of the CRADA is the consideration that the Park receives in exchange for access to the Park's biodiversity. The specifics of the financial agreement are included in Appendix B to the CRADA, which has not been released to the public (nor to this Court) despite the requests of members of Congress and at least two FOIA lawsuits of which the Court is aware. Nevertheless, the defendants have disclosed that Diversa will make annual payments of around \$20,000 to the defendants, as well as provide research equipment and other support for the Park's use and benefit. The most significant aspect of the agreement, however, is that Diversa agrees to pay the Park royalties on any future commercial use or product derived from the company's bioprospecting activities in the Park. Although the specifics are not public, the Park has indicated that it will receive royalties of between .5% and 10% depending upon the nature of the raw material and the final product.

The Yellowstone-Diversa CRADA marks the first time in history that an American national park would stand to gain financially from scientific discoveries made within its borders. To understand the significance of this shift in policy, it is necessary to briefly examine the emerging field of "bioprospecting" and how it relates to the Yellowstone National Park.

#### **B. Bioprospecting**

The term "bioprospecting" refers to a relatively new method

of natural resource exploitation. Natural resource use on federal lands historically has consisted largely of traditional consumptive uses such as timber harvesting, mining, hunting, and grazing.<sup>2</sup> Bioprospecting presents a totally new, related (whether the fundamental nature is different than traditional consumptive or indistinguishable is a matter of much debate) use that targets microscopic resources--the genetic and biochemical information found in wild plants, animals, and microorganisms. See generally John R. Adair, Comment, The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources?, 24 Ecology L.Q. 131 (1997). Pioneered as a resource management strategy by developing nations such as Costa Rica, bioprospecting has enormous commercial potential, which appears to have been among the defendants' motives in introducing it to Yellowstone National Park. See Michael Milstein, Yellowstone Managers Stake a Claim on Hot-springs Microbes, Science, Oct. 13, 1995 (quoting Yellowstone officials); see also Soukup Decl. ¶ 9.

Bioprospecting has developed in conjunction with the booming field of biotechnology, a multibillion dollar industry that uses biological resources such as genes and enzymes to develop industrial products. The uses of such products range from stripping the paint from old Navy boats, to extraction of gold from ore, to DNA fingerprinting, to fighting cancer.

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<sup>2</sup>Such consumptive uses, however, have not historically been permitted in the national parks.

One of the best-known examples of the financial and other benefits to be gained from bioprospecting and biotechnology is an enzyme called Taq polymerase, which was developed from a microbial species named *Thermus aquaticus*, first discovered in 1966 in the Mushroom Pool, a hot spring eight miles from Old Faithful in Yellowstone National Park. Due to its hot spring origins, Taq polymerase can withstand extremely high temperatures, which makes it ideally suited to the chemical processes used by scientists to copy DNA material, a process with numerous applications in medicine, law enforcement, and other fields. In addition to the social benefits of Taq polymerase, it has enormous financial value. The patent on the enzyme was sold in 1991 for \$300 million to a company and now generates an estimated \$100 million per year.

As the benefits of biotechnology have become increasingly visible, the demand for bioprospecting has also grown. This increased demand places greater and greater value on places like Yellowstone National Park that have a high level of biological diversity, where greater concentrations of genetic information offer the best chance of discovering biochemical materials that may lead to important (and commercially rewarding) products.

### C. Biodiversity in Yellowstone National Park

Yellowstone National Park was created by Act of Congress in 1872, whereby "[a] tract of land in the States of Montana and Wyoming, lying near the headwaters of the Yellowstone River" was

"dedicated and set aside as a public park or pleasuring ground for the benefit and enjoyment of the people." 16 U.S.C. § 21. Today, the Park includes more than two million acres in Wyoming, Montana, and Idaho. Some three million people visit the Park each year to enjoy its scenic views, rich variety of wildlife, and world-famous geysers and hot springs.

Although Yellowstone is often associated with bears, bison, and other large animals, scientific discoveries over the last several decades have revealed that the Park's greatest wealth of life may be hidden from the naked eye. Yellowstone is home to an estimated eighty percent of the world's terrestrial geysers and more than half of its thermal features, including hot springs, mud pools, and fumeroles.<sup>3</sup> These areas were once thought to be wastelands, too hot to sustain life. Now, however, scientists have discovered that the Park's thermal features are home to a microbial community whose biological diversity may rival that of the tropical rainforests.

Scientists in the Park, such as those employed by Diversa pursuant to the Yellowstone-Diversa CRADA, take teaspoon-sized samples from geysers and hot springs to be analyzed in laboratories outside the Park. A single test tube's worth of water and sediment can contain thousands of separate species of microscopic organisms. Extrapolate that to the 10,000 geysers,

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<sup>3</sup>In addition to the sheer number of thermal features in Yellowstone, the Park's uniqueness is heightened because it is one of the last thermal fields in the world that has not been harnessed as a geothermal power source.

hot springs, and other thermal features in the Park, and the potential number of as-yet-unidentified species is staggering. Park officials estimate that far less than one percent of the Park's microbes have been catalogued.

Such a wealth of microbial life is a treasure jealously guarded by many, including environmentalists, park enthusiasts, scientists, and (most recently) bioprospectors. Because each species in the microbial soup has its own genetic makeup and unique characteristics, the tremendous diversity of species translates into an equally awesome diversity of genetic and biochemical information for investigation and potential development for commercial or industrial use. Biotechnology companies salivate at the possibility of making a discovery like that of *Thermus aquaticus* (discussed above) or one of the dozen or so other creatures discovered in the Park that have already led to potentially lucrative products.

#### D. Bioprospecting in Yellowstone

The Yellowstone-Diversa CRADA does not represent the first time that the National Park Service has permitted scientific research and collection of microbial specimens from Yellowstone's thermal features. According to a declaration supporting defendants' motion for summary judgment, the earliest research permit authorizing collection of microbial samples from the park was in 1898. In recent years, the number of annual requests by researchers for access to the Park has averaged 1,500, with some

250-300 research permits issued each year (between 40 and 50 of which are for microbial research projects).<sup>4</sup> National Park Service regulations govern this general permit system, to ensure that research activities are consistent with the Park's overall goals.

Before the Yellowstone-Diversa CRADA, researchers were free to remove any specimen within the purview of their permit and develop it as they wished. If such development led to commercial uses, such as in the case of Taq polymerase, the Park Service never saw any proceeds from the derivative products.<sup>5</sup>

In need of funds, and recognizing that potentially valuable natural resources were being removed from Yellowstone with no remuneration to the Park and its owners, the American people, see Soukup Decl. ¶ 9, officials within the Department of Interior began to consider a dramatic shift in park management policy-- from the traditional conception of biochemical and genetic resources as a "common heritage of mankind" to a management scheme (patterned on the successes of Costa Rica and other nations) that uses bioprospecting to provide funds and incentives for the conservation of biological diversity.

To that end, the defendants opened negotiations in 1995 with

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<sup>4</sup>As discussed below, recent changes in DOI policy (calling for a review of all research permits and suggesting that CRADAs be required for all commercial research) may have affected these figures.

<sup>5</sup>Yellowstone even reputedly declined contributions offered by the current holder of the patent on Taq polymerase, reportedly because of uncertainty as to the legality of such a transaction.

the Diversa Corporation and other biotechnology companies to explore possible bioprospecting contracts. Lacking any statutory authority specific to the national parks or other federal lands, the government decided to cast any potential agreement as a cooperative research and development agreement (CRADA) under the Federal Technology Transfer Act of 1986, which authorizes federal laboratories to enter into CRADAs with nonfederal entities to facilitate the sharing of research performed by government scientists. By the fall of 1996, Diversa and the defendants were cooperating to draft a CRADA that would permit the collection of raw environmental materials from Yellowstone.

When plaintiffs learned in 1997 of the defendants' negotiations, they submitted a petition for rulemaking and collateral relief to the defendants requesting that they not enter into the Yellowstone-Diversa CRADA without first performing an environmental impact analysis and giving the public notice of the proposed change in policy. By letter dated September 23, 1997, defendant National Park Service notified plaintiffs that it was initiating a ninety-day internal review of the Yellowstone-Diversa CRADA. By letter dated January 21, 1998, the Park Service denied the plaintiffs all relief requested. A final version of the CRADA was signed by National Park Service Director Robert Stanton and Yellowstone Superintendent Mike Finley on May 4, 1998.

The Yellowstone-Diversa CRADA has signaled a major change in defendants' park management policy on scientific research.

Documents obtained by plaintiffs pursuant to the Freedom of Information Act show that as early as 1996 Park Service officials including Yellowstone Superintendent Mike Finley considered the issue of royalties from bioprospecting to be an issue that transcended Yellowstone. The author of one memorandum stated that "[a]ny precedent set will affect all parks, and may influence profitable resource access by other industries besides biotech/microbiology." Mendelson Decl. attach. 2. A September 10, 1998 memorandum from the Solicitor of the Department of Interior to the Chief of Staff, all Assistant Secretaries, and all heads of Bureaus and Offices, indicated that the issue of bioprospecting was being discussed on a department-wide basis. The Solicitor recommended that each bureau and agency immediately review all research permits and include the following provision in each permit:

Use of collected specimens may be for scientific and educational purposes only

Any specimen collected under this permit, or any component of any specimens--including natural organisms, enzymes, genetic materials, or seeds--may be used for scientific or educational purposes only, and may not be used for commercial purposes unless the permittee has entered into a cooperative research and development agreement (CRADA) with the [relevant agency of the Department of Interior]. Breach of this condition will be grounds for revocation of the permit and denial of future research permits. Furthermore, if the permittee develops commercial products from collected specimens or components thereof without a CRADA, any such commercial product will be subject to the payment of a royalty rate

of ten percent (10%) to the agency or Department.

Pls.' Reply Brief, Ex. 1. Plaintiffs also claim that the Park Service revealed in separate FOIA litigation that between fifteen and eighteen research groups have expressed interest in entering into a CRADA authorizing collection and use of specimens from Yellowstone alone. Mendelson Decl. ¶ 16.

E. The Future of Bioprospecting on Federal Lands

The precise number of bioprospecting CRADAs being considered department-wide by the defendants is unknown, but a number of parks other than Yellowstone hold great potential for bioprospecting. Judging by the DOI Solicitor's September 1998 memorandum, other federal lands may be under consideration for bioprospecting CRADAs. Nevertheless, as far as the Court is aware, the defendants have not conducted a rulemaking procedure for this change in policy, nor have the defendants solicited public comment informally. The defendants have declined requests from members of Congress seeking information about the financial aspects of the Yellowstone-Diversa CRADA. Essentially, the future of bioprospecting on federal lands in the United States appears to be a work in progress, but the government as of yet has not engaged in any public debate on the issue nor made any definitive policy statement through regulations or less formal means.

F. Procedural History of this Case

First, because the defendants challenge plaintiffs' standing, a brief description of the various parties is appropriate.

Plaintiff Edmonds Institute is a nonprofit public interest organization based in Edmonds, Washington. Among the group's goals are the regulation of biotechnology and the maintenance and protection of biodiversity. The Institute's Executive Director is Beth Burrows, who is alleged in the complaint to have visited Yellowstone many times and plans to visit the Park again, where she enjoys the aesthetic and recreational pleasures of the Park, including its thermal features.

Plaintiff Alliance for the Wild Rockies is a nonprofit organization dedicated to the preservation and protection of the native biodiversity of the Northern Rockies Region; it has an office in Bozeman, Montana dedicated primarily to issues dealing with Yellowstone National Park and the surrounding ecosystem. The Alliance has 1,000 member businesses and 3,500 individual members, some of whom are alleged in the complaint to regularly hunt, fish, camp, canoe, and otherwise enjoy Yellowstone, including its thermal features and other distinct ecosystems. In addition, some members of the Alliance have worked or currently work as rangers, researchers (including both businesses and individuals), and as guides in the Park.

Plaintiff International Center for Technology Assessment (CTA) is a Washington, D.C.-based nonprofit corporation focused

on the environmental, economic, and ethical issues surrounding the biotechnology industry (including bioprospecting), particularly as it relates to the national parks.

Finally, plaintiff Phil Knight is a resident of Bozeman, Montana who allegedly visits Yellowstone some twelve times a year to hike, photograph, and otherwise enjoy its aesthetic and recreational qualities. Mr. Knight is specifically alleged to have visited many of the Park's thermal features.

Defendants, of course, are Secretary of the Interior Bruce Babbitt, sued in his official capacity, and Robert Stanton, Director of the National Park Service, also sued in his official capacity only.

As mentioned briefly above, plaintiffs filed a petition in 1997 requesting that the agency not enter into the Yellowstone-Diversa CRADA (or similar agreements) because the agency had failed to provide public notice of its proposed change in policy and had not undertaken the environmental impact assessment required by law. The defendants denied plaintiffs' request in January of 1998.

On March 5, 1998, plaintiffs filed this action, alleging that the Yellowstone-Diversa CRADA violated the Technology Transfer Act of 1986, 15 U.S.C. § 3701 et seq., the National Park Service Organic Act of 1916, 16 U.S.C. § 1 et seq., the Yellowstone National Park Organic Act, 16 U.S.C. § 21, et seq., the National Environmental Policy Act, 42 U.S.C. § 4321 et seq., and the so-called public trust doctrine, as well as the

Administrative Procedure Act, 5 U.S.C. §§ 702, 706. Following the signing of the final CRADA on May 4, 1998, the parties jointly requested a revision of the pleading schedule, and plaintiffs filed a first amended complaint on June 17, 1998.

Defendants filed their motion to dismiss Counts I, II, III, and V on August 28, 1998, along with a motion for summary judgment on plaintiffs' remaining count brought under the NEPA. Plaintiffs filed their opposition with a cross-motion for summary judgment on the NEPA claim on September 24, 1998. These three motions are currently before the Court. Defendants' motion to dismiss alleges that the plaintiffs do not have standing to challenge the Yellowstone-Diversa CRADA and, alternatively, that the plaintiffs have failed to state a claim upon which relief can be granted. Defendants have elected not to challenge plaintiffs' standing to bring the NEPA claim, and the cross-motions for summary judgment address the substantive merits of that issue. The Court will consider the motion to dismiss first, and the cross-motions for summary judgment second.

## II. LAW AND APPLICATION

### A. Defendants' Motion to Dismiss Counts I, II, III, and V

In their motion to dismiss, defendants challenge plaintiffs' ability to bring each of the claims included in the first amended complaint, with the exception of the NEPA claim which the defendants have not sought to have dismissed. In particular, the

defendants argue that the plaintiffs have not met the constitutional and prudential requirements of the standing doctrine,<sup>6</sup> and that the statutes and authorities cited by the plaintiffs do not give rise to a cognizable cause of action.

#### 1. Standing

The Supreme Court and the Court of Appeals have devoted a great deal of attention to the issue of standing in recent decades, including a number of important decisions in the 1990s. In these decisions, two distinct aspects of the standing doctrine have been identified. First, Article III of the Constitution provides the Judiciary with the authority to decide "Cases" and "Controversies." The courts have interpreted that authority to impose a constitutional limitation on what persons or entities may bring suit in federal court. Specifically, a plaintiff must demonstrate (1) that it has suffered "injury in fact," which is defined as an invasion of a judicially cognizable interest that is both (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) that the injury is fairly traceable to the conduct complained of; and (3) that a favorable ruling will likely, as opposed to conceivably, redress the plaintiff's injury. See Lujan v. Defenders of Wildlife, 504

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<sup>6</sup>Defendants have not challenged the standing of any particular plaintiff, but instead have asserted arguments that do not differentiate between the plaintiffs. Therefore, the Court will also address defendants' arguments generally rather than as applied to each plaintiff in turn. Because all plaintiffs have alleged largely identical interests and injuries, this approach should have no practical effect on the Court's determinations.

U.S. 555, 560-61 (1992); Animal Legal Defense Fund v. Glickman, 154 F.3d 426, 431 (D.C. Cir. 1998). Second, in addition to the constitutional standing requirements stemming from Article III, the courts have traditionally imposed so-called prudential requirements on plaintiffs. Among these prudential requirements is a showing that "the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." Association of Data Processing Serv. Orgs. v. Camp, 397 U.S. 150, 153 (1970); see National Credit Union Admin. v. First Nat'l Bank & Trust Co., 118 S. Ct. 927, 933 (1998); Animal Legal Defense Fund, 154 F.3d at 431. The constitutional and prudential requirements are conceptually distinct, and the Court will address them separately.

a. Constitutional Standing Requirements

Defendants argue that the plaintiffs have failed to satisfy both the "injury in fact" requirement and the "redressability" requirement of constitutional standing. The Court disagrees on both issues.

With regard to injury in fact, defendants do not dispute that aesthetic and recreational interests, as a general matter, are cognizable for standing purposes. Indeed, the Supreme Court has left no room for debate on that issue. See Lujan v. Defenders of Wildlife, 504 U.S. at 562-63 ("Of course, the desire to use or observe an animal species, even for purely esthetic

purposes, is undeniably a cognizable interest for purpose of standing."); Sierra Club v. Morton, 405 U.S. 727, 734 (1972) ("The injury alleged by the Sierra Club will be incurred entirely by reason of the change in the uses to which Mineral King will be put, and the attendant changes in the aesthetics and ecology of the area. ...We do not question that this type of harm may amount to an 'injury in fact' sufficient to lay the basis for standing..."); Animal Legal Defense Fund, 154 F.3d at 432. Instead, the defendants argue that plaintiffs' alleged injury is not "actual or imminent." This argument, however, is unpersuasive.

Defendants place great weight on the fact that collection of specimens under the CRADA will amount to taking samples that each contain about a teaspoon of water, sediment, and microbial life. There is no support, however, for the argument that an actual injury will not give rise to standing if it comes in small doses or a if defendant considers it to be insignificant.

In a recent en banc decision, the entire Court of Appeals agreed that a cognizable injury in fact arises where a plaintiff alleges that his aesthetic interest is affected by degradation of the environment or a reduction of the supply of wildlife to be viewed or studied. See Animal Legal Defense Fund, 154 F.3d at 433; id. at 449 (Sentelle, J., dissenting). Neither the majority nor the dissenters expressed concern that small injuries should not be cognizable. Were that the case, then standing analysis would become a question, for example, of whether \$1000 or \$50 or

§2 were required for a plaintiff to state an injury in fact. This type of inquiry has no place in the standing analysis, but is rather an issue going to the merits. In this case, for example, defendants' argument that the environmental impact of the specimen collection is insignificant is relevant to plaintiffs' NEPA claim, but it is not determinative of whether plaintiffs have established a cognizable injury in fact.

In any event, although each sample taken from Yellowstone may be the size of a test tube, the overall impact of the specimen collection authorized by the CRADA and its corresponding permit is not teaspoon-sized. As described in the CRADA's Statement of Work, Diversa plans to study the microbes present in a wide array of ecosystems and "systematically sample[]" the sites in order of their uniqueness and genetic diversity. This will entail a significant amount of collection throughout a large area of the Park and, by the CRADA's own terms, is expected to have a duration of at least five years. Taken together, the amount of teaspoon-sized samples can hardly be considered so inconsequential as to not even constitute a cognizable injury to plaintiffs' legitimate aesthetic and recreational interests.

Also, as defendants concede, the collection of microbial samples, while not rising to the level of strip mining or timber harvesting, does involve some intrusion into the delicate ecosystems around Yellowstone's thermal features. For example, one of the plaintiffs alleges that, since the implementation of the CRADA, he has observed footprints and other signs of human

intrusion around thermal features which disrupted his aesthetic enjoyment of the Park. Such physical damage to the Park's environment is certainly injury in fact, as could be the mere presence of researchers in the Park's ecosystems if this presence is notable to the plaintiffs and arguably interferes with their enjoyment of the Park's natural wonders. Defendants' argument that someone (hikers, or other scientists) could be trampling the geysers even if there was no Yellowstone-Diversa CRADA does not refute the fact that trampled geysers (to give one example of plaintiffs' alleged injuries) constitutes an injury in fact for standing purposes.

This finding is entirely in keeping with the case law of the Supreme Court and the Court of Appeals. Modern decisions have found actual or imminent injury in fact where continued whaling allegedly threatened the interests of whale watchers, see Japan Whaling Assoc. v. American Cetacean Soc'y, 478 U.S. 221, 231 (1986), and where plaintiffs alleged that governmental action made a national forest more vulnerable to forest fire, see Mountain States Legal Found. v. Glickman, 92 F.3d 1228, 1234 (D.C. Cir. 1996). See also Animal Legal Defense Fund, 154 F.3d at 434-35 (and cases cited therein). Because the collection of microbial specimens is an actual invasion of plaintiffs' recognized aesthetic and recreational interests, plaintiffs have established injury in fact for standing purposes.<sup>7</sup>

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<sup>7</sup>Plaintiffs also allege that they have suffered informational and economic harm as a result of the Yellowstone-Diversa CRADA. Because the injury to their aesthetic and

Defendants' next contention--that a favorable ruling would not redress plaintiffs' injuries--is equally unavailing. The essence of defendants' argument is that Diversa would have the opportunity to conduct the same research without the CRADA under an ordinary research and collection permit. This argument fails for several reasons.

As a preliminary matter, the Court disagrees with defendants' implicit assertion that the CRADA is essentially a meaningless document--that Diversa could enter the Park under an ordinary permit, collect specimens, and develop them as it pleases, and that this precludes a finding of redressability. Particularly in light of the DOI Solicitor's September 1998 memorandum, it appears that research conducted on DOI lands now cannot be used for commercial purposes (as opposed to pre-1997, when such commercial development was not prohibited). Therefore, it is clear that one effect of the Yellowstone-Diversa is to authorize Diversa to commercially develop the fruits of its research on Yellowstone specimens.<sup>9</sup>

Defendants argue that removing the commercial aspect of research and collection activity in the Park cannot possibly redress any alleged injury to plaintiffs' aesthetic injuries.

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recreational interests are sufficient to establish standing, the Court will not address the plaintiffs' other theories of standing.

<sup>9</sup>The other effects include a commitment to issue a collection permit to Diversa and to cooperate with Diversa's research and collection activities, neither of which is insignificant in the context of redressability.

This ignores the reality that the commercial nature of an activity can and does affect its impact on the subject environment and particularly on people's aesthetic and recreational interests in the Park. Although parkgoers may be willing to forgive the trespass of their national parkland when the goals of that trespass are scientific and educational, commercial exploitation of that same parkland may reasonably be perceived as injurious. This commonsense notion has not even been challenged in other contexts. For instance, in Alaska Wildlife Alliance v. Jensen, 108 F.3d 1065 (9<sup>th</sup> Cir. 1997), the Ninth Circuit found standing for plaintiffs to challenge the Department of Interior's decision to allow commercial fishing in Glacier Bay National Park. The court reasoned that "[a] finding in plaintiffs' favor, that commercial fishing is statutorily prohibited in Glacier Bay, would result in the elimination of commercial fishing in the relevant areas. This would redress plaintiffs' claimed injuries." Id. at 1069. The same is true in this case, where a favorable ruling from this Court would invalidate (or at least suspend) the Yellowstone-Diversa CRADA, and thus eliminate commercial bioprospecting from Yellowstone National Park, redressing plaintiffs' claimed injuries. There is an undeniable reality that commercial activity is qualitatively different than scientific and educational activity of a similar nature, due to the very different forces and motivations that drive them.

Even were the Court blind to the commonsense distinction

between commercial exploitation and purely scientific investigation, the defendants' argument must fail for another reason. Although defendants may have the discretion to permit Diversa to collect specimens from Yellowstone under an ordinary permit, this fact does not deny plaintiffs the standing to challenge the issuance of permits pursuant to the CRADA. See FEC v. Akins, 118 S. Ct. 1777, 1786 (1998) ("Agencies often have discretion about whether or not to take a particular action. Yet those adversely affected by a discretionary agency decision generally have standing to complain that the agency based its decision upon an improper legal ground."); Animal Legal Defense Fund, 154 F.3d at 442.

The bottom line is that the plaintiffs in this case claim an injury to their aesthetic and recreational interests from Diversa's activities conducted pursuant to the Yellowstone-Diversa CRADA. If the Court invalidates the CRADA, or enjoins its exercise pending the completion of an environmental impact statement, as the plaintiffs request, then the plaintiffs' injuries will be redressed. Therefore, the plaintiffs have established redressability.

Because the plaintiffs have demonstrated that they suffered injury in fact, fairly traceable to the defendants' decision to enter into the Yellowstone-Diversa CRADA,<sup>9</sup> which would likely be

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<sup>9</sup>Defendants did not challenge this aspect of standing. Even had they done so, the Court is satisfied that plaintiffs' alleged injuries are "fairly traceable" to the defendants' decision to enter into the CRADA. See, e.g., Telephone & Data Sys. v. FCC, 19 F.3d 42, 47 (D.C. Cir. 1994) ("[O]ne narrow proposition at

redressed by a ruling in their favor, the Court finds that they have satisfied the standing requirements imposed by Article III.

b. Prudential Standing Requirements

Defendants also argue that plaintiffs do not have standing to bring their claim under the Federal Technology Transfer Act (FTTA) because they do not "arguably fall within the zone of interests to be protected by the statute." Although the issue is a close one, the Court disagrees.

The Supreme Court and the Court of Appeals have made clear that the "zone of interests" requirement is not intended to be overly demanding. The Supreme Court has very recently affirmed that "for a plaintiff's interests to be arguably within the 'zone of interests' to be protected by a statute, there does not have to be an 'indication of congressional purpose to benefit the would-be plaintiff.'" National Credit Union Admin., 118 S. Ct. at 935. As the Court of Appeals has stated, the focus is "not on those who Congress intended to benefit, but on those who in practice can be expected to police the interests that the statute protects." Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1075 (D.C. Cir. 1998). Put another way, standing is precluded only "if the plaintiff's interests are ... marginally related to or inconsistent with the purposes implicit in the statute." National Credit Union Admin., 118 S. Ct. at 934.

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least is clear: injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality.").

The FTTA, codified at 15 U.S.C. § 3701 et seq., authorizes, inter alia, agencies to enter into CRADAs with nonfederal parties and to negotiate licensing agreements to share intellectual property generated by federal research. The law was enacted in response to a congressional concern that, despite billions in federal dollars spent on research and development at federal laboratories, little of this research and development led to commercially valuable uses. See Chem Serv., Inc. v. Environmental Monitoring Sys. Lab.--Cincinnati, 12 F.3d 1256, 1264 (3d Cir. 1993) (citing the Senate Report). The Yellowstone-Diversa CRADA cites the FTTA (along with the National Park Service Organic Act) as its legal basis, apparently taking the view (expressed in defendants' briefs) that Yellowstone National Park is itself a federal "laboratory."

When viewed in terms of recent cases interpreting the "zone of interest" requirement, it is not unreasonable to find that those who use federal laboratories "in practice can be expected to police the interests protected" by the FTTA. This is particularly true if one accepts the government's amazingly broad interpretation of the term "laboratory" under the FTTA to include the national parks and perhaps (if the Solicitor's September 1998 memo is any indication) all federal lands.

This interpretation of the zone of interests arguably protected by the FTTA is not inconsistent with the decision of the only federal court of appeals to consider this issue to date.

In Chem Service, Inc., the Third Circuit found that competitors<sup>10</sup> of a private laboratory that has entered into a CRADA with the EPA had standing. See Chem Serv., Inc., 12 F.3d at 1267. The court determined that, because the FTTA's CRADA provisions were integrally related to federal procurement laws, "[t]o the extent that a CRADA is used to circumvent the statutory and regulatory requirements of the federal procurement laws, we find that Congress intended potential bidders to such a contract to be within the zone of interests protected under the FTTA." Id.

It is not apparent on the face of the FTTA that it shares a similarly "integral" relationship with the laws and regulations governing the national park system. Nevertheless, if the DOI insists on interpreting the FTTA to apply to Yellowstone (and potentially to other parks and federal lands), then the relationship between the two bodies of law grows closer to a point that an "integral" relationship is shown. The intuitive barrier to this decision is that it seems absurd that an entire two-million-acre national park should be considered a "laboratory" under the FTTA. It is precisely the defendants who are to blame for this interpretation, however, and it would be inequitable to allow an agency to avoid review of its action

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<sup>10</sup>Although this theory was not stressed in the parties' briefs, the complaint does allege that some plaintiffs (both individuals and businesses) are researchers. These plaintiffs are in a very tangible sense competitors with Diversa for access to the myriad ecosystems in Yellowstone and even for the very microbes which Diversa seeks to collect. On this theory alone, plaintiffs could reasonably be found to fall within the zone of interests of the FTTA.

taken pursuant to a statute merely by adopting an absurd interpretation of that statute. Therefore, under the particular factual and legal posture of this case, the Court finds that the plaintiffs do indeed arguably fall within the zone of interests to be protected by the CRADA provision of the FTTA, and therefore the Court finds that the plaintiffs have established prudential standing on this claim as well.

To conclude this standing analysis, the Court finds that the plaintiffs have established their standing to bring each of the claims asserted in their first amended complaint. The Court will now proceed to defendants' argument that plaintiffs have failed to state a cause of action in Counts I, II, III, and V of their complaint.

## 2. Failure to State a Claim

Defendants argue that, even if the plaintiffs are found to have standing to bring this action, they fail to state a claim in Counts I, II, III, and V of the first amended complaint. The Court agrees with the defendants in some respects, and disagrees in other respects, as set forth below.

### a. Federal Technology Transfer Act

Defendants first assert that Count I fails to state a claim under the FTTA. In two respects, the Court agrees. First, plaintiffs' assertion that defendants have violated 15 U.S.C. §

3710a(c)(5)(C)(v) cannot possibly state a claim, because that provision by its clear and unambiguous terms applies only to an agency that has contracted out the operation of a federal laboratory to a nonfederal entity, a circumstance which is not present in this case. Second, the Court agrees that 15 U.S.C. § 3710a(f) cannot form the basis for a cause of action; it provides only that "[n]othing in this section is intended to limit or diminish existing authorities of any agency." Such a provision does not provide the Court with any judicially manageable standard by which to review agency action, and thus it cannot give rise to a cause of action. Likewise, defendants are correct that § 3710a(d)(1), which defines CRADA to include agreements between federal laboratories and nonfederal entities, cannot in a vacuum create any enforceable right in plaintiffs.

The Court disagrees, however, that plaintiffs cannot present any claim under the FTTA. Defendants conveniently ignore that plaintiffs' claim that the Yellowstone-Diversa CRADA violates the FTTA is explicitly brought under the APA, alleging that the defendants' action was "arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law ... in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706." As the defendants are undoubtedly well aware, the APA provides plaintiffs a cause of action with which to challenge interpretations of law and other final agency actions alleged to be in violation of a statute. See 5 U.S.C. § 702. The defendants have not argued that the Yellowstone-Diversa CRADA

does not constitute final agency action reviewable under the APA, nor could they. Even if not presented with perfect clarity in their amended complaint, plaintiffs have stated a cause of action under the APA that the defendants have acted in violation of the FTTA.

b. National Park Service and Yellowstone Organic Acts

Defendants likewise assert that the National Park Service Organic Act and the Yellowstone Organic Act cannot "conceivably give rise to a cause of action." This assertion is inconsistent with past decisions of this and other courts. Furthermore, it fails to recognize that plaintiffs are also suing under the Acts' implementing regulations.

This Court and the Court of Appeals have entertained claims based on the National Park Service Organic Act (NPSOA), often in conjunction with a particular park's organic act, on several occasions. In Daingerfield Island Protective Society v. Rabbitt, 40 F.3d 422 (D.C. Cir. 1994), for instance, the Court of Appeals considered claims brought under the NPSOA and other federal laws. After quoting from 16 U.S.C. § 1, the Court of Appeals stated: "As the district court correctly observed, this language gives the Park Service 'broad, but not unlimited discretion in determining what actions are best calculated to protect Park resources.' We must uphold the Park Service's exercise of discretion unless it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law'...."

Likewise, this Court just three months ago considered a claim that the Park Service's deer management program was inconsistent with the NPSOA. See Davis v. Latschar, Civ. Action 97-232, 1998 WL 968474 (D.D.C. 1998). Of particular relevance to the case presently before the Court is a line of decisions by this and other courts that have reviewed the 1970 and 1978 amendments to the NPSOA and found those amendments to reflect a renewed insistence on the part of Congress that the national parks be managed in accordance with the primary purpose of the NPSOA, namely the conservation of wildlife resources. See National Rifle Assoc. of Am. v. Potter, 628 F. Supp. 903, 909-10 (D.D.C. 1986); Sierra Club v. Andrus, 487 F. Supp. 443, 447-49 (D.D.C. 1980); see also Michigan United Conservation Clubs v. Lujan, 949 F.2d 202, 207 (6<sup>th</sup> Cir. 1991) (expressly agreeing with and adopting the reasoning of National Rifle Assoc. of Am. v. Potter); Bicycle Trails Council of Marin v. Babbitt, 82 F.3d 1445, 1449-50 n.2 (9<sup>th</sup> Cir. 1996) (expressly adopting the findings in Potter). In addition to the decisions of other circuits just cited, the Fifth and Eighth Circuits have also entertained claims under the NPSOA and the APA. See Dunn-McCampbell Royalty Interest, Inc. v. NPS, 112 F.3d 1283, 1286 (5<sup>th</sup> Cir. 1997) (finding that, although NPSOA alone did not directly provide cause of action, plaintiffs could sue under the APA); Maugolf v. Babbitt, 125 F.3d 661, 668-69 (8<sup>th</sup> Cir. 1997) (referring to the NPSOA and its implementing regulations and stating: "[The Park Superintendent's discretion] must be

exercised with an eye toward promoting specific regulatory objectives ... and it is subject to the arbitrary-and-capricious standard of review...").

It is also relevant that the plaintiffs' first amended complaint specifically alleges that the defendants have also violated the regulations implementing the NPSOA, including 36 C.F.R. § 2.1(c)(3)(v), which generally prohibits the "Sale or commercial use of natural products." Defendants of course claim that this regulation is inapplicable because the Yellowstone-Diversa CRADA does not call for the "sale" or "commercial use" of natural products from the Park. Whether or not this interpretation can be sustained, it is clearly a question on the merits which should be addressed later--not an appropriate ground for finding that plaintiffs have failed to state a claim. Defendants also argue that other, more specific, regulations such as those governing research and collection (36 C.F.R. § 2.5) make the general provisions of 36 C.F.R. § 2.1 inapplicable. This reasoning is not convincing, primarily because the regulations governing research permits by their own terms are applicable only to scientific and educational research and do not contemplate commercial research. Finally, defendants argue that "[a]t a minimum, [their] interpretation of [their] own regulations is certainly a reasonable one that should be upheld under the reasoning of Chevron U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984)." That may well be, but it also is a question that goes substantially to the merits and should be

decided on summary judgment, not on a motion to dismiss for failure to state a claim.

For all of these reasons, the Court finds that the plaintiffs have sufficiently stated a cause of action under both the National Park Service Organic Act and the Yellowstone National Park Organic Act.

c. Public Trust Doctrine

Defendants' final argument relative to their motion to dismiss is that plaintiffs have no cause of action under the so-called "public trust doctrine." On this issue, the Court agrees with the defendants and will dismiss Count V of plaintiffs' complaint.

In Sierra Club v. Andrus, 487 F. Supp. 443 (D.D.C. 1980), this Court considered a claim similar to this one insofar as plaintiffs invoked the organic acts of both the Park Service and the particular park at issue and also the public trust doctrine. There, as here, the court recognized that the NPSOA imposed a limited discretion on the Secretary of Interior, reviewable by the courts. See id. at 448-49. The court also examined plaintiffs' trust theory and found that Congress had supplanted any trust obligations by enacting the detailed regulatory system governing the national parks. See id. at 449. The plaintiffs do not contest this view, except to argue that their public trust doctrine claim should be heard if the Court were to dismiss their claims under the Park Service and Yellowstone Organic Acts.

Because the Court will not dismiss plaintiffs' claims under those two statutes and their implementing regulations, there is no reason to question the holding of Sierra Club v. Andrus in this case. Therefore, Count V of plaintiffs' complaint will be dismissed.

For all of the reasons set forth above, the Court finds that the plaintiffs have established constitutional and prudential standing and have stated claims under the FTTA, the NPSOA, and the Yellowstone National Park Organic Act. Defendants' motion to dismiss is denied as to those claims. However, plaintiffs have not stated a claim under the public trust doctrine, and the defendants' motion to dismiss will be granted as to Count V of the complaint.

**B. Cross-Motions for Summary Judgment on the NEPA Claim**

Defendants elected not move to dismiss plaintiffs' claim under the National Environmental Policy Act (NEPA) and instead filed a motion for summary judgment. Plaintiffs then filed a cross-motion for summary judgment. Upon consideration of these motions, the oppositions thereto, and the record in this case, the Court will deny defendants' motion, grant plaintiffs' motion, and enter partial summary judgment on this claim, including an injunction ordering the defendants to prepare an environmental assessment (EA).

In the NEPA, Congress declared a "broad national commitment

to protecting and promoting environmental quality." Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 348 (1989) (citing 42 U.S.C. § 4331). To implement this commitment, the NEPA includes what its principal sponsor in the Senate referred to as "action-forcing" provisions, see id. at 349; Calvert Cliffs' Coordinating Comm. v. Atomic Energy Comm'n, 449 F.2d 1109, 1113 (D.C. Cir. 1971) (quoting Senator Jackson), including the mandate in 42 U.S.C. § 4332 that

to the fullest extent possible ... all agencies of the Federal Government shall--

(C) include in every recommendation or report on proposals for ... major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on--

- (i) the environmental impact of the proposed action,
- (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
- (iii) alternatives to the proposed action,
- (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
- (v) any irreversible or irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

This "detailed statement," typically referred to as an Environmental Impact Statement or EIS, "ensures that the agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant

information will be made available to the larger audience that may also play a role in both the decisionmaking process and the implementation of that decision." Methow Valley Citizens Council, 490 U.S. at 349.

As the statutory language indicates, the duty to prepare an EIS is triggered only by a proposal for "major federal action significantly affecting the quality of the human environment." See Fund for Animals v. Thomas, 127 F.3d 80, 83 (D.C. Cir. 1997). To guide agencies in determining whether this threshold has been met, the Council on Environmental Quality (created by the NEPA) has issued regulations setting forth three levels of initial review. First, those proposals that normally require an EIS should immediately trigger preparation of an EIS. Second, the agency may designate types of actions that normally do not require the preparation of an EIS and can therefore be "categorically excluded." Third, any action that is not covered by the first or second option will be subject to an Environmental Assessment or EA. See 40 C.F.R. § 1501.4 (Whether to prepare an environmental impact statement); see also 40 C.F.R. §§ 1508.4 (Categorical exclusion), 1508.9 (Environmental assessment). Using these guidelines, the agency makes the initial determination of what level of review is appropriate for any particular action, subject to judicial review under an arbitrary-and-capricious standard. See National Trust for Historic Preservation v. Dole, 828 F.2d 776, 781 (D.C. Cir. 1987).

Defendants in this case prepared neither an EA nor an EIS

before entering into the Yellowstone-Diversa CRADA. Instead, defendants argue that they are entitled to summary judgment because (1) the activities performed under the CRADA fall under a categorical exclusion for "day-to-day resource management and research activities," see Department of the Interior Department Manual, 516 DM 7, App. 7, § 7.4(E)(2), and (2) approval of the CRADA was not a "major federal action." Both of these arguments fail.

As a preliminary matter, it is significant (practically determinative, in fact) that, while defendants have relied on a categorical exclusion before this Court, they have provided no evidence whatsoever of such a determination being made before the CRADA was finalized. Although the Court of Appeals has not addressed this particular issue, both judges of this Court that have considered the issue have found that a post hoc invocation of a categorical exclusion during litigation cannot justify a failure to prepare an EA or EIS. See Anacostia Watershed Soc'y v. Babbitt, 871 F. Supp. 475, 481 (D.D.C. 1994); Fund for Animals v. Espy, 814 F. Supp. 142, 149-51 (D.D.C. 1993). On this basis alone, the Court finds that the defendants' failure to prepare an EA or an EIS was arbitrary and capricious.<sup>11</sup>

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<sup>11</sup>The Court does not intend to establish a requirement that an agency prepare a full-blown statement of reasons for invoking a categorical exclusion. Such a requirement would detract from the legitimate governmental interest in avoiding unnecessary paperwork for actions that legitimately fall under a categorical exclusion and do not require an EA or EIS. The Court simply holds that a post hoc assertion of a CE during litigation, unsupported by any evidence in the administrative record or elsewhere that such a determination was made at the appropriate

Even had the defendants provided some evidence of a contemporaneous decision to invoke the categorical exclusion for "day-to-day" research and resource management, the Court has serious doubts as to whether such an invocation could survive arbitrary-and-capricious review. First, commercial exploitation of natural resources does not strike the Court as logically equivalent to "day-to-day resource management and research activities." Second, and frankly more weighty in terms of arbitrary-and-capricious review, the DOI's own Department Manual identifies several exceptions applicable to all categorical exclusions. These exceptions include actions that may "[h]ave adverse effects on such unique geographic characteristics as ... ecologically significant or critical areas, including those listed on the Department's National Register of Natural Landmarks," 516 DM 2, App. 2, § 2.2, "[h]ave highly controversial environmental effects," *id.* § 2.3, "[h]ave highly uncertain and potentially significant environmental effects or involve unique or unknown environmental risks," *id.* § 2.4, "[e]stablish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects," *id.* § 2.5, or "be directly related to other actions with individually insignificant but cumulatively significant environmental effects," *id.* § 2.6. Even had the defendants complied with the initial determination procedures mandated by the NEPA, the CEQ regulations, and their very own department time, cannot justify a failure to prepare either an EA or an EIS.

manual, the Court finds that they could not reasonably have found none of the exceptions listed above to apply. The defendants themselves proclaim the ecological significance of Yellowstone's thermal features, and Old Faithful at least must be on the Department's National Register of Natural Landmarks. Cf. id. § 2.2. Likewise, there can be no debate that the Yellowstone-Diversa CRADA is a precedent-setting agreement within the National Park System and the DOI in general. The first agreement of its kind, the CRADA was announced in the presence of the Vice-President, the Secretary of the Interior, the Director of the Park Service, and the Superintendent of Yellowstone. As many as eighteen other entities have already discussed similar agreements with the defendants. Finally, the very Solicitor of the DOI has called for a reevaluation of all research permits on lands controlled by the Department and recommended insertion of a provision prohibiting commercial development of the fruits of such research without a CRADA. Any argument that 516 DM 2, App. 2, § 2.5 does not apply here cannot possibly pass muster even under the deferential arbitrary-and-capricious standard of review.

The Court declines to decide at this time that the defendants must prepare an EIS, rather than merely an EA, preferring to leave that determination to the agency so long as those procedures mandated by law are complied with. The Court does consider defendants' argument that the CRADA somehow maintains the status quo to be counterintuitive and to defy the

defendants' own treatment of the agreement in the planning stages and at its announcement. The Court understands that, even without this or a similar CRADA, scientists with collection permits may still enter the Park's thermal features and scoop up test tubes full of water, sediment, and microbes. Nevertheless, the introduction of commercial bioprospecting into the nation's parks represents a dramatic change in Park Service policy both in Yellowstone and more generally. With regard specifically to Yellowstone, the defendants have offered no persuasive counter to plaintiffs' assertion that the CRADA, on its face, allows for a tremendously broad range of activities spanning a broad range of ecosystems. Although the CRADA appears aimed primarily at the Park's thermal features, the Statement of Work describes a survey of "microbes and fungi residing in YNP's alpine tundra ecosystems, subalpine forests; riparian habitats, sedge marshes, bogs, swamps, streams and lakes." These sites will then be "prioritized and systematically sampled," with the samples to include "biological tissues, soils, sediments, water and rock." In the Court's estimation, the scope of this language is indeed substantial.

Despite some misgivings, however, the Court is not prepared to hold that a Finding of No Significant Impact, reached after the preparation of an EA and a bona fide effort by defendants to comply with the letter and spirit of the NEPA, could never be upheld. The novel legal and factual issues raised by bioprospecting in Yellowstone require an intensive deliberation

by the defendants, ideally with public input--precisely the deliberation mandated by Congress through the NEPA. The Court will therefore defer to this process, rather than substitute its own judgment for that of the agency without the benefit of a well-developed record.<sup>12</sup>

For the reasons just set forth, the defendants will be ordered to suspend operation of the Yellowstone-Diversa CRADA and prepare an environmental assessment in accordance with the requirements of the NEPA. Summary judgment on Count IV will be entered in favor of the plaintiffs.

### III. CONCLUSION

For the reasons set forth above, defendants' motion to dismiss will be granted in part and denied in part, and Count V of the first amended complaint will be dismissed. Defendants' motion for summary judgment on the NEPA claim will be denied, plaintiffs' cross-motion for summary judgment on that issue will

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<sup>12</sup>The Court is concerned here solely with enforcing the procedural requirements of the NEPA. The Court does not express any view as to the substantive validity of bioprospecting as a natural resource management strategy, in the national parks or elsewhere. Indeed, that issue is one of considerable debate among and within many groups, including environmentalists and park enthusiasts. Some view bioprospecting (along with biotechnology) as an important tool for highlighting the value of biodiversity, and as providing a welcome incentive to preserve and protect our nation's natural resources, while others fear that it could open national parks and their resources to destructive (and perhaps unforeseen) abuses. Such substantive debates are usually best left to the political branches, and the Court's role is merely to ensure that the agencies act through the processes mandated by Congress in reaching their substantive determinations.

be granted. Summary judgment will be entered on Count IV against the defendants, and they will be ordered to suspend the implementation of the Yellowstone-Diversa CRADA pending completion of an EA or an EIS.

A separate order will issue this date.

  
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Royce C. Lamberth  
United States District Judge

DATE: 3-24-99

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

EDMONDS INSTITUTE, et al., )  
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Plaintiffs, )  
 )  
v. )  
 )  
BRUCE BABBITT, )  
Secretary of the Interior, )  
et al., )  
 )  
Defendants. )

Civ. Action No. 98-561 (RCL)

**FILED**

APR 12 2000

NANCY HAYES WHITING, CLERK  
U.S. DISTRICT COURT

MEMORANDUM OPINION

This matter comes before the court on the parties cross-motions for partial summary judgment. Plaintiffs, three environmental advocacy organizations and a frequent visitor to Yellowstone National Park ("Yellowstone" or "Park"), challenge as arbitrary and capricious the Department of the Interior's ("Interior") entry into a research agreement with a private biotechnology company for the "bioprospecting" of microbial organisms from geysers and other thermal features in Yellowstone. Upon consideration of the motions, the oppositions thereto, the relevant record, and the applicable law, the court GRANTS defendants' motion for summary judgment and DENIES plaintiffs' motion for summary judgment.

I. BACKGROUND

This court has previously detailed the factual background underlying the present dispute. *Edmonds Institute v. Babbitt*, 42

F.Supp. 2d 1, 4-9 (D.D.C. 1999). Accordingly, the court now provides only an abbreviated review the salient facts and procedural history of this case.

A. *The Yellowstone-Diversa CRADA*

Yellowstone is the nation's oldest national park. To commemorate its 125<sup>th</sup> anniversary, defendants hosted a ceremony on August 17, 1997, which was attended by top environmental policymakers, including Vice President Al Gore, Secretary of the Interior Bruce Babbitt, National Park Service Director Robert Stanton, and Yellowstone Superintendent Mike Finley. At the ceremony, it was announced that the federal government had entered into a novel contract with San Diego-based Diversa Corporation, by which Diversa would obtain a nonexclusive right to "bioprospect"<sup>1</sup> microbial organisms in Yellowstone, in exchange for an agreement to share with Yellowstone a portion of any financial returns generated by commercial applications or products developed from these research materials.

This novel agreement, officially termed a Cooperative

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<sup>1</sup>As this court has previously explained, bioprospecting refers to a relatively new method of natural resource utilization that targets microscopic resources, such as the genetic and biochemical information found in wild plants. *Edmonds Institute v. Babbitt*, 42 F. Supp. 2d 1, 5-6 (D.D.C. 1999). Bioprospecting is an extension of the field of biotechnology, which uses biological resources like genes and enzymes to develop beneficial pharmaceutical and industrial products and applications. *Id.*

Research and Development Agreement ("CRADA"), was the first of its kind to involve a national park. The Statement of Work in the CRADA explains how Yellowstone and Diversa will cooperate in researching and cataloguing the Park's biological diversity, primarily in the Park's thermal features such as geysers, hot springs, fumaroles, and mud pots, as well as in Yellowstone's "alpine tundra ecosystems, subalpine forests; riparian habitats, sedge marshes, bogs, swamps, streams and lakes." CRADA, Statement of Work at 2. Following an initial survey, sites will be "prioritized and systematically sampled by [Diversa] scientists," using techniques to be "jointly selected by YNP and [Diversa] to ensure that there is no significant impact to park resources or other appropriate park uses." *Id.* Once raw samples have been extracted from the selected sites, nucleic acids will be isolated, purified and used to create a library of genetic information. *Id.* at 2-3. The resulting gene libraries will be the starting point for the discovery and cloning of biocatalytic and bioactive compounds, which will be evaluated for potential commercial applications. *Id.* These libraries of genetic information will also be available to Park scientists for their own research. The CRADA and Statement of Work explicitly state that all activity carried on under the agreement will be in accordance with applicable law, including Yellowstone's management policy. Accordingly, to conduct the research under the

CRADA, Diversa applied for and was issued a Research Authorization/Collection Permit, which authorized the collection of certain biological materials from Yellowstone. Since 1994, prior to its entry into the CRADA, Diversa, under its previous name Recombinant Biocatalysis, Inc., had already been conducting the same sort of sampling from Yellowstone, pursuant to permits issued in accordance with Park regulations. The main difference, however, is that prior to the CRADA, the company was under no obligation to share any of the economic or other benefits that might result from its research on Park resources.

Thus, perhaps the most notable feature of the CRADA is the consideration that Yellowstone stands to receive in exchange for access to its biodiversity. Defendants have disclosed that Diversa will make annual payments of around \$20,000 to the defendants, as well as provide research equipment and other support for Yellowstone's use and benefit. More importantly, however, Diversa will pay royalties to Yellowstone on any future commercial use or product derived from the company's bioprospecting activities in the Park. Although the specifics are not public, Yellowstone has indicated that it will receive royalties of between .5% and 10% depending upon the nature of the raw material and the final product. By virtue of the CRADA, Yellowstone will share in any revenues generated by future beneficial applications or products developed from Diversa's

research at Yellowstone.

*B. Bioprospecting in Yellowstone*

Notwithstanding the novelty of the Yellowstone-Diversa CRADA itself, this agreement is not the first time that the National Park Service has permitted scientific research and collection of microbial specimens from Yellowstone's thermal features. To the contrary, the earliest research permit authorizing collection of microbial samples from Yellowstone was in 1898. Indeed, in recent years, the number of annual requests by researchers for access to Yellowstone has averaged 1,500, with some 250-300 research permits issued each year (between 40 and 50 of which are for microbial research projects). Declaration of Michael Soukoup ("Soukoup Decl."), at ¶ 8 Exhibit 1 to Defendants' Motion to Dismiss and for Summary Judgment. National Park Service regulations govern this permit system and ensure that research activities are consistent with the Yellowstone and Interior's overall goals.

Prior to the CRADA, Diversa or other researchers were free to remove any specimen within the purview of their permit and develop it as they wished. If such development led to commercial uses, the Park Service never saw any proceeds from the derivative products. Thus, recognizing that resources yielding potentially valuable properties were being removed from

Yellowstone with no remuneration to Yellowstone or the American people, see Soukup Decl. ¶ 9, officials at Interior began to consider a resource management scheme, patterned on the successes of Costa Rica and other nations, which would use bioprospecting to provide funds and incentives for the conservation of biological diversity. To that end, the defendants opened negotiations in 1995 with the Diversa Corporation and other biotechnology companies to explore possible bioprospecting contracts. These potential agreements would be drafted as cooperative research and development agreements (CRADA) under the Federal Technology Transfer Act of 1986, which authorizes federal laboratories to enter into CRADAs with nonfederal entities to facilitate the sharing of research developed in conjunction with government scientists. By the fall of 1996, Diversa and the defendants had begun drafting a CRADA that would permit the collection of raw environmental materials from Yellowstone. The final version of the CRADA was signed by National Park Service Director Robert Stanton and Yellowstone Superintendent Mike Finley on May 4, 1998.

*C. Procedural History*

Plaintiff Edmonds Institute is a nonprofit public interest organization based in Edmonds, Washington. The group advocates the regulation of biotechnology and the maintenance and

protection of biodiversity. Plaintiff Alliance for the Wild Rockies is a nonprofit organization committed to the preservation and protection of the native biodiversity of the Northern Rockies Region. Plaintiff International Center for Technology Assessment (CTA) is a Washington, D.C.-based nonprofit corporation focused on the environmental, economic, and ethical issues surrounding the biotechnology industry (including bioprospecting), particularly as it relates to the national parks. Finally, plaintiff Phil Knight is a resident of Bozeman, Montana who allegedly visits Yellowstone some twelve times a year to hike, photograph, and otherwise enjoy its aesthetic and recreational qualities.

Defendants, of course, are Secretary of the Interior Bruce Babbitt, sued in his official capacity, and Robert Stanton, Director of the National Park Service, also sued in his official capacity only.

In 1997, plaintiffs filed a petition requesting that the agency not enter into the Yellowstone-Diversa CRADA (or similar agreements) because the agency had failed to provide public notice of its proposed change in policy and had not undertaken the environmental impact assessment required by law. The defendants denied plaintiffs' request in January of 1998. On March 5, 1998, plaintiffs filed this action, alleging that the Yellowstone-Diversa CRADA violated the Federal Technology

Transfer Act of 1986, 15 U.S.C. § 3701 et seq., the National Park Service Organic Act of 1916, 16 U.S.C. § 1 et seq., the Yellowstone National Park Organic Act, 16 U.S.C. § 21, et seq., the National Environmental Policy Act, 42 U.S.C. § 4321 et seq., and the so-called public trust doctrine, as well as the Administrative Procedure Act, 5 U.S.C. §§ 702, 706. Following the signing of the final CRADA on May 4, 1998, the parties jointly requested a revision of the pleading schedule, and plaintiffs filed a first amended complaint on June 17, 1998.

In late August 1998, defendants moved to dismiss Counts I, II, III, and V, and moved for summary judgment on plaintiffs' NEPA claim (Count IV). Plaintiffs filed their opposition along with a cross-motion for summary judgment on the NEPA claim on September 24, 1998. In March 1999, this court denied defendants' motion to dismiss plaintiffs' statutory claims under Counts I, II and III of the complaint, while granting defendants' motion with respect to plaintiffs' public trust doctrine claim in Count V. At the same time, however, the court granted plaintiffs' cross-motion for summary judgment on the NEPA claim and ordered defendants to suspend implementation of the CRADA pending the completion of "any and all review mandated by [NEPA], including but not limited to the preparation of an Environmental Assessment." *Edmonds Inst.*, 42 F. Supp.2d at 20.

The parties now move for summary judgment as to the remaining

claims under Counts I, II and III.

## II. DISCUSSION

Where a controversy presents no genuine issue as to any material fact, summary judgment is appropriate and the moving party is entitled to judgment as a matter of law. FED.R.Civ.P. 56(c); *FDIC v. Bender*, 127 F.3d 58, 63 (D.C. Cir. 1997); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). Here, the parties agree that no genuine issue of material fact exists and that the central dispute concerns whether defendants acted in accordance with the FTTA, the National Park Service Organic Act, the Yellowstone National Park Organic Act, and Park Service regulations by entering into the CRADA with Diversa.

Under the Administrative Procedure Act, courts must set aside agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2) (A). As the Supreme Court has instructed,

the 'arbitrary and capricious standard' is 'highly deferential' and presumes the validity of agency action. If the court can discern a rational basis for the agency's decision, the decision must be affirmed. Similarly, the court must uphold the agency's construction of the statute unless it is unreasonable.

*United Transp. Union v. Lewis*, 711 F.2d 233, 252 (D.C. Cir. 1983) (citations omitted); see also *American Horse Protect. Ass'n v. Yeutter*, 917 F.2d 594, 595 (D.C. Cir. 1990).

In light of this standard, the starting point for this court's review is the language of the FTTA, for where Congress has spoken to a particular matter, Congress' plainly expressed intent governs. *Independent Petroleum Ass'n of America v. Babbitt*, 92 F.3d 1248, 1255 (D.C. Cir. 1996). The validity of this CRADA under the FTTA turns upon whether Yellowstone falls within the meaning of "laboratory" as that term is defined in the statute. By its terms, the FTTA defines "laboratory" as

a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.

15 U.S.C. § 3710a (2) (A).

Plaintiffs object to the application of the FTTA to the Yellowstone CRADA because they assert that the plain meaning of "laboratory" forecloses application of that term to the research facilities in Yellowstone. Specifically, plaintiffs argue that Yellowstone is not a "facility" because Yellowstone's organic statute describes the Park only as a "tract of land." 16 U.S.C. § 21.

While the court agrees that a national park does not immediately conjure the term "laboratory," the court finds that defendants have provided a reasoned basis for concluding that the broad, statutorily-assigned definition encompasses Yellowstone's extensive research facilities. *Cf. Perrin v. United States*, 444 U.S. 37, 42 (1979) (stating that "unless otherwise defined, words

will be interpreted as taking their ordinary, common meaning"); see also S. Rep. No. 283, 99th Cong. 2d Sess. 1, 11 (1986), reprinted in 1986 U.S.C.A.A.N. 3442, 3453 (stating that statutory definition of "laboratory" in FTTA was "a broad definition which is intended to include the widest possible range of research institutions operated by the Federal Government") (emphasis added). As a preliminary matter, the court notes that because the statute has specifically defined laboratory to include facilities owned or otherwise used by a federal agency, plaintiffs "plain meaning" argument with respect to the term "laboratory" is misplaced. As noted above, where Congress has assigned a particular definition to a term, courts may not simply cast such definitions aside in favor of the term's "ordinary" meaning. *Id.* Thus, the specific definition of laboratory provided in the statute governs the court's review.

Yellowstone's research facilities fall within the definition of laboratory under the FTTA as a "facility owned . . . or otherwise used by a Federal agency," a "substantial purpose of which is the performance of research." While the term "laboratory" is defined in the statute, "facility" is not. Thus, the court must look to the ordinary meaning of that word. *Perrin*, 444 U.S. at 42. "Facility" is broadly defined as "something (as a hospital, machinery, plumbing) that is built, constructed, installed or established to perform some particular

function or to serve or facilitate some particular end". WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 812 (1961) (emphasis added). The extensive array of research facilities at Yellowstone plainly satisfy this definition. To begin with, as defendants correctly note, the statute makes no requirement that the entire facility be used exclusively for research. To the contrary, the only statutory restriction is that a "substantial purpose" of the facility be for "the performance of research, development or engineering by employees of the Federal government." 15 U.S.C. § 3710a (2) (A). Defendants have adequately demonstrated that a substantial purpose of the facilities at Yellowstone is scientific research. See Affidavit of John Varley, at ¶3 ("Varley Aff."), September 16, 1999, Attachment to Defendant's Motion for Partial Summary Judgment. Specifically, Yellowstone employs approximately 43 individuals engaged in scientific activities. Many of these scientific researchers possess doctorates or other advanced degrees, and are members of leading scientific societies. And, to coordinate scientific research at the Park, Yellowstone has established the Yellowstone Center for Resources ("YCR"), which oversees all aspects of research by Park scientists, including research concerning the Park's abundant mammalian wildlife such as bison or wolf populations, as well as the vast array of microorganisms contained in Yellowstone's hot springs and thermal features. Moreover, the plethora of

scientific and research structures and equipment at Yellowstone plainly fall within the FTTA definition. For instance, Yellowstone maintains "wet" and "dry" laboratories at Yellowstone headquarters that are approved and regulated by the Occupational Safety and Health Administration, in addition to other scientific research facilities throughout the Park. Varley Aff., at ¶ 10-12. And, many of the research facilities at Yellowstone are equipped with standard laboratory equipment, including

spectrophotometers, microscopes, stereoscopes, genetic thermal cyclers, balancers, centrifuges, refrigerators, freezers, evaporators, dryers, ovens, bunsen burners, deionizers, and other chemical, physical, and biological measuring and processing instruments, and computers. . . .

This laboratory equipment enables YNP personnel to perform a wide range of scientific analyses and tests that include but are not limited to animal necroscopies, DNA extraction, water analysis, soil characterization, and acid rain sampling and analysis.

Varley Aff., at ¶ 11. Yellowstone's research facilities also include geographic information systems ("GIS") and a remote sensing facility, which collects, records and analyzes environmental data from satellites and aircraft. Thus, in light of these extensive scientific research facilities, the court finds that Yellowstone falls within the meaning of "laboratory" under the FTTA.

Legislation enacted subsequent to the Yellowstone-Diversa CRADA also reinforces the conclusion that application of the FTTA to this CRADA is consistent with Congressional intent regarding

cooperative scientific research agreements with units of the National Park System. Notably, in 1998, Congress enacted the National Parks Omnibus Management Act ("Parks Management Act"), 16 U.S.C. §§ 5901-6011, for the purpose of "enhanc[ing] management and protection of national park resources by providing clear legal authority and direction for the conduct of scientific study in the National Park System and to use information gathered for management purposes" and "to encourage others to use the National Park System for study to the benefit of park management as well as broader scientific value." 16 U.S.C. § 5931. To achieve this end, the statute specifically authorizes the Secretary of the Interior to "solicit, receive and consider requests from Federal or non-Federal public or private agencies, organizations, individuals, or other entities for the use of any unit of the National Park System for purposes of scientific study." *Id.* at § 5935(a). Moreover, the statute further empowers the Secretary to "enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements." *Id.* at § 5935(d). Under these broad terms, the CRADA at issue here plainly constitutes an "equitable, efficient benefits-sharing arrangement" with a private entity for the purposes of scientific study. *Id.* Had Congress wished to foreclose units of the National Park System from entering into cooperative scientific research agreements with private

industry in the wake of the Yellowstone-Diversa CRADA, its subsequent enactment displays a contrary intent. Instead, the far-reaching terms of the Parks Management Act reinforce the conclusion that the Yellowstone-Diversa CRADA is proper.

Having concluded that defendants have provided a rational basis for their determination that the FTTA definition of laboratory encompasses Yellowstone's myriad scientific research facilities, the court must next consider whether the CRADA is consistent with the relevant Park Service statutes and regulations. Plaintiffs contend that the CRADA conflicts with defendants' statutory mandates under the relevant organic statutes, the National Park Service Organic Act ("NPS Act"), 16 U.S.C. § 1, et seq., and the Yellowstone National Park Organic Act ("YNP Act"), 16 U.S.C. § 21, et seq. Specifically, plaintiffs maintain that the CRADA constitutes a "consumptive use," and hence, is contrary to the conservation emphasis of the NPS Act and the YNP Act. See *Michigan United Conservation Clubs v. Lujan*, 949 F.2d 202, 206 (6th Cir. 1986) (citing *National Rifle Ass'n*, 628 F. Supp. at 909). Plaintiffs further argue that the CRADA violates the Park Service's own regulations, which prohibit the "[s]ale or commercial use of natural products." 36 C.F.R. § 2.1(c)(3)(v). As explained below, this court disagrees with plaintiffs' contentions and finds that defendants have offered a reasoned basis explaining how the CRADA is consistent

with the organic statutes and regulations.

Review of plaintiffs' challenges under the Park Service authorizing statutes, like plaintiffs' FTTA claim, is governed by the APA. Thus, as Congress has delegated the administration and preservation of national park resources to Interior and the Park Service, these agencies enjoy broad discretion in implementing their statutory responsibilities under the authorizing statutes. *National Rifle Ass'n of America v. Potter*, 628 F. Supp. 903, 911 (D.D.C. 1986); see also *Sierra Club v. Andrus*, 487 F. Supp. 443, 449-50 (D.D.C. 1980). Accordingly, their actions should be upheld as long as they are "based on a reasoned, permissible construction of the statute." *Daingerfield Island Protective Soc. v. Babbitt*, 40 F.3d 442, 446 (D.C. Cir. 1994).

As its name indicates the National Park Service Organic Act ("NPS Act") is the general authorizing statute for the National Park Service. In relevant part, the NPS Act provides that

[t]here is created in the Department of the Interior a service to be called the National Park Service. . . . The service thus created shall promote and regulate the use of the Federal areas known as national parks, monuments, and reservations hereinafter specified . . . by such means and measures as conform to the fundamental purpose of said parks, monuments, and reservations, which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.

16 U.S.C. § 1. The Yellowstone National Park Organic Act ("YNP Act") established Yellowstone as a unit of the National Park

service, by providing that

The tract of land in the States of Montana and Wyoming [within specified boundaries] is reserved and withdrawn from settlement, occupancy, or sale under the laws of the United States, and dedicated and set apart as a public park or pleasuring ground for the benefit and enjoyment of the people; and all persons who locate, or settle upon, or occupy any part of the land thus set apart as a public park, except as provided in section 22 of this title, shall be considered trespassers and removed therefrom.

16 U.S.C. § 21.

The court finds that defendants reasonably determined that the Yellowstone-Diversa CRADA is consistent with the above-quoted statutory authority and is not an impermissible "consumptive use" of park resources. *Michigan United Conserv. Clubs v. Lujan*, 949 F.2d 202, 206 (6th Cir. 1992). Specifically, defendants concluded that the CRADA does not authorize consumptive use of natural resources because it does not grant Diversa the authority to sell any living material taken from the Park. *Varley Aff.*, ¶ 37. In fact, as Yellowstone's Research Permitting Policy makes clear, Diversa never actually owns the specimens it collects, and thus has no right to transfer ownership of them. A.R. I.1, at 3 ("All specimens collected within the park are the property of the National Park Service and, regardless of where the collections are housed, must be properly accessioned and catalogued into the National Park Service's cataloguing system."); see also *Varley Aff.*, ¶ 75 ("A sale of [Yellowstone's] resources will not occur

pursuant to a CRADA.").

More fundamentally, however, the CRADA does not conflict with the conservation mandate of the organic statutes because it does not grant Diversa the right to collect any research specimens at all. Indeed, contrary to plaintiffs' assertion, neither the CRADA nor its Scope of Work authorizes Diversa to take any natural materials from Yellowstone. Rather, the CRADA outlines the rights and responsibilities of Yellowstone and Diversa with respect to information and inventions developed after the conclusion of research specimen collection and analysis. Thus, the legal force and scope of the CRADA covers the use, ownership, development and allocation of revenues from useful discoveries or potential proprietary information developed from the research activities. By contrast, to conduct its research activities at Yellowstone, Diversa--like all other researchers in the Park-- must apply for and obtain a research permit, which prescribes the terms and conditions of on-site research activities. 36 C.F.R. § 2.5; see also A.R. § II.20, ¶2.18 (noting that "[t]he term 'Research Specimen' means those items [Diversa] has the authority to collect under the collection permit or permits issued by [Yellowstone]"). Thus, while in certain respects the CRADA may impose restrictions on Diversa's research activities over and above those provided by a permit

alone, the research permit, not the CRADA, provides the legal basis for Diversa to collect specimens.

In mounting a frontal attack on the CRADA, plaintiffs fail to recognize this critical legal distinction. While they challenge the CRADA, they do not in any way contend that the research permit issued to Diversa is improper or is otherwise invalid. Indeed, plaintiffs' misconception of the legal force of the CRADA reveals the fundamental flaws in their challenge. If the court were to find that the CRADA was improper under the relevant statutes, Diversa could still collect specimens under a research permit, as it has since 1994. The only--albeit critical--difference would be that Yellowstone could not share in any of the potential benefits from Diversa's research. Instead, the positive gains from the research would go exclusively to Diversa. Plaintiffs' challenge is further undermined by the fact that finding the CRADA to be an impermissible "consumptive use" of Park resources would necessarily imply that every other scientific research permit issued over the past century was equally invalid. Soukoup Decl., at ¶ 8 (stating that the earliest research permit allowing the collection of microbial samples was

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<sup>2</sup>For example, the CRADA may give Park officials greater control over specimen extraction, as it expressly provides that "the specific sampling techniques and strategies will be jointly selected by [Yellowstone] and Diversa to ensure that there is no significant impact to park resources or to other appropriate uses." A.R. § II.20, Statement of Work, at 2; see also Varley Aff., at ¶ 66.

issued in 1898 and the Park currently issues approximately 250-300 research permits per year). But plaintiffs have offered no argument, evidence or suggestion that Diversa's research permit or the research permit program at Yellowstone are improper. Thus, in light of the longstanding policy and practice of allowing specimen collection at the Park, and because they are not properly before the court, the court need not reach the questions of the validity of the permit or the permit program.

Finally, the court finds that defendants properly determined that the CRADA was consistent with the governing statutes because it would produce direct, concrete benefits to the Park's conservation efforts by affording greater scientific understanding of Yellowstone's wildlife, as well as monetary support for Park programs. As early as 1994, defendants recognized that cooperation between Park officials and private researchers would be mutually beneficial. See A.R. § II.211; Varley Aff., at ¶ 44. Defendants determined that the potential scientific and economic benefits resulting from collaboration with private industry would support and strengthen the Park Service's primary mission of resource conservation. Varley Aff., at ¶ 46-47. Agreements like the Yellowstone-Diversa CRADA would allow the Park to share in revenues generated by beneficial developments, and thus, provide a valuable source of funding to support the Park Service's ongoing wildlife preservation,

protection, and study initiatives. Equally critical to the Park's conservation efforts as adequate funding, improved scientific knowledge and understanding of Yellowstone's habitat generated by these types of joint research projects would be shared with the Park and used to support its efforts to preserve the environment.

In addition to their challenges under the organic statutes, plaintiffs also contend that the CRADA violates a Park Service regulation that bars the "sale or commercial use" of natural materials from the Park. 36 C.F.R. § 2.1(c)(3)(v) ("Section 2.1"). Specifically, plaintiffs advance that Park Service officials proceeded with the CRADA despite their awareness that such action was "illegal" under Park regulations. But, as both the Court of Appeals for the District of Columbia Circuit and the Supreme Court have recognized, "the [Park] Service's interpretation of its own regulations will prevail unless it is 'plainly erroneous or inconsistent' with the plain terms of the disputed regulations." *Everett v. United States*, 158 F.3d 1364, 1367 (D.C. Cir. 1998) (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).

The court finds that the Park Service reasonably determined that the Yellowstone-Diversa CRADA does not involve the "sale or commercial use" of park resources within the meaning of Section 2.1. The record discloses that defendants have provided a thoughtful and rational approach to research conducted on Park

resources. In concluding that the regulations did not foreclose the CRADA, the Park Service determined that there was a critical distinction between researchers profiting from the sale of the actual specimens themselves, which is prohibited by Section 2.1, and profiting from a future development based on scientific discoveries resulting from research on those resources, which is permitted. See A.R. II.40, Memorandum from Director of Yellowstone Center for Resources to Yellowstone Superintendent (May 21, 1997), at 3; see also A.R. II.20, CRADA (distinguishing between "research specimens" collected under the agreement (§ 2.18) and "products" derived from research involving those specimens (§ 2.14). In reaching this conclusion, the Park Service considered several critical factors. First, it recognized that permit holders, such as Diversa, do not, by virtue of either the permit or the CRADA, acquire title to the specimens or the right to transfer them to third parties. A.R. II.1, Yellowstone Permitting Policy, at 3 (stating that "[a]ll specimens collected within the park are the property of the National Park Service and regardless of where the collections are housed, must be properly accessioned and catalogued in the National Park Service's cataloging system"); *id.* at 5 (noting that the "[s]ale of collected research specimens and other transfer to third parties is prohibited"). Second, the Park Service determined that permittees like Diversa, who later develop useful products,

information or applications, are making "commercial use" of scientific discoveries, not Park resources. A.R. II. 45.m, at 3 (noting that "to date no firm has asked Yellowstone for a permit to collect research specimens for the purpose of replication and subsequent commercialization"). This interpretation accords with the fact that patent rights derive from human ingenuity brought to bear on scientific specimens, not the specimens themselves. See *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) (stating that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions, . . . the result of human ingenuity and research"); see also *Varley Aff.* at ¶ 39.

Plaintiffs do not persuade the court that the defendants' interpretation of the regulation is unreasonable. Plaintiffs aver that because patent law allows scientists to obtain intellectual property rights over natural organisms, the CRADA at issue in this case necessarily involves the prohibited sale of natural materials. But this view of the scope of patent law ignores relevant precedent, which instructs that a substance occurring in nature may not be patented in that form. *Diamond*, 447 U.S. at 313. Instead, to obtain a patent rights, a researcher must bring to a naturally-occurring substance a contribution that is non-obvious, novel and demonstrably useful. See 35 U.S.C. § 101-103. Thus, in accord with these fundamental

principles, the Park Service has interpreted its regulations only to allow researchers to study, not sell, Park resources. The CRADA, in turn, accords with the regulations because any "commercial use" flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves. Accordingly, the court finds that defendants reasonably construed Park regulations and concluded that the CRADA was consistent with their requirements.

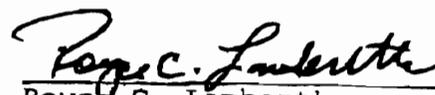
V. CONCLUSION

For the reasons set forth above, the court hereby GRANTS defendants' motion for partial summary judgment and DENIES plaintiffs' motion for partial summary judgment.

A separate order shall issue this date.

SO ORDERED.

DATE: 4-12-00

  
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Royce C. Lamberth  
United States District Court

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