

National Park Service

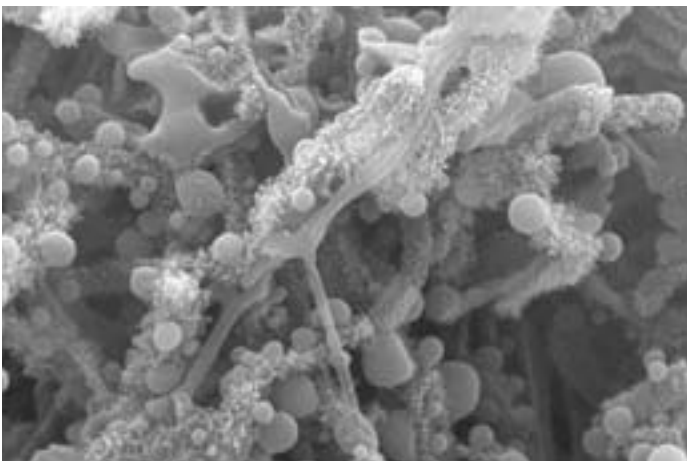
U.S. Department of the Interior



Benefits-Sharing

Draft Environmental Impact Statement

September 2006



Service-wide

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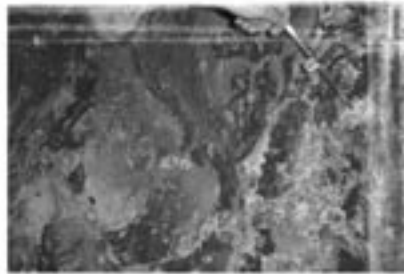
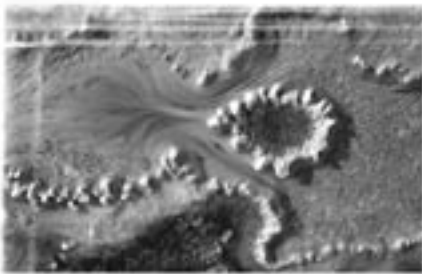
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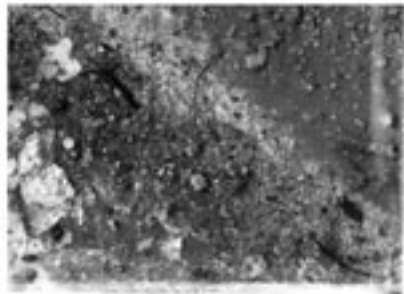
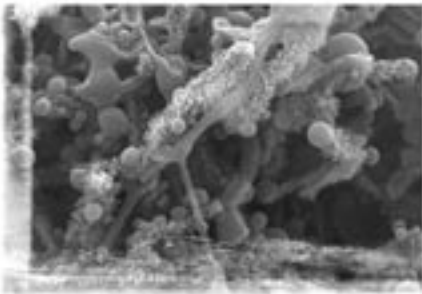


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Cover photos, clockwise from top left: filamentous bacteria and algae, Upper Geyser Basin, NPS/Hirschman; bacterial products, Spider Cave, Carlsbad National Monument, Kenneth Ingham; bacteria from bacterial mats on the walls of Pahoehoe Cave, El Malpais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

Servicewide Benefits-Sharing DEIS

COVER SHEET

(A) Responsible Agency: Prepared by the National Park Service, U.S. Department of the Interior

(B) Title and Location: Servicewide Benefits-Sharing Draft Environmental Impact Statement

(C) For information contact: NPS Benefits-Sharing EIS

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(D) This is a draft of the DEIS for review.

(E) Abstract: This draft environmental impact statement (DEIS) presents and analyzes a servicewide programmatic proposal to clarify the rights and responsibilities of researchers and 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 DEIS 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 DEIS 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 DEIS, 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 DEIS, the affected environment and relevant impact topics have the potential to include all units of the National Park System.

(F) Comments on this draft must be received by December 15, 2006.

How to comment: Public participation is very important to the decision that the DEIS describes. Therefore, we ask for your thoughtful evaluation and comment. Comments can be provided directly via the Internet at <http://parkplanning.nps.gov/>, select “Washington Office” from the park choice menu and then follow the link for benefits-sharing. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at the Yellowstone Center for Resources, 307-344-2203. You may also mail comments to the name and address above. Finally, you may hand-deliver comments to the Yellowstone Center for Resources in Yellowstone National Park, Wyoming.

Our practice is to make comments, including names, home addresses, home phone numbers, and email addresses of respondents, available for public review. Individual respondents may request that we withhold their names and/or home addresses, etc., but if you wish us to consider withholding this information you must state this prominently at the beginning of your comments. In addition, you must present a rationale for withholding this information. This rationale must demonstrate that disclosure would constitute a clearly unwarranted invasion of privacy. Unsupported assertions will not meet this burden. In the absence of exceptional, documentable circumstances, this information will be released. We will always make submissions from organizations or businesses, and from individuals identifying themselves as representatives of or officials of organizations or businesses, available for public inspection in their entirety.

We thank you in advance for your attention and we appreciate your concern for the future of the National Park System.

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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 NPS research specimens. 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 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 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 draft EIS (DEIS) 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 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. This DEIS 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 DEIS:

Alternative A: No Benefits-Sharing/No Action;

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

Alternative B1. Mandatory disclosure of all terms and conditions;

Alternative B2. Optional disclosure of all terms and conditions (*Preferred Alternative*); and

Alternative B3. No disclosure of any royalty rate or related information; and

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

This DEIS 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 DEIS 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, and does not include site-specific details. 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 DEIS, “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.² 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 in the event that 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

The DEIS process began with scoping, the open process to determine the scope of environmental issues and alternatives to be addressed in an EIS. The public plays an integral role in scoping. During scoping (June–August 2001 and April–May 2002), two newsletters were mailed to more than 5,000 people requesting their comments, a web site invited comments, and articles appeared in a variety of newspapers. In total, 118 comment messages were received from the public.

All of the public's concerns were considered. Some of the concerns raised during scoping were analyzed as impact topics. Other concerns, such as general approval or disapproval of benefits-sharing, were addressed by incorporating the concern into one or more alternatives. The public also expressed concerns about issues that are not within the scope of the decision to be made in the Final EIS, or will not be significantly impacted by any of the alternatives; these were not analyzed further.

ES.1.3 Issues and Concerns

This DEIS is being prepared to provide a programmatic NEPA analysis for benefits-sharing agreements servicewide. In addition, the DEIS 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 DEIS

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 DEIS.

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 DEIS 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 DEIS 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 DEIS.

The alternatives were developed based on information provided in comments received from the public and the DEIS Interdisciplinary Team, as well as from the internal scoping process conducted by the NPS for this DEIS. 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: Mandatory disclosure of all terms and conditions;

Alternative B2: Optional disclosure of all terms and conditions (*Preferred Alternative*); and

Alternative B3: No disclosure of any 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 DEIS:

- 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.

Research specimens 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, the burden of coming forward to initiate benefits-sharing negotiations with the NPS would rest with individual researchers.

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 or desired 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 a secondary result 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.”

A standardized CRADA (*see* 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. 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 DEIS focuses on the research 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 requires written authorization from the NPS.

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. 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 on the transactions from NPS 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 with mandatory disclosure of all terms and conditions

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 with optional disclosure of all terms and conditions (Preferred Alternative)

Under Alternative B2, 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). An objecting party would be required to demonstrate that the information was proprietary or that disclosure would harm an interest protected by FOIA. A non-confidential summary of such 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.

Alternative B3: Implement benefits-sharing agreements with no disclosure of any 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 non-confidential 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.

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 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 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 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 DEIS 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 FY2004 congressional appropriation (funding) for the NPS Natural Resource Challenge. In part, this DEIS 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

Natural resources are essential to the quality of many visitors’ experiences in and enjoyment of most parks. An understanding of natural resources enhances visitor experience, and is valued by visitors. Such understanding is 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 DEIS 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 DEIS 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.”

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 DEIS 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 DEIS 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 DEIS 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 four effects. It could (1) limit payment equitability, (2) create an artificial “rate ceiling,” (3) discourage some research, and (4) 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 four effects of Alternative B1: they would not limit payment equitability, create an artificial “rate ceiling,” 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.

Service-wide, 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 DEIS 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: service-wide, 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 DEIS 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, researchers who transfer NPS research specimens or other material originating as an NPS research specimen to third parties or who receive such transfers, 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 terms of the benefits obligated by each CRADA would have been negotiated individually, the beneficial impact of revoking this requirement would be negligible (*see also* Section ES.4.3.2).

Because Alternative A would not provide a servicewide standardized MTA, third-party researchers and any researchers who wish to supply third-party researchers with research specimens 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. However, the terms of the non-monetary and monetary benefits in each CRADA would be negotiated individually and would be acceptable to all CRADA parties. Therefore, the impact of CRADA obligations to researchers is not expected to rise above a negligible impact.

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 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 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 DEIS 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 DEIS, 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 an estimated two-to-nine new CRADAs annually.

Implementation of mitigation measures 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 DEIS 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.

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Table ES-1. Summary of Effects*

Natural Resource Management				
Alternative A No Benefits-Sharing/No Action	Alternative B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially Related Research
<p>All contexts</p> <ul style="list-style-type: none"> Choosing not to implement benefits-sharing would result in no change in the availability of “science for parks.” 	<p>All contexts</p> <ul style="list-style-type: none"> 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. 		<p>All contexts</p> <ul style="list-style-type: none"> 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. 	
<p>Servicewide</p> <ul style="list-style-type: none"> No impact. 	<p>Servicewide and Yellowstone</p> <ul style="list-style-type: none"> 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. 	<p>Servicewide</p> <ul style="list-style-type: none"> Non-monetary benefits could have negligible-to-major beneficial impacts. Short-term beneficial impacts of monetary benefits could be negligible. Long-term beneficial impacts of monetary benefits could range from negligible to minor. 		<p>Servicewide</p> <ul style="list-style-type: none"> The loss of a few current and potential future research projects would have negligible adverse impacts to the NPS.
<p>Yellowstone</p> <ul style="list-style-type: none"> The return of all monetary benefits provided to Yellowstone by Diversa would have a negligible adverse impact. 		<p>Yellowstone</p> <ul style="list-style-type: none"> Non-monetary benefits could have minor-to-major beneficial impacts. Monetary benefits could have short-term negligible beneficial impacts. Monetary benefits could have long-term negligible-to-major beneficial impacts. 		<p>Yellowstone</p> <ul style="list-style-type: none"> The potential loss of at least 3% of independent research projects would have negligible adverse impacts. The potential loss of a single scientific study revealing important new information about Yellowstone’s natural resources could be negligible-to-major.
<p>Individual parks</p> <ul style="list-style-type: none"> No impact. 	<p>Individual parks</p> <ul style="list-style-type: none"> Fewer parks would experience the beneficial impacts of Alternative B2. 	<p>Individual parks</p> <ul style="list-style-type: none"> Beneficial impacts to parks that receive non-monetary benefits could be negligible-to-major. 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. Beneficial impacts to parks that receive monetary benefits during the deferred benefits period could range from negligible to major. 		<p>Individual parks</p> <ul style="list-style-type: none"> The impacts of a potential loss of knowledge from abandoned or never-begun research could be long-term, adverse, and negligible-to-major.

Table ES-1. Summary of Effects, continued

Visitor Experience and Enjoyment				
Alternative A No Benefits-Sharing/No Action	Alternative B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially Related Research
<p>All contexts</p> <ul style="list-style-type: none"> 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. 	<p>All contexts</p> <ul style="list-style-type: none"> 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. 	<p>All contexts</p> <ul style="list-style-type: none"> Increased availability of “science for parks” would have a beneficial impact in all contexts. 	<p>All contexts</p> <ul style="list-style-type: none"> Increased availability of “science for parks” would have a beneficial impact. Impacts in all contexts would be the same as for Alternative B2. 	<p>All contexts</p> <ul style="list-style-type: none"> Decreased availability of “science for parks” could have adverse impacts in all contexts.
	<p>Servicewide and Yellowstone</p> <ul style="list-style-type: none"> 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. 	<p>Servicewide</p> <ul style="list-style-type: none"> At least negligible and possibly minor impacts. 		<p>Servicewide</p> <ul style="list-style-type: none"> Negligible impact.
	<p>Yellowstone</p> <ul style="list-style-type: none"> Negligible-to-minor impacts. 	<p>Yellowstone</p> <ul style="list-style-type: none"> Negligible-to-minor impacts. 		<p>Yellowstone</p> <ul style="list-style-type: none"> Negligible-to-minor impacts.
<p>Individual parks</p> <ul style="list-style-type: none"> Fewer parks would experience the beneficial impacts of Alternative B2. 	<p>Individual parks</p> <ul style="list-style-type: none"> Negligible-to-moderate impacts. 	<p>Individual parks</p> <ul style="list-style-type: none"> Negligible-to-major impacts. 		

Table ES-1. Summary of Effects, continued

Social Resources: The Research Community				
Alternative A No Benefits-Sharing/No Action	Alternative B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially Related Research
	<p>Declared bioprospectors</p> <ul style="list-style-type: none"> The obligation to share benefits would have a long-term negligible adverse impact. 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. 	<p>Declared bioprospectors</p> <ul style="list-style-type: none"> The obligation to share benefits would have a long-term negligible adverse impact. 	<p>All contexts</p> <ul style="list-style-type: none"> Impacts in all contexts would be the same as for Alternative B2. 	<p>Declared bioprospectors</p> <ul style="list-style-type: none"> Denial of permission to collect research specimens would have a minor-to-moderate adverse impact.
				<p>Inadvertent and undeclared bioprospectors</p> <ul style="list-style-type: none"> Denial of authorization to use research results for commercial purposes could prevent potential beneficial impacts. Those who abandon or never begin park-related research would have negligible-to-major adverse impacts.
<p>Third-party researchers</p> <ul style="list-style-type: none"> 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. 		<p>Third-party researchers</p> <ul style="list-style-type: none"> The provision of a standard Material Transfer Agreement would have a negligible beneficial impact. 		<p>Third-party researchers</p> <ul style="list-style-type: none"> The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.
<p>All other contexts</p> <ul style="list-style-type: none"> Researchers who make valuable discoveries from research involving NPS specimens would have long-term, negligible beneficial impacts. 	<p>All other contexts</p> <ul style="list-style-type: none"> Impacts to all other researchers would be the same as for Alternative B2. 	<p>All other contexts</p> <ul style="list-style-type: none"> 99% of researchers would experience no adverse impacts. 		<p>Other researchers</p> <ul style="list-style-type: none"> 99% of researchers would experience no adverse impacts.

Table ES-1. Summary of Effects, continued

Social Resources: NPS Administrative Operations				
Alternative A No Benefits-Sharing/No Action	Alternative B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially-Related Research
<p>Servicewide and individual parks</p> <ul style="list-style-type: none"> • Not having any benefits-sharing agreements to administer would result in no impact. • Not providing a standardized Material Transfer Agreement would result in adverse, negligible impacts. 	<p>All contexts</p> <ul style="list-style-type: none"> • Fewer benefits-sharing agreements would result in less adverse impacts than Alternative B2. 	<p>All contexts</p> <ul style="list-style-type: none"> • The institution of Material Transfer Agreements would have a beneficial impact. • The need to administer benefits-sharing agreements would have an adverse impact. • Impacts would be negligible in all contexts. 	<p>All contexts</p> <ul style="list-style-type: none"> • Impacts would be the same as Alternative B2. 	<p>All contexts</p> <ul style="list-style-type: none"> • A reduction in the number of submitted research proposals and the institution of Material Transfer Agreements would have negligible beneficial impacts in all contexts.
<p>Yellowstone</p> <ul style="list-style-type: none"> • Not having any benefits-sharing agreements to administer would result in no impact. • Not providing a standardized Material Transfer Agreement would result in no impact. 				

*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 year 2011 (five years after the EIS decision is reached).

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Chapter One

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 draft EIS (DEIS) 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.¹ 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 DEIS, 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 DEIS to evaluate the proposed implementation of benefits-sharing as well as reasonable alternatives to it. This DEIS reveals the possible environmental impacts of choosing whether or not to implement a certain type of contract; hence, the nature of this DEIS 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 DEIS, “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.² 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 DEIS 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 is presented at the general level, and does not include site-specific details. 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,³ and some benefits resulting from research are shared with the NPS,⁴ 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.⁵ This DEIS uses the term “bioprospecting” to describe biological research that could result in a discovery with some commercial application (*see* 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 sort of grand-scale resource consumption required by the kinds 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.⁶

(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 DEIS provides a programmatic NEPA analysis for benefits-sharing agreements servicewide. In addition, this DEIS analyzes the potential impact 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 DEIS 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.⁷ 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.⁸ 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.⁹ 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.¹⁰ 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.

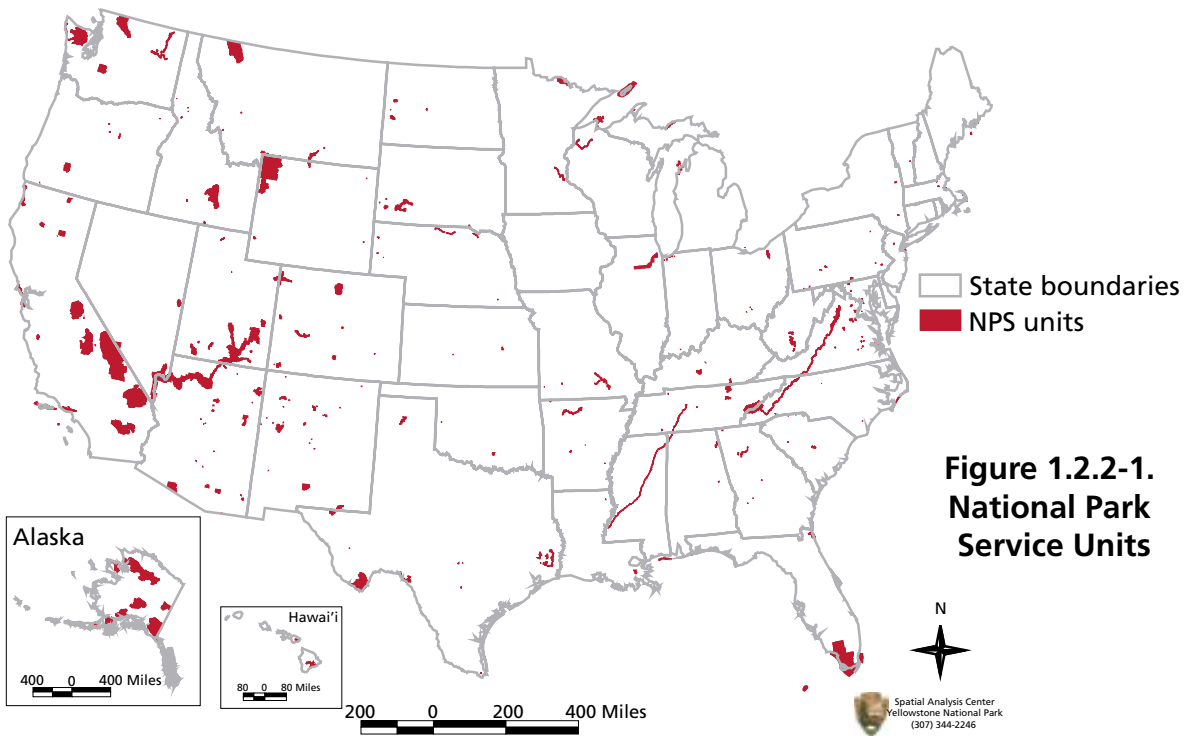


Figure 1.2.2-1. National park units are spread across the United States.

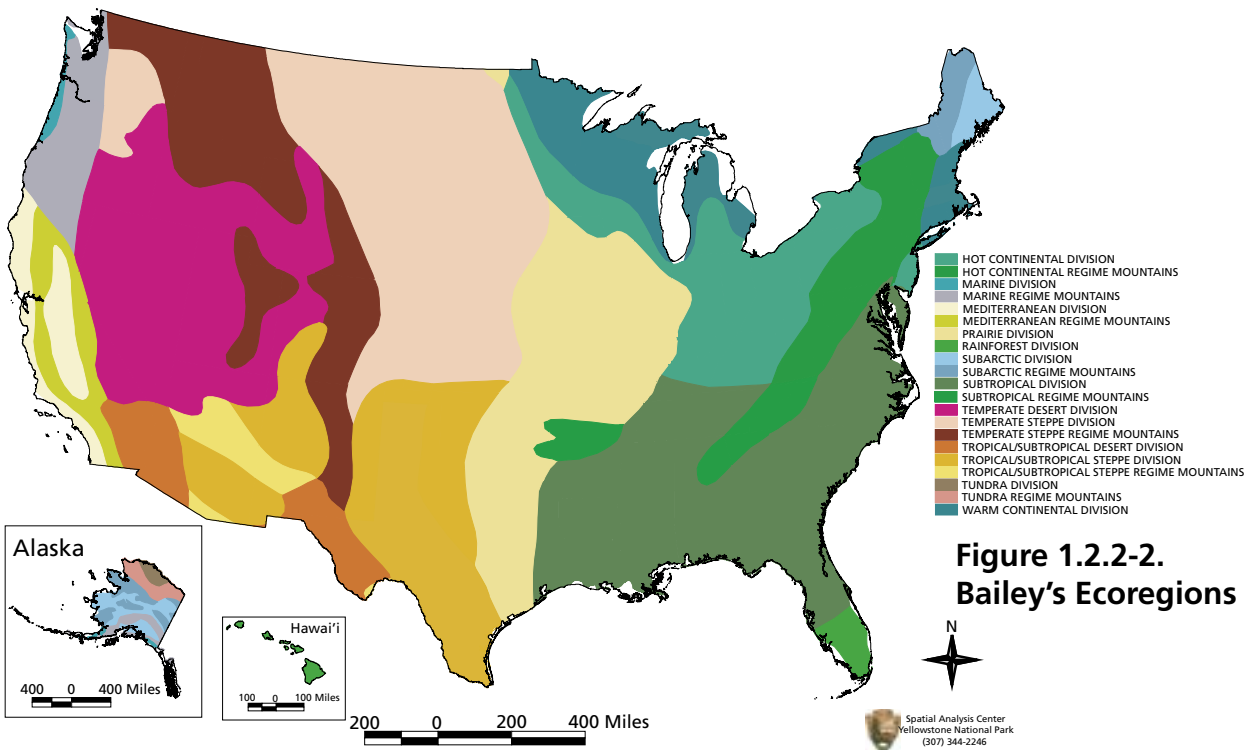


Figure 1.2.2-2. National park units are located within every terrestrial ecoregion of the U.S.

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

Ecoregion division	Park units	NPS acres
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.¹¹ Park superintendents are required to “include in a permit the terms and conditions that the superintendent deems necessary to protect park resources.”¹²

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.¹³ 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.¹⁴ 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.¹⁵

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 (IAR). In addition, copies of field notes and scientific publications may be required by the park. From 1992 through 2004, the NPS received approximately 30,000 IAR reports about permitted scientific studies occurring in national parks (*see also* Chapter 3, Section 3.4.1).¹⁶ Between 1992 and 2004, 289 different park units received IAR reports (*see* figure 1.2.3).¹⁷ The number of parks

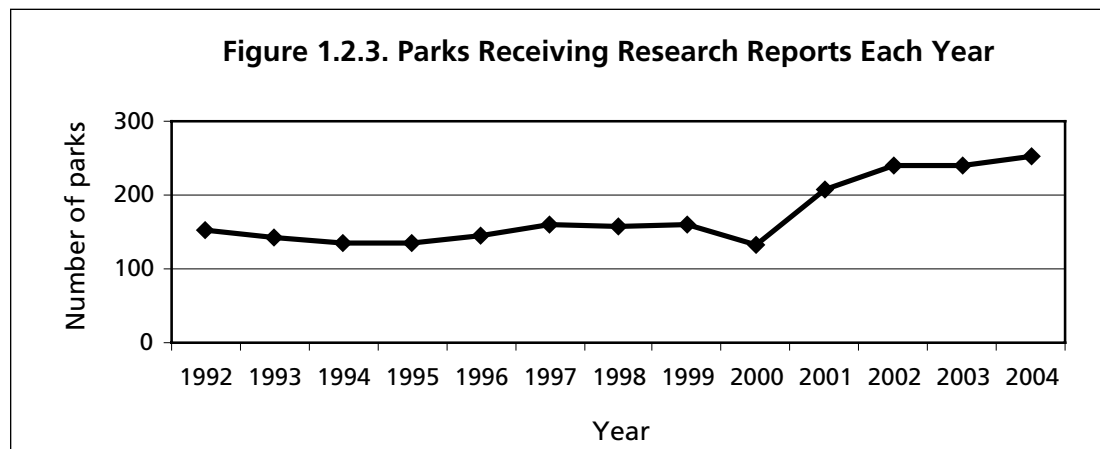


Figure 1.2.3. An average of 235 parks received research reports (IARs) each year during 2001–2004.

receiving IARs has been significantly larger in recent years (2001–2004, when an average of 235 parks received IARs each year), than it was in the past (1992–1999).

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.¹⁸

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 2003, the U.S. Patent Office issued at least 45 patents that involved research results related to the study of biological material originating in U.S. national parks (*see figure 1.2.4.1*). Forty-three of these patents related to inventions involving research specimens first collected at Yellowstone National Park. Two involved research specimens collected at Yosemite National Park. 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.¹⁹

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*).”²⁰

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.²¹

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.²²

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.²³

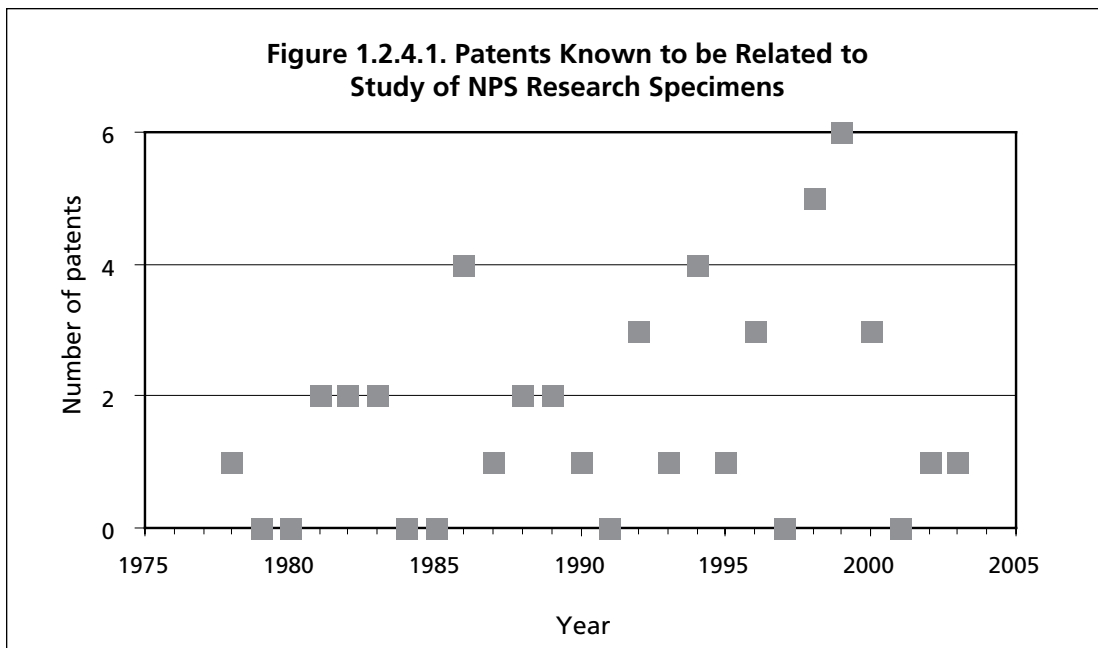


Figure 1.2.4.1. Between 1978 and 2003, The U.S. Patent and Trademark Office granted at least 45 patents based upon research results related to the study of biological material originating in U.S. national parks.

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.²⁴

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 the 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 three NPS-related patent applications were filed in 2002, and at least six in 2003.

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 Need for a Proposal to Implement Benefits-Sharing

(Specific Problems with Existing Procedures)

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 DEIS 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 in concept, 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.²⁵ 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.²⁶ 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 "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 "unauthorized transfers [of collected research specimens] to third parties is prohibited."²⁷ This provision enables the NPS to monitor the disposition of specimens. However, the servicewide standardized procedures to authorize such transfers apply only to permanently retained specimens and do not provide guidance about transfers of specimens that are intended to be consumed in analysis. The

absence of such systematic guidance for non-permanent 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 specimen transfer authorizations must be requested and how 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.²⁸ 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.²⁹ 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 Purpose of the EIS*)

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 DEIS. Meeting the objectives will advance the NPS from existing conditions toward desired future conditions.

1.4.1 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 DEIS.

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.

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.

1.4.2 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.”³⁰

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.³¹ 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.³²

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.

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

1.4.3 Research Permit Issuance Is Not Influenced By Potential Benefits-Sharing

In the absence of any mitigation measures, 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 DEIS.

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 DEIS.

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.³³ 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).³⁴

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.

Objective 3

Ensure that the NPS research permitting process is independent, objective, and unaffected by actions proposed in this DEIS.

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 DEIS.

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

1.5 Benefits-Sharing by National Parks and Other Organizations

Although this DEIS 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 DEIS, 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 DEIS.

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, 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.”³⁵

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.”³⁶

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.”³⁷

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.*).”³⁸ 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.”³⁹ 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.⁴⁰ Finally, it specifically authorizes the NPS to “enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements.”⁴¹

Individual NPS unit enabling legislation

Each unit of the National Park System is governed by its own enabling legislation, which provides specific legal authorities and direction for each park.⁴² Parks must review their park’s 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.”⁴³ This DEIS has been prepared as NEPA directs to analyze the potential environmental impacts of benefits-sharing as well as alternatives to benefits-sharing. The DEIS 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.⁴⁴

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.”⁴⁵

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.”⁴⁶ 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.⁴⁷ 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.⁴⁸

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.”⁴⁹ 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.

1.7.3 NPS Regulations

Specific NPS regulations that have guided the preparation of this DEIS 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 1.6)

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).⁵⁰

1.7.4 NPS Management Policies

Specific NPS policies that have guided the preparation of this DEIS 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 policy to interpret the ambiguities of the law and to fill in the details left unaddressed by Congress in statutes. 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 DEIS: whether or not to implement benefits-sharing.

Chapter 1: The Foundation

Chapter 1 of *NPS Management Policies 2001* 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, in the professional judgment of the responsible NPS manager, that would harm the integrity of the park resources and values, including the opportunities that would otherwise be present for the enjoyment of those resources and values.” *NPS Management Policies 2001* 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.⁵¹

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.”⁵²

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 DEIS 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.”⁵³ It prohibits the NPS from undertaking any activity that “would, or is likely to, impair park resources or values.”⁵⁴

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.”

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.”⁵⁵ 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.⁵⁶

Two of the alternatives considered in this DEIS would require further clarification of these conditions through preparation of new 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.”⁵⁷ 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.⁵⁸ 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.”⁵⁹

National Park Service Strategic Plan FY2001–2005

The NPS Strategic Plan states that the mission of the NPS is to preserve resources and serve the public, and explains that the NPS “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.”⁶⁰ It notes that the NPS cooperates with partners to extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.⁶¹ It establishes that the NPS’s guiding principles include “[a]pplying scientific information to park management decisions to preserve park resources” and “[p]romoting parks as centers for broad scientific and scholarly inquiry to benefit society.”⁶²

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,⁶³ does not authorize an impermissible “consumptive use” of park resources,⁶⁴ does not conflict with the conservation mandate of the NPS and Yellowstone Organic Acts,⁶⁵ and does not involve the “sale or commercial use” of park resources.⁶⁶

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.⁶⁷

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 Summary of Public Involvement/Scoping

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 submitted for this EIS to frame the issues to be resolved through the NEPA process and documented in this DEIS.

Scoping for this DEIS occurred June–August 2001 and April–May 2002. During the scoping period, two newsletters were mailed to more than 5,000 people, requesting comments.⁶⁸ 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 DEIS. 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. Issues framed by scoping are described below in Section 1.12 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 this DEIS. 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 this DEIS might propose wholesale commercialization of park resources. These concerns have been answered in this DEIS by the specific details included in the Alternatives as described in Chapter 2.

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). Other concerns, such as general approval or disapproval of benefits-sharing, were addressed by incorporating the concern into one or more alternatives (*see* Chapter 2, Section 2.6). Issues, impacts, and concerns that were not within the scope of the decision to be made in the Final EIS, or 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.

1.9.3 Issues Not Evaluated Further in this DEIS

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 DEIS, are explained in the following sections. Potential impacts on the following topics were not evaluated in the DEIS.

1.9.3.1. 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 DEIS is proposed to modify any existing U.S. intellectual property rights laws.⁶⁹

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 DEIS would not change the compliance procedures under which research activities could be conducted.

1.9.3.2 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 DEIS 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.⁷⁰ 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, will be completed. As part of the consultation process, the NPS is seeking the review and concurrence of the USFWS with its determination of effect on threatened and endangered species.

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, will occur through consultation with National Conference of State Historic Preservation Officers (NCSHPO). Specifically, the identification and evaluation of potential effects on cultural resources will be conducted with NPS staff, American Indian tribes, and NCSHPO. The NPS is seeking review and concurrence of this determination from NCSHPO.

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 DEIS, it would be speculative to attempt to describe any specific impact on public health that could result.

Sacred sites and Indian Trust resources

Native American tribes who may be affected by the alternatives will be contacted for their input and comment on this document. 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.

Notes

Section 1.1 Introduction

¹ This DEIS uses the term “national parks” to include any unit of the National Park System.

² 36 CFR 2.1.

Section 1.2 Background

³ See 48 Fed. Reg. 30252, 30274 (June 30, 1983).

⁴ 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.

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

⁶ 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.”).

⁷ 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>, last accessed February 1, 2006).

⁸ National Park Service, *NPS Management Policies 2001*, 1.4.3. (Washington, D.C.: U.S. Department of the Interior, 2000), hereafter *NPS Management Policies 2001*.

⁹ 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>, last accessed February 1, 2006).

¹⁰ R. G. Bailey, *Descriptions of the Ecoregions of the United States*, 2d ed. (1st ed. 1980) (Washington, D.C.: USDA Forest Service, 1995).

¹¹ National Park Service, “Application Procedures and Requirements for Scientific Research and Collecting Permits (2002), available online at <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006.

¹² 36 CFR 1.6(e).

¹³ See, e.g., National Research Council, *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).

¹⁴ See also National Parks Omnibus Management Act of 1998, at Section 205(a) (16 USC 3935(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.”

¹⁵ 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).”

¹⁶ National Park Service Research Permit Reporting System (RPRS) data, available online at <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006.

¹⁷ 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006).

¹⁸ W. Schumacher, NPS Bibliographic Coordinator, pers. comm. to Benefits-Sharing Evaluation Team, August 16, 2005.

¹⁹ *Billings Gazette*, “Microbes Have Variety of Uses” (December 5, 1993).

²⁰ *Genetic Engineering News* (March 15, 1994): 35.

²¹ *San Jose Mercury News* (July 25, 1994): 8F.

²² *Discover*, “Rubber Reborn” (July 1996): 88.

²³ T. M. Burton, “Yellowstone’s Geysers Spout Valuable Microorganisms,” *Wall Street Journal* (August 11, 1997): B1.

²⁴ 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)

²⁵ 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006).

²⁶ 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).

²⁷ See National Park Service, “General Conditions for Scientific Research and Collecting Permit,” Section 6, which reads, in part: “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 collected research specimens or other unauthorized transfers to third parties is prohibited.”

²⁸ 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).

²⁹ *NPS Management Policies 2001*, Chapter 7.

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

³⁰ National Parks Omnibus Management Act of 1998, Section 5932.

³¹ See, e.g., National Research Council, *Science and the National Parks*, and Sellars, *Preserving Nature in the National Parks*.

³² *NPS Management Policies 2001*, 4.2.

³³ National Park Service, “Application Procedures and Requirements for Scientific Research and Collecting Permits.”

³⁴ 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 2001* requires the NPS to comply with these instructions (see *NPS Management Policies 2001*, 1.8.1). This DEIS follows OMB direction to ensure that those who approve park research permits are not influenced by benefits-sharing considerations.

Section 1.7 Legal framework

³⁵ 16 USC 1.

³⁶ *Ibid.*

³⁷ 16 USC 1a-1.

³⁸ 16 USC 5931.

³⁹ 16 USC 5932.

⁴⁰ 16 USC 5935(a).

⁴¹ 16 USC 5935(d).

⁴² *See* 16 USC 21 *et seq.*

⁴³ 42 USC 4331–4332.

⁴⁴ 15 USC 3701(1), (3).

⁴⁵ 15 USC 3710a(d)(1).

⁴⁶ 15 USC 3710a(d)(2)(A).

⁴⁷ 15 USC 3710a(a), (a)(1).

⁴⁸ *See Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).

⁴⁹ 52 Fed. Reg. 13414 (April 22, 1987).

⁵⁰ *See Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).

⁵¹ *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.”

⁵² *Ibid.*, “Chapter 8: Use of the parks, Section 8.10 Natural and cultural studies research and collection activities.”

⁵³ National Park Service. 2001. *Director’s Order 12: Conservation planning, environmental impact analysis, and decision-making*, Section 4.4.

⁵⁴ *Ibid.*, Section 4.7.

⁵⁵ *See* National Park Service, “General Conditions for Scientific Research and Collecting Permit,” Section 6.

⁵⁶ *See ibid.*

⁵⁷ *NPS Natural Resource Challenge*, “Section 1, Goals.”

⁵⁸ *Ibid.*, “Introduction.”

⁵⁹ *Ibid.*, “Challenges and strategies: collaboration”; and “Challenges and strategies: parks for science.”

⁶⁰ National Park Service, “Introduction” and “Mission statement,” *National Park Service Strategic Plan FY2001–2005* (United States Department of the Interior, NPS D-1383/August 2000).

⁶¹ *Ibid.*

⁶² *Ibid.*, “Introduction, Guiding Principles: Science and Research.”

⁶³ 93 F. Supp. 2d 63, at 67–71.

⁶⁴ 93 F. Supp. 2d 63, at 70.

⁶⁵ *Ibid.*

⁶⁶ 93 F. Supp. 2d 63, at 71–72.

⁶⁷ 42 F. Supp 2d 1, at 16–17 and 20.

Section 1.8 Summary of public involvement/scoping

⁶⁸ 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.

⁶⁹ 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).

⁷⁰ 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 DEIS.

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Chapter Two

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 draft environmental impact statement (DEIS), 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.”¹

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 DEIS. 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:** Mandatory disclosure of all terms and conditions;
- **Alternative B2:** Optional disclosure of all terms and conditions (*Preferred Alternative*); and
- **Alternative B3:** No disclosure of any royalty rate or related information; and

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

DEIS objectives

The DEIS objectives shown below (*see* Chapter 1, Section 1.4) help to guide the selection of the preferred alternative. Accordingly, the DEIS alternatives need to meet the DEIS 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 DEIS, 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 DEIS's Interdisciplinary Team, as well as from the internal scoping process conducted by the NPS for this DEIS (*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 Section 2.4.6.

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. All NPS research permit applications 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 of the General Conditions and Park-Specific and Permit-Specific Conditions, if any, contained in their permits. Third-party transfer of research specimens, 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.²

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 to be the case 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 2001* 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 cause the NPS to delete the current but inactive research permit General Condition regarding benefits-sharing. 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 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.

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).³

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.⁴ 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.** Mandatory disclosure of all terms and conditions
- Alternative B2.** Optional disclosure of all terms and conditions
(*Preferred Alternative*)
- Alternative B3.** No disclosure of any 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 Appendix B) to facilitate compliance with the research permit General Condition that third-party transfer of research specimens requires written authorization from the NPS.⁵ 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 specimens 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.⁶ 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 2001*.

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. The burden of coming forward to initiate benefits-sharing negotiations with the NPS would rest with individual researchers and would conform to the provisions of the research permit or MTA to which the researcher had agreed when accepting the permit or MTA.

Entering into a benefits-sharing agreement would be a two-step process. First, the researcher and the park could establish a benefits-sharing agreement at the discovery stage of research and development (e.g., during the time when the researcher began collecting material, screening for potentially useful properties, or isolating and purifying new and active biochemicals and compounds) that would clarify the rights and obligations of both the researcher and the park, and would provide that any resulting intellectual property would be utilized equitably and efficiently. Second, the researcher and the park could defer negotiations of specific monetary benefits unless and until the researcher subsequently decided to pursue commercial development of research results, for example, product development (*see* Section 3.4.3).

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.⁷ 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 Section 2.4.6.

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).⁸

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 FTFTA, as the appropriate agreement type for implementing benefits-sharing under Alternative B.

The proposed standardized agreement 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.⁹ The proposed standardized CRADA is also designed to further the fundamental mission of the National Park Service: conservation of park resources.

If the proposal to implement benefits-sharing is adopted, the NPS will explore possible uses of other types of agreement instruments.¹⁰

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 DEIS 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.¹¹

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 benefits-sharing agreements

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 entities (*see also* the description of technical assistance that would be available to parks in Section 2.4.6). 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).¹²

Agreements would be recommended by the regional director, reviewed by the Department of Interior Solicitor’s Office, approved by the NPS director, and 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.¹³

The NPS would submit annual reports to Congress summarizing the amount of royalties or other income received from CRADAs, as provided by the FTTA.¹⁴

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.¹⁵

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 (Alternatives B1, B2, and B3), the NPS would provide Congress and the public with an annual report on the

transactions from NPS benefits-sharing agreements. However, the three variations described below 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 with mandatory disclosure of all terms and conditions

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 with optional disclosure of all terms and conditions (Preferred Alternative)

Under Alternative B2, 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). An objecting party would be required to demonstrate that the information was proprietary or that disclosure would harm an interest protected by FOIA.¹⁶ A non-confidential summary of such 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.

2.4.4.3 Alternative B3: Implement benefits-sharing agreements with no disclosure of any 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 non-confidential 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 with mandatory disclosure of all terms and conditions

Alternative B2. Implement benefits-sharing agreements with optional disclosure of all terms and conditions (Preferred Alternative)

Alternative B3. Implement benefits-sharing agreements with no disclosure of any 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.¹⁷ 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.¹⁸ 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.¹⁹

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.²⁰

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 DEIS. 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 Technical assistance to parks

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. NPS personnel with specialized 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. Such technical assistance would be centrally coordinated and include:

- Providing training 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 associated with the management of benefits-sharing, including operational functions such as monitoring and evaluating, accounting, auditing, licensing, or negotiating to universities, non-governmental organizations, or other private sector entities.

2.4.6.2 Financial support for administration

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

2.4.6.3 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 2.5.²¹ 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 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 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 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 2001* to provide that there is no requirement for negotiation of a benefits-sharing agreement prior to issuance of any permit.

2.4.6.4 Management controls

Management controls would minimize the risk that benefits-sharing might inappropriately influence research permitting decisions.²² 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.²³ 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.²⁴

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.²⁵

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.²⁶ 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 reviewed by the regional director, 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 NPS 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.²⁷

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.²⁸

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 2001*. 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 2001* 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).²⁹

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 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 requires written authorization from the NPS.³⁰ 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 specimens 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.

Table 2.6. Issues addressed in the alternatives

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

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 scientific research must not be allowed if its goal is to discover useful products or processes from the study of nature.

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 DEIS 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.

Every alternative complies with the NPS regulation that prohibits any sale or commercialization of natural products.³¹ However, the commercial development of research results is not prohibited by federal law, regulation, or policy.³² The alternatives differ regarding whether or not research results may be used for commercial purposes. Specifically, under Alternative A (No Benefits-Sharing/No Action), commercialization of research results would be left entirely up to the researcher, with no involvement by the NPS. Alternative B (Implement Benefits-Sharing), would require that commercialization of research results related to study of NPS specimens proceed only under the terms of a benefits-sharing agreement. Alternative C would not implement benefits-sharing and would also prohibit the commercial development of any unexpected or other 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. Alternative C also addresses the request of some scoping respondents that the NPS consider the commercial use of research results as “commercialization,” and disallow it.

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.³³ 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.

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.³⁴ 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.

2.7 Alternatives Considered But Not Analyzed Further

The following alternatives were considered during preparation of this DEIS, 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 DEIS (*see* Chapter 1, Section 1.4).³⁵

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."³⁶ 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.

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 biological 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.³⁷

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.”³⁸ 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 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 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.
- Under Alternative C, researchers would be prohibited from conducting most research for applications that could improve health, safety, and productivity. Researchers would also be prohibited from developing unexpected research results

for 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.

- Alternative B intends to permit research that has the potential to generate beneficial uses of the knowledge derived from research involving study of NPS specimens. 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. Under Alternative B, NPS-related research results could be used to develop a wide variety of beneficial applications in fields such as health, agriculture, nutrition, and a host of other industries.
- 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 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 natural 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 DEIS, because none of the alternatives propose any use of resources.

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 DEIS, because none of the alternatives propose any use of resources.

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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 all monetary terms	B2. Evaluate disclosure of monetary terms on case-by-case basis	B3. Never disclose monetary terms	
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 B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially Related Research
<p>All contexts</p> <ul style="list-style-type: none"> Choosing not to implement benefits-sharing would result in no change in the availability of “science for parks.” 	<p>All contexts</p> <ul style="list-style-type: none"> 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. 		<p>All contexts</p> <ul style="list-style-type: none"> 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. 	
<p>Servicewide</p> <ul style="list-style-type: none"> No impact. 	<p>Servicewide and Yellowstone</p> <ul style="list-style-type: none"> 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. 	<p>Servicewide</p> <ul style="list-style-type: none"> Non-monetary benefits could have negligible-to-major beneficial impacts. Short-term beneficial impacts of monetary benefits could be negligible. Long-term beneficial impacts of monetary benefits could range from negligible to minor. 	<p>Servicewide</p> <ul style="list-style-type: none"> The loss of a few current and potential future research projects would have negligible adverse impacts to the NPS. 	
<p>Yellowstone</p> <ul style="list-style-type: none"> The return of all monetary benefits provided to Yellowstone by Diversa would have a negligible adverse impact. 		<p>Yellowstone</p> <ul style="list-style-type: none"> Non-monetary benefits could have minor-to-major beneficial impacts. Monetary benefits could have short-term negligible beneficial impacts. Monetary benefits could have long-term negligible-to-major beneficial impacts. 		<p>Yellowstone</p> <ul style="list-style-type: none"> The potential loss of at least 3% of independent research projects would have negligible adverse impacts. The potential loss of a single scientific study revealing important new information about Yellowstone’s natural resources could be negligible-to-major.
<p>Individual parks</p> <ul style="list-style-type: none"> No impact. 	<p>Individual parks</p> <ul style="list-style-type: none"> Fewer parks would experience the beneficial impacts of Alternative B2. 	<p>Individual parks</p> <ul style="list-style-type: none"> Beneficial impacts to parks that receive non-monetary benefits could be negligible-to-major. 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. Beneficial impacts to parks that receive monetary benefits during the deferred benefits period could range from negligible to major. 	<p>Individual parks</p> <ul style="list-style-type: none"> The impacts of a potential loss of knowledge from abandoned or never-begun research could be long-term, adverse, and negligible-to-major. 	

Table 2.9-2. Summary of Effects, continued

Visitor Experience and Enjoyment				
Alternative A No Benefits-Sharing/No Action	Alternative B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially Related Research
<p>All contexts</p> <ul style="list-style-type: none"> 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. 	<p>All contexts</p> <ul style="list-style-type: none"> 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. 	<p>All contexts</p> <ul style="list-style-type: none"> Increased availability of “science for parks” would have a beneficial impact in all contexts. 	<p>All contexts</p> <ul style="list-style-type: none"> Increased availability of “science for parks” would have a beneficial impact. Impacts in all contexts would be the same as for Alternative B2. 	<p>All contexts</p> <ul style="list-style-type: none"> Decreased availability of “science for parks” could have adverse impacts in all contexts.
	<p>Servicewide and Yellowstone</p> <ul style="list-style-type: none"> 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. 	<p>Servicewide</p> <ul style="list-style-type: none"> At least negligible and possibly minor impacts. 		<p>Servicewide</p> <ul style="list-style-type: none"> Negligible impact.
	<p>Yellowstone</p> <ul style="list-style-type: none"> Negligible-to-minor impacts. 	<p>Yellowstone</p> <ul style="list-style-type: none"> Negligible-to-minor impacts. 		<p>Yellowstone</p> <ul style="list-style-type: none"> Negligible-to-minor impacts.
<p>Individual parks</p> <ul style="list-style-type: none"> Fewer parks would experience the beneficial impacts of Alternative B2. 	<p>Individual parks</p> <ul style="list-style-type: none"> Negligible-to-moderate impacts. 	<p>Individual parks</p> <ul style="list-style-type: none"> Negligible-to-major impacts. 		

Table 2.9-2. Summary of Effects, continued

Social Resources: The Research Community				
Alternative A No Benefits-Sharing/No Action	Alternative B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially Related Research
	<p>Declared bioprospectors</p> <ul style="list-style-type: none"> The obligation to share benefits would have a long-term negligible adverse impact. 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. 	<p>Declared bioprospectors</p> <ul style="list-style-type: none"> The obligation to share benefits would have a long-term negligible adverse impact. 	<p>All contexts</p> <ul style="list-style-type: none"> Impacts in all contexts would be the same as for Alternative B2. 	<p>Declared bioprospectors</p> <ul style="list-style-type: none"> Denial of permission to collect research specimens would have a minor-to-moderate adverse impact.
				<p>Inadvertent and undeclared bioprospectors</p> <ul style="list-style-type: none"> Denial of authorization to use research results for commercial purposes could prevent potential beneficial impacts. Those who abandon or never begin park-related research would have negligible-to-major adverse impacts.
<p>Third-party researchers</p> <ul style="list-style-type: none"> 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. 		<p>Third-party researchers</p> <ul style="list-style-type: none"> The provision of a standard Material Transfer Agreement would have a negligible beneficial impact. 		<p>Third-party researchers</p> <ul style="list-style-type: none"> The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.
<p>All other contexts</p> <ul style="list-style-type: none"> Researchers who make valuable discoveries from research involving NPS specimens would have long-term, negligible beneficial impacts. 	<p>All other contexts</p> <ul style="list-style-type: none"> Impacts to all other researchers would be the same as for Alternative B2. 	<p>All other contexts</p> <ul style="list-style-type: none"> 99% of researchers would experience no adverse impacts. 		<p>Other researchers</p> <ul style="list-style-type: none"> 99% of researchers would experience no adverse impacts.

Table 2.9-2. Summary of Effects, continued

Social Resources: NPS Administrative Operations				
Alternative A No Benefits-Sharing/No Action	Alternative B1 Implement Benefits-Sharing with Mandatory Disclosure of All Terms and Conditions	Alternative B2 Implement Benefits-Sharing with Optional Disclosure of All Terms and Conditions	Alternative B3 Implement Benefits-Sharing with No Disclosure of Any Royalty Rate or Related Information	Alternative C Prohibit Specimen Collection for Commercially-Related Research
<p>Servicewide and individual parks</p> <ul style="list-style-type: none"> • Not having any benefits-sharing agreements to administer would result in no impact. • Not providing a standardized Material Transfer Agreement would result in adverse, negligible impacts. 	<p>All contexts</p> <ul style="list-style-type: none"> • Fewer benefits-sharing agreements would result in less adverse impacts than Alternative B2. 	<p>All contexts</p> <ul style="list-style-type: none"> • The institution of Material Transfer Agreements would have a beneficial impact. • The need to administer benefits-sharing agreements would have an adverse impact. • Impacts would be negligible in all contexts. 	<p>All contexts</p> <ul style="list-style-type: none"> • Impacts would be the same as Alternative B2. 	<p>All contexts</p> <ul style="list-style-type: none"> • A reduction in the number of submitted research proposals and the institution of Material Transfer Agreements would have negligible beneficial impacts in all contexts.
<p>Yellowstone</p> <ul style="list-style-type: none"> • Not having any benefits-sharing agreements to administer would result in no impact. • Not providing a standardized Material Transfer Agreement would result in no impact. 				

*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 year 2011 (five years after the EIS decision is reached).

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Notes

Section 2.1 Introduction

¹ 67 Fed. Reg. 18034, 18035 (April 12, 2002).

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

² Investigator's Annual Reports are available online at <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 21, 2006.

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

³ 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 21, 2006.

Section 2.4 Alternative B: Implement Benefits-Sharing

⁴ This DEIS is a programmatic document, meaning that it is general and comprehensive in scope.

⁵ 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).

⁶ 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.

⁷ 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.

⁸ 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).

⁹ *See* Chapter 1, Section 1.8.1.1 of this document, for a description of federal court review of the Yellowstone-Diversa CRADA.

¹⁰ 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.

¹¹ 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"))).

¹² 16 USC 5935(d).

¹³ *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.

¹⁴ *See* 15 USC 3710c(c).

¹⁵ *See* 15 USC 3710a(d)(1) and 3710c.

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

¹⁷ 36 CFR 2.1.

¹⁸ *See, e.g.*, 36 CFR 2.1(c).

¹⁹ 36 CFR 2.1.

²⁰ 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).

²¹ 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*.

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

²³ *See* 36 CFR 1.6 and 2.5.

²⁴ *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.").

²⁵ *See* 36 CFR 1.6 and 2.5

²⁶ Pursuant to OMB Circular No. A-123, Management Accountability and Control.

²⁷ *See* OMB Circular A-123.

²⁸ *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

²⁹ 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*.

³⁰ 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

³¹ 36 CFR 2.1.

³² 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).

³³ 36 CFR 2.1.

³⁴ 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 biological research specimens if researchers identify or acknowledge their proposed biological 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

³⁵ 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.”

³⁶ 16 USC 5395(d).

³⁷ 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

³⁸ 46 Fed. Reg. 18026 (1981).

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Chapter 3

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 DEIS (*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 DEIS 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 DEIS.

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.¹ Therefore,

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

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 FY2004 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 2001*. 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.⁴ 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), 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).

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.⁵

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 2001

NPS Management Policies 2001 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:⁶

- 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.⁷ 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.⁸
- 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.⁹
- 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.¹⁰
- 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. Thirteen of the 32 Learning Centers planned for the NPS were funded by 2002.
- 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.”¹¹ 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 1.6).

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 FY2004 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.¹² 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.¹³ 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 DEIS, to illustrate the state of natural resource management servicewide. Their funding levels are used in Chapter 4's impact analysis as a metric to

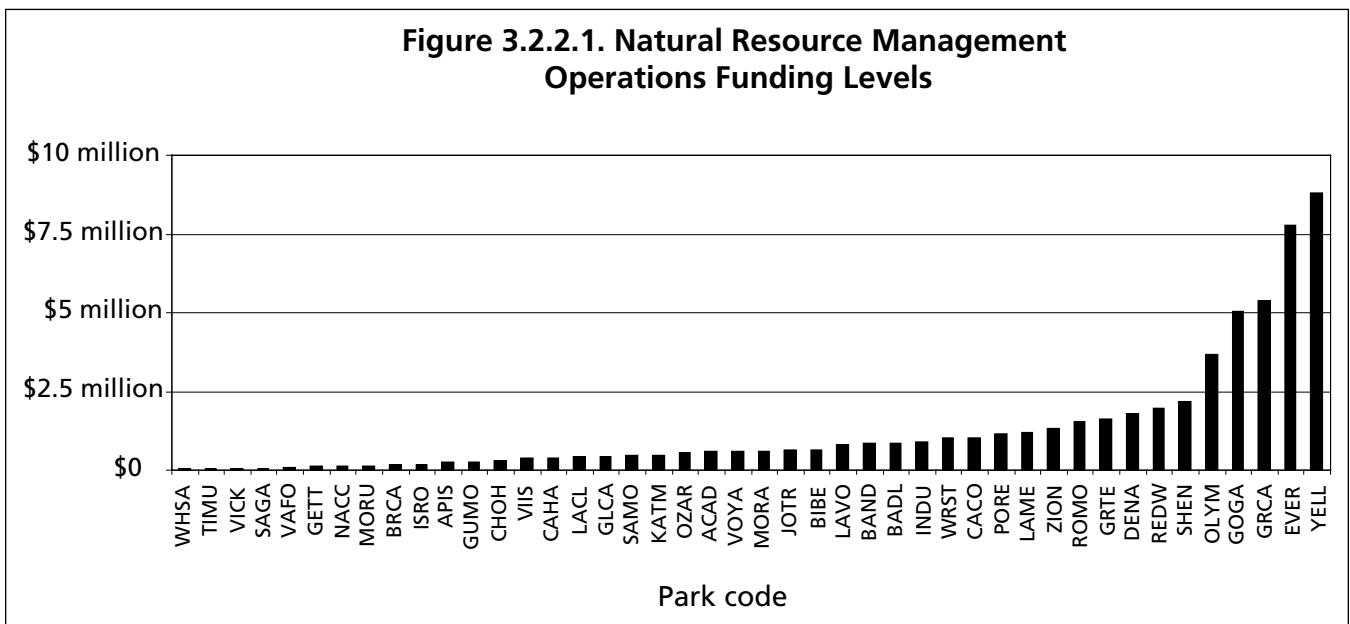


Figure 3.2.2.1. The NPS Business Plan Initiative identified funding levels for natural resource management operations.

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.¹⁴ 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),¹⁵
- Eliminate the most critical resource problems, and
- Attract scientists and good science (parks for science).

In 2004, the NRC program reported total funding of approximately \$73 million for programs supported by the NRC.¹⁶

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 DEIS.

The alternatives in this DEIS 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, including the impact of interpretive services designed to specifically meet natural resource management goals. Second, visitors could be affected by changes in interpretation through potential impacts on the scientific information and assistance available for use in NPS interpretive services.

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.¹⁷ The NPS’s official web site was accessed more than 124 million times in 2002.¹⁸

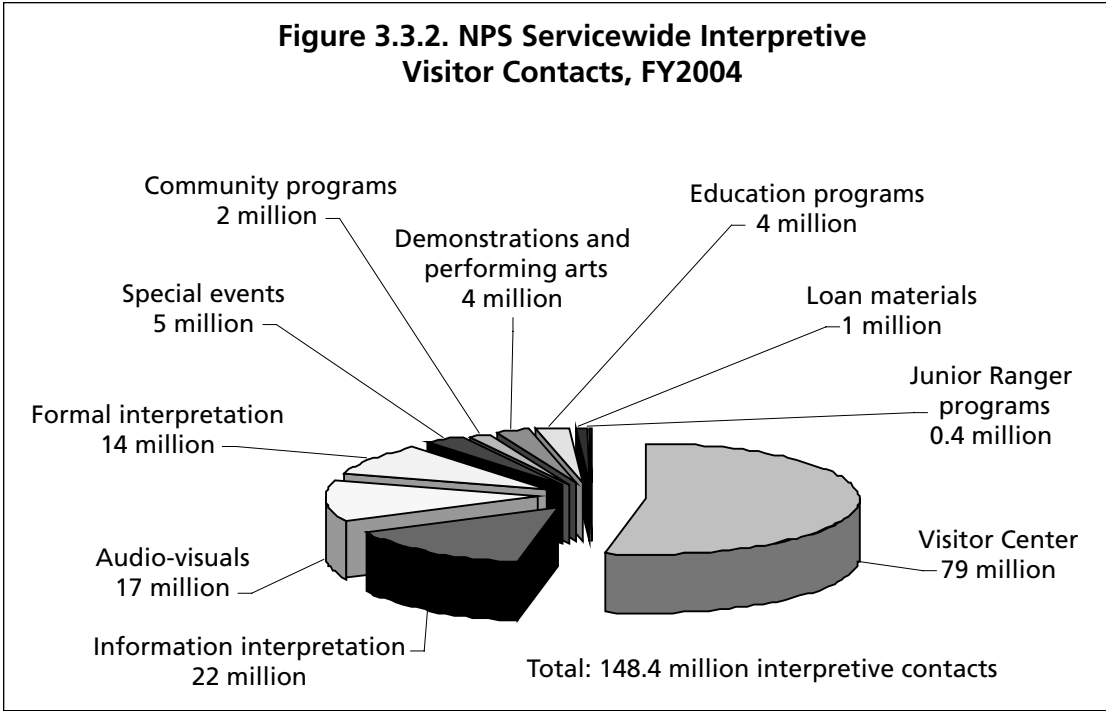


Figure 3.3.2. Millions of park visitors experienced NPS interpretive services in 2004.

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.¹⁹ 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.²⁰

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.²¹

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.²²

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.²³ 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.²⁴

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 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 DEIS. These researchers are sometimes called “bioprospectors,” and are described in detail later in this chapter (*see* Section 3.5.3).

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.²⁵ 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.²⁶ 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).²⁷ 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.²⁸ The NPS has not historically prohibited researchers from developing any valuable inventions or other scientific discoveries for any lawful purpose.²⁹

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.³⁰ 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.³¹ 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.³² After research has concluded, researchers are requested to provide the park with copies of all published material resulting from their park-related research activities.³³ 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 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 specimens (including descendants or derivatives of those 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.³⁴ 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.³⁵

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.”³⁶ However, the terms “biodiversity prospecting” and “bioprospecting” have no legal significance or single, universally-accepted definition (*see* box, Definitions for “Bioprospecting”).

This DEIS 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.”³⁷ 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.”³⁸ 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.”³⁹ 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.”⁴⁰

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.”⁴¹

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.⁴²

The greatest benefit from the initial discovery is developed at the subsequent stages of the research process.⁴³ 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.”⁴⁴ 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.”⁴⁵

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.⁴⁶ 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.⁴⁷ 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 43 of the 45 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.

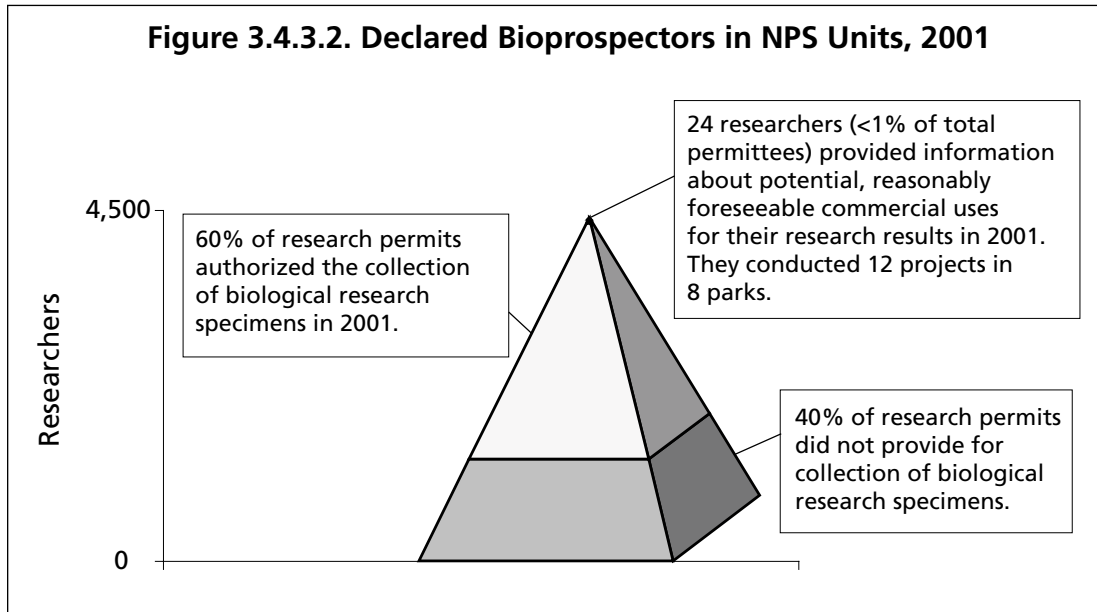


Figure 3.4.3.2. Less than 1% of all independent researchers performing research in NPS units were declared bioprospectors in 2001.

There are several reasons why the number of declared bioprospectors studying national park specimens 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 specimens 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,

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.

which 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.⁴⁸

Undeclared bioprospectors

There are some scientists in fields known to be particularly likely for commercial application who consider their studies to be strictly “basic research,” because they have no intention of conducting research for the purpose of developing commercial products unless and until they actually discover some valuable research result. Such researchers can be characterized as “undeclared bioprospectors,” because their research activities are conducted in fields where there is widely acknowledged interest in potential applications that have some foreseeable commercial purpose and value.

Undeclared bioprospectors are distinguishable from inadvertent bioprospectors because

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.⁵⁰

their research activities are in fields known to produce reasonably foreseeable research results with potentially valuable commercial applications. In other words, the research focus of undeclared bioprospectors is in fields of research where the likelihood of discovering a novel bioactive compound with some potential commercial utility is not entirely speculative or serendipitous. Additionally, undeclared bioprospectors differ from declared bioprospectors in that they do not consider their own research activities to have any potential for commercial development until there has been an actual discovery with some demonstrated commercial application.⁴⁹ When undeclared bioprospectors recognize a commercial use for their research 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 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.⁵¹

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.⁵² 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.⁵³ 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.⁵⁴

The procedures for entering into, reviewing, and terminating agreements are well established.⁵⁵ 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.⁵⁶

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.⁵⁷

As the National Park System Advisory Board reported in *Rethinking the National Parks for the 21st 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

As of November 2005, there were 12 federal agencies, 160 universities and colleges, and 39 other partners involved in interagency Cooperative Ecosystem Studies Units.⁵⁹ In 2001, the NPS inaugurated a new network of 13 Research Learning Centers where scientists, park managers, and the public come together to advance and share learning about park natural resources.⁶⁰ 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.⁵⁸

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.⁶¹

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 without prior authorization from the NPS.⁶² 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 specimens that are 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, 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.⁶³ 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 DEIS, 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 at White Sands National Monument to 109 at Yellowstone National Park. 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.

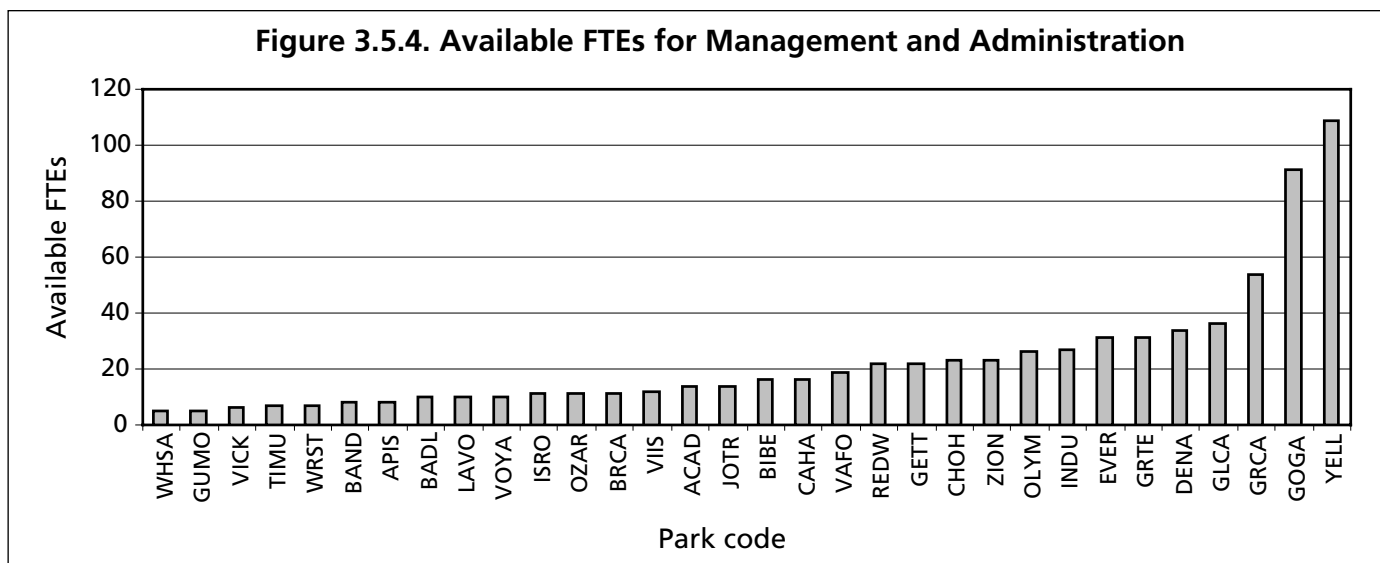


Figure 3.5.4. The number of available administrative FTEs per park varies considerably.

Notes

Section 3.2 Natural Resource Management

¹ See, e.g., National Research Council, *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).

² National Park Service, *National Leadership Council Journal* (April 2001).

³ 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.

⁴ 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.

⁵ Council on Environmental Quality (CEQ), *Incorporating Biodiversity Considerations into Environmental Impact Analysis Under the National Environmental Policy Act* (Washington, D.C.: CEQ, 1993).

⁶ National Park Service, *National Park Service Management Policies 2001*, Chapter Four: “Natural Resource Management,” Section 4.4.1 (Washington, D.C.: U.S. Department of the Interior, 2000).

⁷ *Ibid.*, Section 4.0.

⁸ National Park Service, *Natural Resource Challenge in Alaska* (March 2002).

⁹ National Park Service, *Northeast Region Natural Resource Challenge Annual Report, 2002*.

¹⁰ 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.

¹¹ National Park Service, *Management Policies 2001*, Section 4.2 “Studies and Collecting.”

¹² 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.

¹³ 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.

¹⁴ 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*.

¹⁵ 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.

¹⁶ 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

¹⁷ 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.

¹⁸ 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.

¹⁹ 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).

²⁰ 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.

²¹ National Park Service, *Interpretive Development Program*, available online at <<http://www.nps.gov/idp/interp>>, last accessed March 14, 2006.

²² Widner, “Reducing Theft of Petrified Wood at Petrified Forest National Park.”

²³ National Park Service, *Management Policies 2001*, Chapter 7.

²⁴ Mount Rainier National Park, *Long-range Interpretive Plan* (Longmire, Wash.: Mount Rainier National Park, 2000).

Section 3.4 Social Resources: The Research Community

²⁵ 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed March 14, 2006. 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.

²⁶ 69 *Federal Register* 31402–31403.

²⁷ 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed March 14, 2006).

²⁸ 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed March 14, 2006). 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).

²⁹ 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.”

³⁰ National Park Service, “NPS Scientific Research and Collecting Permit General Conditions,” available online at <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed March 14, 2006.

³¹ Analysis of 2001 RPRS data, on file at Yellowstone National Park.

³² “RPRS Application Procedures and Requirements for Scientific Research and Collecting Permits,”

available online at <<http://science.nature.nps.gov/research>>, last accessed March 14, 2006.

³³ *Ibid.*

³⁴ 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed March 14, 2006).

³⁵ 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 that are intended to be consumed in analysis.

³⁶ 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).

³⁷ W. Reid et al., *Biodiversity Prospecting*, 1.

³⁸ A. Sittenfeld and A. Lovejoy, “Biodiversity Prospecting,” in *Our Planet* (Nairobi: U.N. Environment Programme, 1997), 20.

³⁹ Resources and Networks Branch, Ministry of Economic Development, Government of New Zealand, *Bioprospecting in New Zealand* (2002), 5.

⁴⁰ 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).

⁴¹ Harvard Business School, Case Study No. N1-593-015 (October 23, 1992), 5.

⁴² 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.).

⁴³ 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.

⁴⁴ A. Artuso, *Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing* (Binghamton, New York: The Haworth Press, 1997), 21.

⁴⁵ *Ibid.*, 51 and 64 (“... the models and analytical techniques presented [by Artuso] can easily be applied to evaluate other natural product R&D programs. . .”).

⁴⁶ 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).

⁴⁷ Deutch, A., “Analysis of the NPS Research Permit Database for Calendar Year 2001,” (2002), on file at Yellowstone National Park.

⁴⁸ L. Mallory, “Isolation of Cancer Chemotherapeutic Natural Products from Cave Microorganisms” (NPS Investigator’s Annual Report, 1994), available online at <<http://science.nature.nps.gov/research/ac/iars/search/iarView?reportId=2698>>, last accessed March 14, 2006. 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.

⁴⁹ 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.

⁵⁰ See, e.g., Madigan and Marrs, “Extremophiles,” *Scientific American* (April 1997): 82–87.

⁵¹ 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

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⁵² 16 USC 5933.

⁵³ National Park Service, *Agreements Handbook*, Chapter 7. (Washington, D.C.: Government Printing Office, 2003).

⁵⁴ 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.

⁵⁵ *National Park Service Agreements Handbook*, available online at <<http://www.nps.gov/hfc/acquisition/agreements.htm>>, last accessed March 15, 2006.

⁵⁶ National Park Service, *NPS Director's Order 20: Agreements*.

⁵⁷ 16 USC 5932.

⁵⁸ See, e.g., National Park Service, *National Leadership Council Journal*, April 2001 and November 2002.

⁵⁹ Cooperative Ecosystem Studies Unit briefing statement, November 18, 2005, available online at <<http://www.cesu.org/news/briefings.html>>, last accessed March 14, 2006.

⁶⁰ See <<http://www.nature.nps.gov/learningcenters/centers.cfm>>, last accessed March 20, 2006.

⁶¹ National Park Service, Paperwork Reduction Act submission.

⁶² 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://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed March 14, 2006).

⁶³ Most Business Plans prepared in 1999 (the first year of the Initiative) did not include FTE information.

Chapter 4

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 DEIS 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 DEIS 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.¹ The NPS anticipates that benefits-sharing would be conducted through the use of Cooperative Research and

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).

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.² Therefore, this DEIS focuses on the research aspect of resource conservation and management.

4.2 Methodologies for Evaluating Impacts

This DEIS 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.

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

Impact category	Definition
Beneficial impact	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.
Adverse impact	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.
Direct impact	An impact that is caused by an action and occurs at the same time and place.
Indirect impact	An impact that is caused by an action but is later in time or farther removed in distance, but is still reasonably foreseeable.
Qualitative impact	An impact that can only be measured by subjective comparison to objectives.
Quantitative impact	An impact that can be measured objectively, usually in numerical terms.
Short-term impact	An impact that in a short time after an action is taken will no longer be detectable. This DEIS considers any change that is evident for 5 years or less to be short-term.
Long-term impact	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) 2004. 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 FY 2004 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.

Table 4.2.1. Intensity of quantitative impacts to natural resource management

Impact intensity	Equivalent to X% of individual park natural resource management funding levels	Equivalent to X% of servicewide FY2004 Natural Resource Challenge funding
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 FY2004 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 FY2004 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 FY2004 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 FY2004 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 because the historical patent record suggests that multiple discoveries with commercial application were based on research involving research material originating in Yellowstone (*see* Chapter 1, Section 1.2.4), which suggests that under Alternative B, the majority of NPS benefits-sharing agreements would occur between researchers and Yellowstone.

4.2.2 Visitor Experience and Enjoyment

Potential impacts to visitor experience and enjoyment are assessed by determining the extent to which each alternative would change 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).

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.³

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; 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 because the historical patent record suggests that multiple discoveries with commercial application were based on research involving research material originating in Yellowstone (*see* Chapter 1, Section 1.2.4), which suggests that the majority of NPS benefits-sharing agreements could be established between researchers and Yellowstone.

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 DEIS. 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).⁴

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 because specimens cannot be 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 DEIS 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.⁵

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 DEIS 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 DEIS.

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.⁶ 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 DEIS 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.

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.⁷ 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.⁸

4.3.1.4 Mitigation measures

The NPS has not identified any mitigation measures.

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 FY2004, the total annual funding for the Natural Resource Challenge was approximately \$73 million.

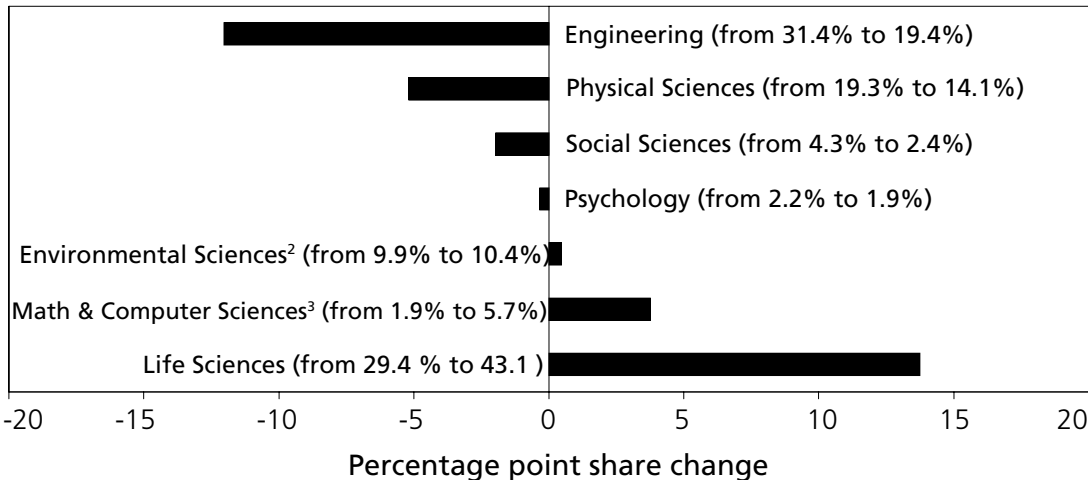
The linchpin of the NPS Natural Resource Challenge is the Inventory and Monitoring (I&M) Program, specifically required by NPOMA. The I&M Program provides the information needed to understand and measure performance regarding the condition of resources in parks, including the condition of watersheds, landscapes, marine resources, and biological communities. This information guides park management actions to improve and sustain the health of park resources. Based on the FY2006 budget proposal, by the end of FY2008, the I&M Program plans to identify the vital signs for natural resource monitoring in all 270 parks with significant natural resources and to have implemented vital signs monitoring in 80% (216 of 270) of those parks. In FY2006, the NPS requested \$4.9 million for this program.

The NPS participates in 17 Cooperative Ecosystem Studies Units (CESUs) to conduct cooperative multi-disciplinary research about NPS resources. CESU's 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.⁹ As of August 2005, there were 13 federal agencies, 160 universities, and 39 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

Figure 4.3.1.6. Changes in Field Shares of Total Federal Research Funding, 1970–1997¹



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.

¹This analysis deals with federal funds that support basic and applied research, but not development.
²In a number of surveys and reports, the designation earth, atmospheric, and oceanographic sciences is used in lieu of environmental sciences.
³These 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 federal research funding has shifted over the last three decades in favor of the life sciences. In 2003, life sciences research was estimated to account for 54% of federal research funding.¹⁰

resources, especially those related to NPOMA and the Natural Resource Challenge will continue to have beneficial impacts on management of natural resources.

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.¹¹ 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. As funding priorities have shifted to the life sciences, more funding has been 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 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 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 mitigation measures.

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.¹² 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 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.

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 mitigation measures.

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 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.¹³ 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 DEIS.

Equally 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 DEIS.

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.¹⁴ 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 DEIS 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 DEIS.

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 DEIS, 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 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.

Choosing not to provide a standardized MTA under Alternative A would continue to result in confusion within some parts of the NPS regarding when specimen transfer authorizations (other than permanently retained museum collections) must be requested and how to act upon such requests. Information relevant to estimating the number of specimen transfer authorizations issued servicewide and determining the impact of Alternative A is unavailable, because no systematic way has been established to conduct, manage, or report on them. However, 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, Yellowstone National Park adopted a standardized MTA for specimen transfers in the year 2000. 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 4.2.3).

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. Information for estimating the number of parks that might be affected is unavailable, because no systematic way has been established to conduct, manage, or report on these authorizations. However, 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 mitigation measures.

4.3.4.5 Conclusion

Under Alternative A, the NPS would choose not to implement benefits-sharing or 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 DEIS 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 DEIS 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.¹⁵

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.¹⁶ Any funds received by the NPS from CRADA-related activities would be managed in compliance with these provisions.¹⁷

Table 4.4.1. Potential benefit types and timing generated by a single CRADA

	Short-term	Long-term
Non-monetary	Knowledge and research relationships, training or education, research-related equipment, or special services	Some non-monetary benefits possible
Up-front monetary	Funding for park research (not expected in every agreement)	n/a
Performance-based monetary	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.¹⁸

Non-monetary benefits, such as scientific equipment for research to answer management related questions and improved 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 cumulative terms for the entire proposed benefits-sharing program and in terms of a single benefits-sharing agreement. 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.

Cumulatively, the estimated potential monetary benefits under Alternative B would be larger with each succeeding year (*see* Table 4.4.1.2-1).

Table 4.4.1.2-1. 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

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 4.4.1.2-2).

Table 4.4.1.2-2. Estimated range of potential monetary benefits used to analyze the impacts of a proposed NPS benefits-sharing program on individual parks other than Yellowstone

Duration of potential impact	Potential annual payment	% of agreements likely to yield this average benefits level (see Appendix C, Section C.9.3)	See Appendix C (Sections referenced) for the derivation of this estimate
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)

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 natural 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 all 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.¹⁹ 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 all monetary terms)

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 four effects. It could (1) limit payment equitability, (2) create an artificial “rate ceiling,” (3) discourage some research, and (4) 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.²⁰ This could affect the amount and timing of monetary benefits actually provided to the NPS (*see* Chapter 4, Section 4.4.1.3).

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.²¹ 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.²²

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 such researchers who could refrain from studying park resources or from entering into benefits-sharing agreements under Alternative B1 cannot be derived from available information, it is anticipated that any potential loss of monetary benefits is captured within the estimated range of monetary benefits presented in this DEIS (*see* Section 4.4.1.2).

Impacts specific to Alternative B2 (evaluate disclosure of monetary terms on case-by-case basis)

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.²³

Implementation of Alternative B2 would avoid the four effects of Alternative B1; it would not limit payment equitability, create an artificial “rate ceiling,” 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 (*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 affect the estimate of monetary benefits provided in this DEIS. The impact of Alternative B2 on potential monetary benefits is captured within the estimates provided in this DEIS.

Impacts specific to Alternative B3 (never disclose monetary terms)

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 four effects of Alternative B1; it would not limit payment equitability, create an artificial “rate ceiling,” 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 affect the estimate of monetary benefits provided in this DEIS. The impact of Alternative B3 on potential monetary benefits is captured within the estimates provided in this DEIS.

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. Range of Cumulative Potential Monetary Benefits of an NPS Benefits-Sharing Program

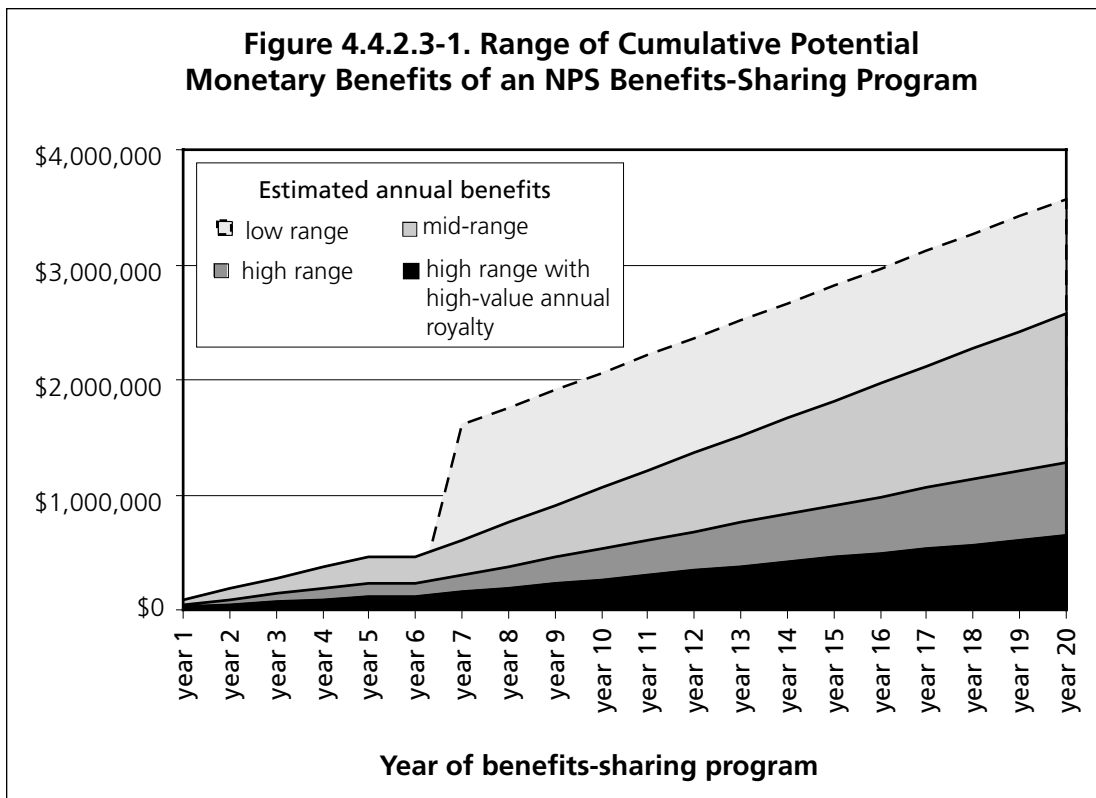


Figure 4.4.2.3-1. An NPS benefits-sharing program could generate monetary benefits that would increase over time because CRADAs would obligate researchers to make performance-based payments and such obligation would survive termination of the CRADA.

To provide a servicewide perspective, the total amount of estimated monetary benefits was compared to the budget for the Natural Resource Challenge. In 2004, the Natural Resource Challenge program accounted for approximately \$73 million of the NPS budget.²⁴ This comparison is presented in the table below.

Table 4.4.2.3. All potential monetary benefits compared to the \$73 million NPS Natural Resource Challenge funding, FY2004

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%	0.07%	0.15%	No royalties expected this year
5	0.17%	0.33%	0.75%	No royalties expected this year
10	0.37%	0.74%	1.65%	3.02%
20	0.87%	1.74%	3.91%	5.29%

Table 4.4.2.3. The comparison of potential monetary benefits generated by an NPS benefits-sharing program to the FY2004 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 FY2004. Accordingly, potential short-term monetary benefits would represent short-term, beneficial, negligible impacts to servicewide natural resource management.

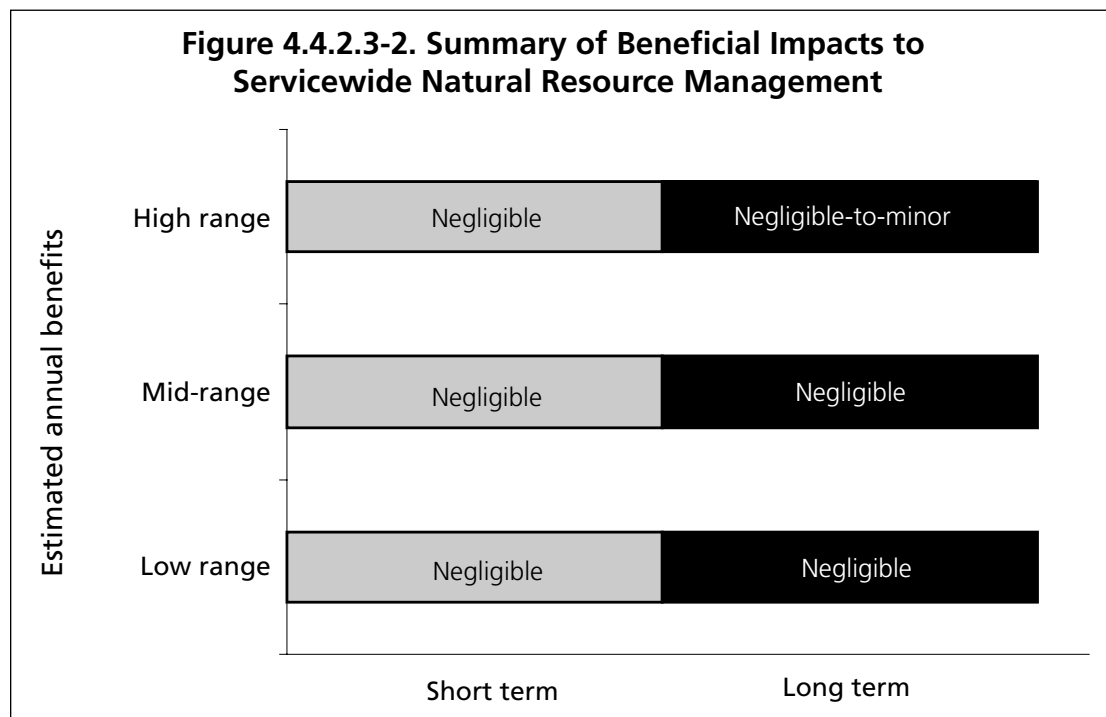


Figure 4.4.2.3-2. Monetary benefits could have a negligible and, in some instances, minor beneficial impacts on servicewide natural resource management.

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 FY2004. 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.²⁵ 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.

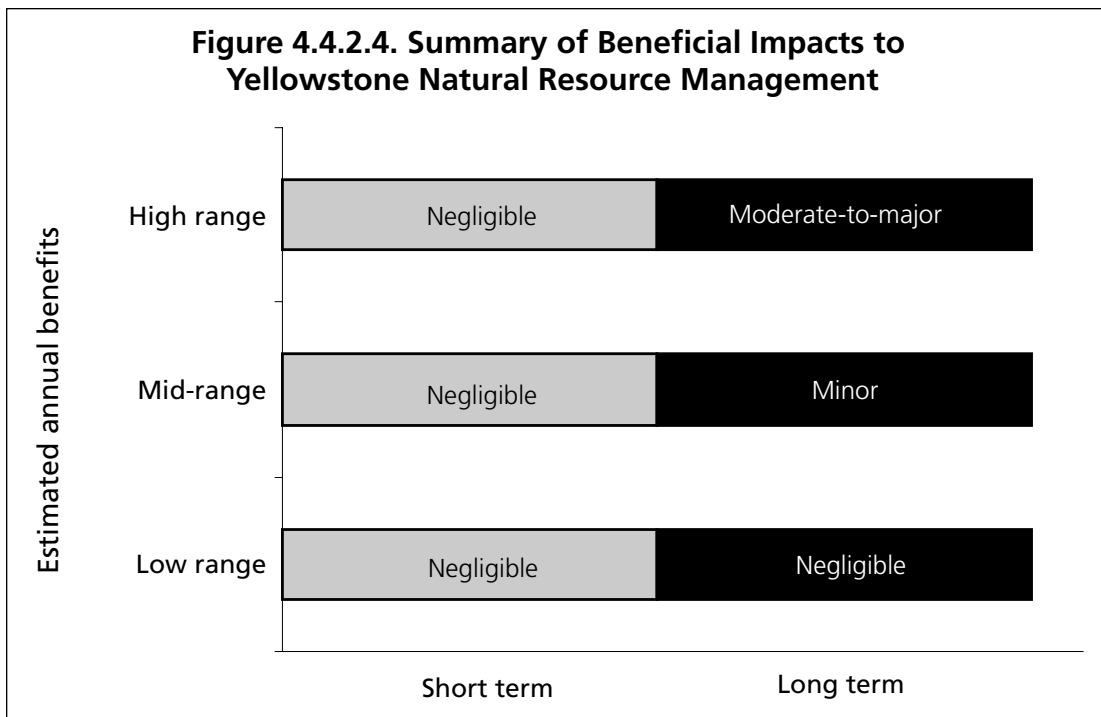


Figure 4.4.2.4. The monetary benefits derived from benefits-sharing program could have a negligible short-term beneficial impact on Yellowstone natural resource management and a long-term negligible-to-major beneficial impact.

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 4.4.1.2-2, 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.

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 4.3.2.6.

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). Examples 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.²⁶

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.²⁷ 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.²⁸ 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 NPS units in an unimpaired condition. 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 Interpretive 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.²⁹ 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.

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 when the material is not cataloged as part of a museum collection because it will be consumed in analysis.

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 that terms of the non-monetary and monetary benefits in 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 DEIS 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).³⁰

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 specimens that will be consumed during analysis and are therefore not suitable for permanent retention as museum specimens. 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 all monetary terms)

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.³¹

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 (evaluate disclosure of monetary terms on a case-by-case basis)

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 monetary terms)

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 in 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.³²

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.³³

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 2001, AUTM reporting institutions required a total of 717.91 FTE for a variety of activities associated with licensing. In that year, 4,058 new licenses were executed out of a total of 22,939 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.³⁴

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. If parks servicewide

established two, four, or nine new benefits-sharing agreements in one year, the FTE required for that purpose would range from 0.36 to 1.62 FTE. 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.³⁵ Information relevant to evaluating the number of MTAs that have been executed servicewide is unavailable, because no systematic way has been established to conduct, manage, or report on these authorizations. However, 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

	2 new agreements annually	4 new agreements annually	9 new agreements annually
Number of FTE needed	2 x 0.18 = 0.36	4 x 0.18 = 0.72	9 x 0.18 = 1.62
Impact	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. If Yellowstone established between two and nine benefits-sharing agreements in one year, the FTE required for that purpose would range from 0.36 to 1.62, and would represent, at most, 1.5% of available administration and management FTE. 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

	2 new agreements annually	4 new agreements annually	9 new agreements annually
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.³⁶ The number of available administrative FTE per park varies considerably (*see* Table 4.4.5.3, below). If individual parks established a single benefits-sharing agreement, the FTE required for that purpose would represent, at most, 3.75% of available FTE. It is possible that a park might not contain the in-house expertise necessary to enable it to negotiate a benefits-sharing agreement. In such a case, the park 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 FTE	Percentage of available FTE	Park Code	Available FTE	Percentage of available FTE
GUMO	4.8	3.75%	CAHA	16.1	1.12%
WHSA	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 negligible long-term 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 all monetary terms)

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. 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.

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, the impacts on NPS administrative operations of implementing Alternative B1 could be less adverse (require less work) than Alternative B2 or B3. The NPS believes that the breadth of the estimated range of the number of new benefits-sharing agreements each year (two, four, or nine) is adequate to include the potential impact of Alternative B1.

Impacts specific to Alternative B2 (evaluate disclosure of monetary terms on case-by-case basis)

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.³⁷

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. The NPS believes that the estimated range of the number of new benefits-sharing agreements each year (two, four, or nine) is adequate to include the potential impact of Alternative B2.

Impacts specific to Alternative B3 (never disclose monetary terms)

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 B3. In contrast to Alternative B1, Alternative B3 would have no additional impact on NPS administrative operations beyond that already identified for Alternative B. The NPS believes that the estimated range of the number of new benefits-sharing agreements each year (two, four, or nine) is adequate to include the potential impact of Alternative B3.

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.³⁸ NPS 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.³⁹

Workload

NPS implementation of standardized MTAs to authorize third-party transfers of research specimens that have not been cataloged into NPS museum collections would help to minimize administrative burdens and, as such, any adverse impacts on NPS administrative operations.⁴⁰ 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.⁴¹ No estimate has been made for this DEIS 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.⁴² 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

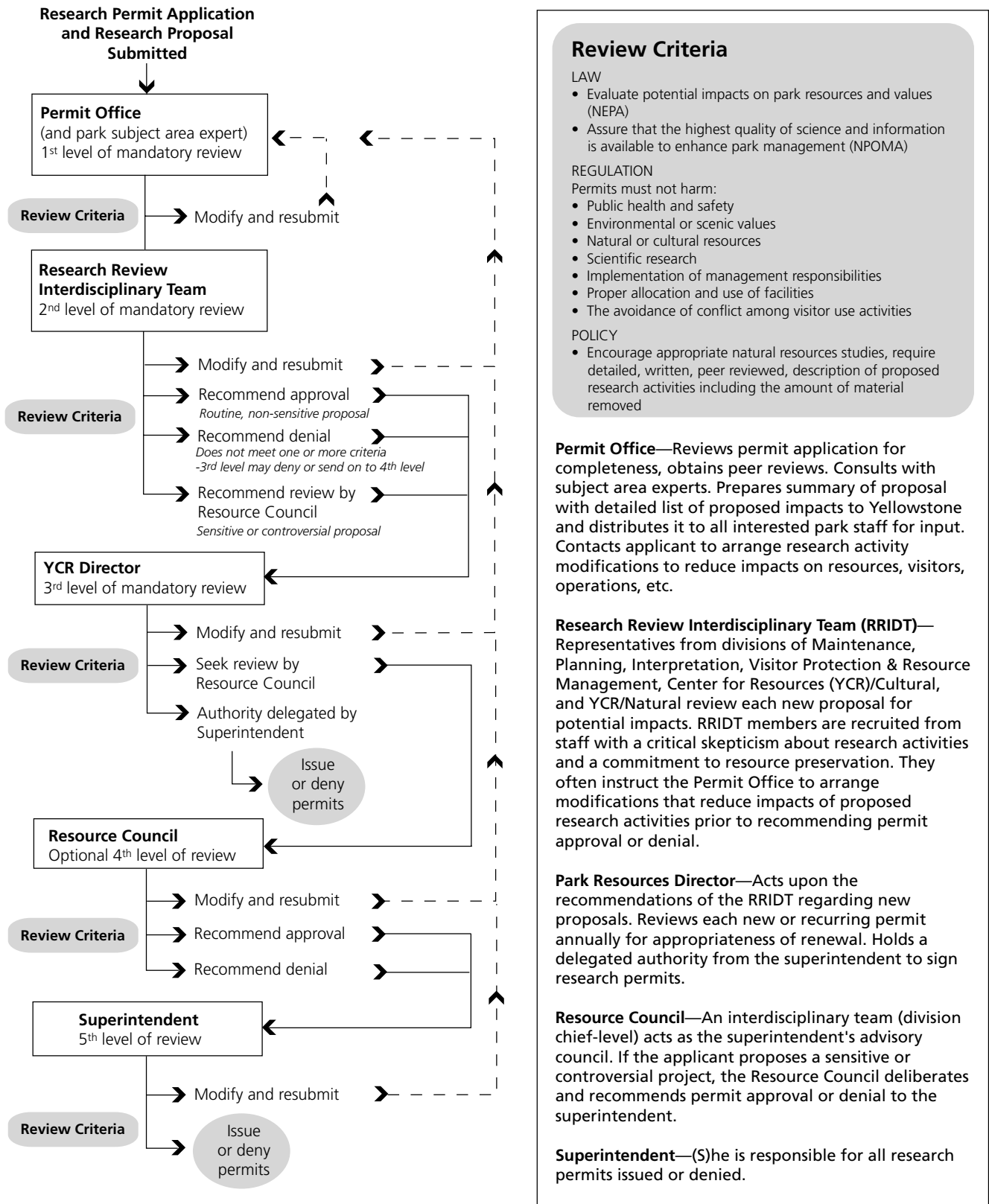
(Director's Order 12) that would not be affected by implementation of Alternative B. These regulations and policy directives would continue to protect NPS natural resources against impairment or other adverse impacts by applying the mitigation considerations provided in 36 CFR 1.6. These considerations 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 1. Research permit review procedures, Yellowstone National Park



Delegation of authority and organization

As suggested by the U.S. Office of Management and Budget (OMB), an appropriate organizational structure would be established to effectively carry out program responsibilities.⁴³

Three 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.⁴⁴
- 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) 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.

Parks would be provided with technical assistance from NPS personnel with specialized benefits-sharing expertise. 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 OMB, it would also function as a guard against individuals exceeding or abusing their assigned authorities.⁴⁵

These mitigation measures also would be applied to any future actions that are guided by this DEIS. 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 Irretrievable 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.⁴⁶ 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 DEIS 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.

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, below. 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

	Servicewide	Yellowstone	Individual parks
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.⁴⁷ 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, which is the specialized field of biological research that has resulted in every known patent resulting from study of biological material originating in the NPS. 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.⁴⁸

Information developed by microbiologists, whether or not they are bioprospectors, can add substantially to natural resource managers' knowledge base. In 2001, at least 72 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. 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.⁴⁹ 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, appropriate 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 mitigation measures.

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 4.3.2.6.

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 mitigation measures.

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).⁵⁰

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 researchers in 8 parks of the 4,568 total permitted researchers (0.5% of researchers), accounting for 12 of the 2,160 total research projects (0.6% of projects) that were registered in the RPRS could have been denied

permission to collect NPS research specimens. These 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 these 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 collect specimens in degraded thermal areas outside the protection of parks at some loss of specimen quality. 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 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 specimens that will be consumed during analysis and are therefore not suitable for permanent retention as museum specimens. 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, 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 DEIS). 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 specimens not suitable for permanent retention as museum collections 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.⁵¹ Information relevant to evaluating the number of MTAs that would be executed servicewide is unavailable, because no systematic way has been established to conduct, manage, or report on these authorizations. 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.⁵² 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 mitigation measures.

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 DEIS reveals the possible environmental impacts of choosing whether or not to implement a certain type of contract. Hence, the nature of this DEIS 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

¹ National Park Service Organic Act, 16 USC 1.

² The Federal Technology Transfer Act of 1986 (FTTA) requires that benefits generated for parks be used for research 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

³ *See, e.g.,* C. J. Widner, "Reducing Theft of Petrified Wood at Petrified Forest National Park," *Journal of Interpretation Research* 5(1):1-18.

⁴ 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.

⁵ National Park Service, *National Park Service Management Policies 2001* (Washington, D.C.: U.S. Department of the Interior, 2000).

⁶ *See* 40 CFR 1508.7.

Section 4.3 Alternative A: No Benefits-Sharing/No Action

⁷ 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.

⁸ 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.

⁹ For additional information and materials, see <<http://www.cesu.org/cesu>>.

¹⁰ 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.

¹¹ 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)

¹² 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.)

¹³ AUTM 2003 reports that 66% of research expenditures that year were funded from federal sources.

¹⁴ NPS Natural Resource Year in Review --- 2004. see also National Research Council. 1992. Science and the National Parks. National Academy Press, Washington, D.C. "The parks are invaluable for unraveling the mysteries of natural and human history, evolutionary adaptation, ecosystem dynamics, and other natural processes."

Section 4.4 Alternative B: Implement Benefits-Sharing

¹⁵ 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 DEIS 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.

¹⁶ See 15 USC 3710c.

¹⁷ See 15 USC 3710a(d)(1) and 3710c.

¹⁸ 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.

¹⁹ 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).

²⁰ 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).

²¹ *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).

²² Ibid.

²³ 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)).

²⁴ 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.

²⁵ Yellowstone National Park, *Resource Management Plan* (1995).

²⁶ See, e.g., Widner, "Reducing Theft of Petrified Wood at Petrified Forest National Park."

²⁷ 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).

- ²⁸ See Appendix A, Article 7.1, requiring the benefits-sharing partners to disclose all inventions.
- ²⁹ Similar assistance has recently been given by researchers to Yellowstone National Park.
- ³⁰ 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.
- ³¹ 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.)).
- ³² 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)).
- ³³ 15 USC 3710c.
- ³⁴ 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.
- ³⁵ C. Hendrix, Yellowstone Research Permit Coordinator, pers. comm. to A. Deutch, November 2003.
- ³⁶ Most Business Plans that were prepared in 1999 (the first year of the Business Plan Initiative) did not include FTE information.
- ³⁷ See 5 USC 552 (b)(4).
- ³⁸ Such assistance would be consistent with the guidelines relating to development of CRADAs first published by the Department of the Interior in May 1996.
- ³⁹ 15 USC 3710c(a)(1)(B)(iv).
- ⁴⁰ 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.
- ⁴¹ C. Hendrix, Yellowstone Research Coordinator, pers. comm. to A. Deutch, November 2003.
- ⁴² See OMB Circular A-123, Management Accountability and Control (1995).
- ⁴³ *Ibid.*
- ⁴⁴ 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)).
- ⁴⁵ See OMB Circular A-123.

Section 4.5 Alternative C: Prohibit Research Specimen Collection for Any Commercially Related Research Purposes

- ⁴⁶ Material Transfer Agreements (MTAs) are not “benefits-sharing” agreements, because they do not contain revenue-sharing or other benefits-sharing terms or obligations.
- ⁴⁷ 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.
- ⁴⁸ 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 (*High Country News*, “Biologist Jayne Belnap,” January 19, 2004; see also R. Constanza et al., “The Value of the World’s Ecosystem Services and Natural Capital,” *Nature* 387:253–260).
- ⁴⁹ 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://science.nature.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://science.nature.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://science.nature.nps.gov/research/ac/iars/search/iarView?reportId=27141>>, all last accessed April 18, 2006).
- ⁵⁰ 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).

⁵¹ C. Hendrix, Yellowstone Research Permit Coordinator, pers. comm. to A. Deutch, November 2003.

⁵² Most Business Plans that were prepared in 1999 (the first year of the Business Plan Initiative) did not include FTE information.

Chapter 5

Consultation and Coordination

CORE TEAM (Yellowstone National Park, Yellowstone Center for Resources)

Name	Responsibility	Education	Experience
Susan Mills	Project Manager, Servicewide Benefits- Sharing EIS	BA Biology, BA Psychobiology	20 years National Park Service
Ann Deutch	Writer, Servicewide Benefits-Sharing EIS, former Research Permit Coordinator	BS Outdoor Recreation, MA Biological Sciences	16 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	8 years National Park Service
Alice Wondrak Biel	Technical Writer-Editor	PhD Geography	7 years National Park Service
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Mike Soukup	Co-Chair Servicewide Benefits-Sharing Management Group, NPS Associate Director, Natural Resources Stewardship and Science	PhD Limnology	30 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	20 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	27 years National Park Service
John Dennis	NPS Deputy Chief Scientist	PhD Botany	34 years National Park Service
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Name	Responsibility	Education	Experience
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	11 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	28 years National Park Service, experience in environmental planning and compliance, 106 compliance, and regulatory issues

INTERDISCIPLINARY TEAM

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Thomas O Clark	Integrated Resources Program Manager, Division Chief for Resource Mgmt. & Science, Capitol Reef National Park	BS Wildlife Management, MS Zoology	11 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	25 years National Park Service
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Name	Responsibility	Education	Experience
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Gary Vequist	ARD for Natural Resource Stewardship	BS Zoology, MS Water Quality–Environmental Science	34 years National Park Service
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Chapter 6

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.

ex-situ: reference to the location of the components of biological diversity outside natural habitats.

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.

in-situ: reference to the location of the components of *biological diversity* within natural habitats and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

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 DEIS, 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 DEIS, 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
DEIS: Draft 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

Model Cooperative Research and Development Agreement (CRADA)

NOTE TO REVIEWERS

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 public review version of the Draft Environmental Impact Statement, but they will not be included in any final (signed) CRADA.

**COOPERATIVE RESEARCH AND
DEVELOPMENT AGREEMENT
for a project between
[NAME OF PARK UNIT] /
NATIONAL PARK SERVICE
and
[NAME OF COOPERATING RESEARCHER]**

General Provisions

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.

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.

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.

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.”

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.

Now, therefore, in consideration of the promises contained in this agreement, the parties agree as follows:

Article 1. Legal Authority

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).

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

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.

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

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.

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.

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.

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**.

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.

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.

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.

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

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.

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

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.

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.

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.

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

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.

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]

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.

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

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.

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

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.

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

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.

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

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.

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

Article 11 summarizes NPS's rights in data generated pursuant to research activities conducted under the CRADA.

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

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.

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

Article 13 contains the provisions relating to procedures intended to resolve any disputes arising between the parties under the CRADA.

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

Article 14 relates to the parties' liability for losses or damage incurred under the CRADA.

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

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.

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

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.

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
[name of collaborating unit of the National Park System]

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

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.

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

Model Material Transfer Agreement (MTA)

NOTE TO REVIEWERS

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 public review version of the Draft Environmental Impact Statement, but they will not be included in any final (signed) MTA.

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 DEIS.

Defined terms appear in bold-faced print throughout the MTA.

B.1 Definitions

1.1 Provider

The term “**Provider**” means the person(s) providing the **Material**. The name and address of Provider is:

(Name)

(Address)

2.2 Recipient

The term “**Recipient**” means the person(s) receiving the **Material**. The name and address of Recipient is:

(Name)

(Address)

2.3 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**.

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.

B.2 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. **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. **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**.

3. **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**.

4. **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.**

5. **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.**

B.3 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] _____
Superintendent Date
[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] _____
[Title] Date
[Name of Provider (if different from signatory)]

Mailing address for notices: [name and address]

FOR RECIPIENT:

[Signatory's name] _____
[Title] Date
[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

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 Chapter 1, Sections 1.9.1 (Federal Technology Transfer) and 1.9.2 (Academic Technology Transfer). Annual reports about income generated by licenses held by federal laboratories are compiled by the U.S. Department of Commerce (DOC).¹ 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).² A four-year dataset, FY1999–FY2002, from AUTM’s Licensing Survey Report for 2002, was analyzed and is presented below.³

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 DEIS 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 DEIS, 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.

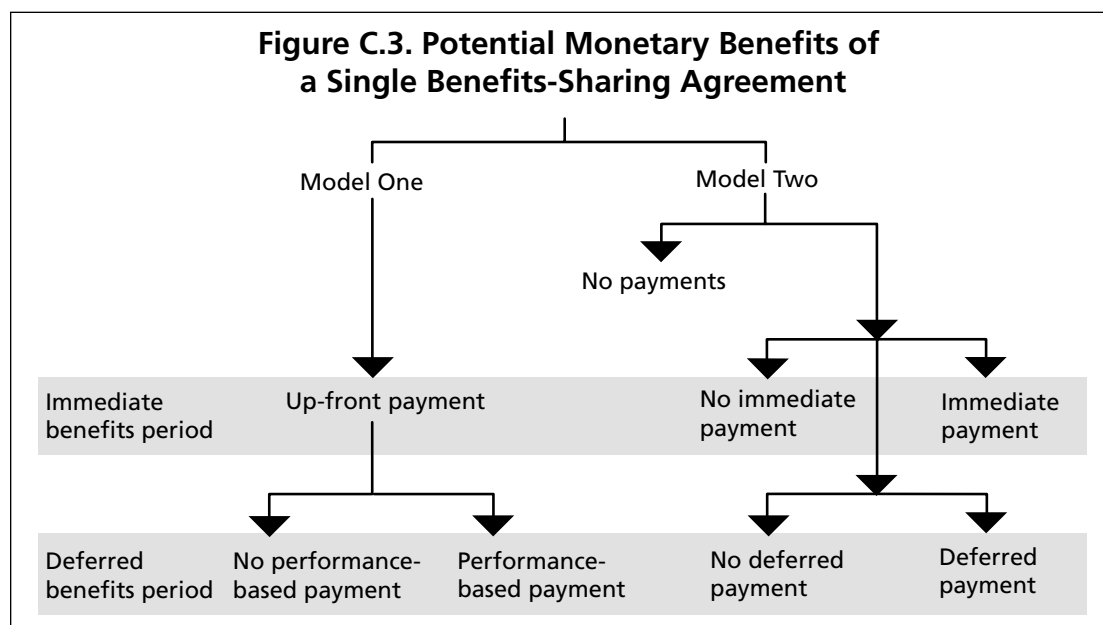


Figure C.3. A benefits-sharing agreement could generate monetary benefits during either the immediate benefits period, the deferred benefits period, both periods, or neither period.

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 DEIS 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 licenses⁴

	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 DEIS 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.⁵

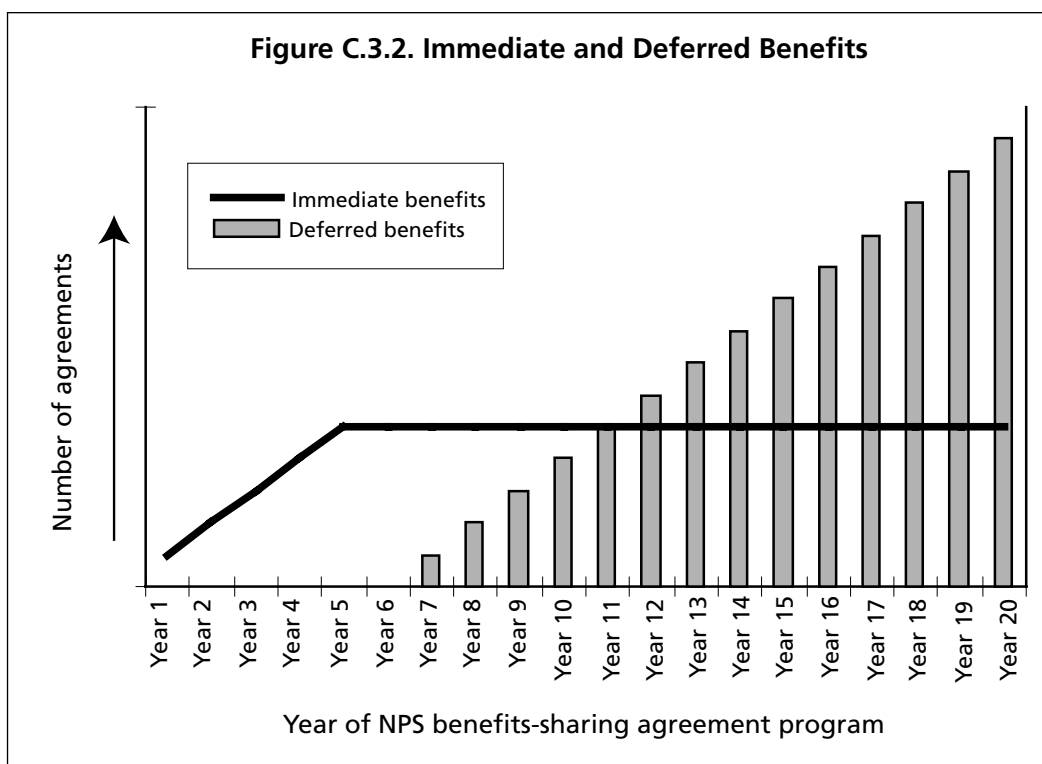


Figure C.3.2. Each agreement's obligation to provide immediate benefits would expire, but its obligation to provide performance-based payments through the 20-year DEIS analysis period would continue. As the years pass, more agreements each year might generate deferred benefits. (See Section C.7 and Table 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.⁶ For example, development of new medicines can require 15 years or more between the discovery stage and the marketing stage.⁷ 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 model CRADA (*see* Appendix A), any obligation to make performance-based payments would survive termination of the agreement.⁸ 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.⁹

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.¹⁰ Royalty income from licensing is related to performance—a licensee must make money before it owes royalties.

For purposes of analysis in this DEIS, the reported royalty income from licensing was used to represent all performance-based payments to academic and federal institutions from licensing of research results.¹¹ 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 DEIS, total license income received by an institution relative to research results, minus royalty income from licensing, is termed “other license income.”¹² 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.¹³

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 DEIS used these proportions for modeling potential monetary benefits.

Table C.4.1-1. Proportion of AUTM licenses that yielded income¹⁴

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 royalties¹⁵

	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.¹⁶ 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.”¹⁷

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 DEIS. The best information about the proportion of commercially related research projects that could 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.¹⁸

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 the number of inventions that might have been discovered related to the study of specimens originating in the NPS (*see* Section C.7.2).¹⁹ The estimated number of inventions is based on the number of patents known to have been granted related to the study of specimens originating in the NPS (*see* Section C.7.1). 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

It is possible that on average, two benefits-sharing agreements could be established annually, which is consistent with the rate at which patents were granted for research results related to the study of specimens originally collected from NPS units during the 1994–2003 period (*see* Table C.7.1 and Chapter 1, Section 1.2.4).

Table C.7.1. NPS-related patents granted annually

Grant year	No. of patents	Grant year	No. of patents
1978	1	1991	0
1979	0	1992	3
1980	0	1993	1
1981	2	1994	4
1982	2	1995	1
1983	2	1996	3
1984	0	1997	0
1985	0	1998	5
1986	4	1999	6
1987	1	2000	3
1988	2	2001	0
1989	2	2002	1
1990	1	2003	1

Total patents granted: 45

Average per year: 2

Average per year, most recent decade (1994–2003): 2

Table C.7.1. An average of two patents related to study of NPS specimens are known to have been granted each year.

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). This DEIS 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 patenting and inventing in other institutions. Under Alternative B, each invention could trigger a benefits-sharing agreement.

Federal laboratories and academic institutions report the number of inventions as well as patents made annually by researchers in their institutions. In every year, more inventions are recorded than 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. However, each invention, whether patented or not, represents a potential commercial application for research results (*see* Chapter 1, Figures 1.9.1-3 and 1.9.2-2).

C.7.2.1 Best available information

Table C.7.2-1, below, shows the comparative rate of patenting and inventing by federal laboratories and academic institutions, with special emphasis on two federal departments: the Department of the Interior (DOI) and the Department of Health and Human Services (HHS). The DOI was examined separately—not only because it is the NPS’s Departmental affiliate, but also because the relatively few patents and inventions reported by the DOI are managed by agencies that are, like the NPS, concerned with natural resources: the U.S. Geological Survey and the Bureau of Reclamation.²⁰ HHS was examined separately because the majority of its reported patents and inventions are generated by the National Institutes of Health (NIH) and, like the research expected to be most likely to trigger a benefits-sharing agreement, are related to biological research.²¹ Data supporting Table C.7.2-1 are shown in Section C.10.1.

Table C.7.2-1. Comparative rates of inventing and patenting in federal laboratories and academic institutions

	DOI 1999–2001*	HHS 1999–2003	Federal laboratories, 1999–2003	AUTM, 1999–2002	Combined federal and AUTM data
Inventions	30	2,040	19,660	54,498	74,158
Patents	7	683	7,604	14,819	22,423
Comparative rate (CR) = Inventions (I) / Patents (P), or X times as many inventions as patents	4.3	3.0	2.6	3.7	3.3

*DOI did not report invention or patent numbers for 2002–2003.

Table C.7.2-1. Federal laboratories and academic institutions report from 2.6 to 4.3 times as many inventions each year as patents.

Federal laboratories and academic institutions report from 2.6 to 4.3 times as many inventions each year as patents (*see* Table C.7.2-1). 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 patents known to have been granted each year relating to research involving NPS biological material was approximately two (*see* Table C.7.2-2). If the range of comparative rates of inventing to patenting (2.6 to 4.3) is calculated according to this average, then the annual number of inventions would have been between five and nine.

Table C.7.2-2. Estimated annual number of NPS-related inventions

	DOI rate	HHS rate	Federal laboratories rate	AUTM rate	Average rate
Average number of patents per year	2	2	2	2	2
Comparative rate of inventing and patenting	4.3	3.0	2.6	3.7	3.3
Estimated number of inventions per year	8.6	6.0	5.2	7.4	6.6

Table C.7.2-2. Research involving the study of biological material originally collected from a national park is estimated to generate an average of seven inventions annually.

In addition, multiple discoveries, inventions, or patents could be made by a single researcher. However, this DEIS 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

The estimate of the range of total annual monetary benefits that could be generated under Alternative B is based on potential average monetary benefits per agreement, multiplied by the number of benefits-sharing agreements that could generate such payments each year. Three benchmark levels for the number of new agreements executed each year 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 DEIS 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 DEIS, 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%.²² 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%.²³ 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 DEIS, 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.²⁴ 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.

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.³³ 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.³⁴ 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.³⁵

Table C.8.3.1. Global markets

Industrial sector	Estimated market value (U.S. dollars)²⁵
Pharmaceuticals	\$300 billion ²⁶
Agricultural crop protection	\$30 billion ²⁷
Soil remediation	\$10–25 billion ²⁸
Industrial enzymes ²⁹	
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 ³⁰	\$0.24 billion
Biocatalysts	\$0.02–0.1 billion ³¹
Diagnostics	\$0.15–0.2 billion ³²

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.

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.³⁶ 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).³⁷

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.³⁸

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 million³⁹

Department	License/years (1 license active in 1 year = 1 license/year)	License/years yielding more than \$1 million
Defense 2001 ⁴⁰	288	1 (0.3%)
Energy 2001–2003 ⁴¹	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).⁴² 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.⁴³

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 45 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 DEIS 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.

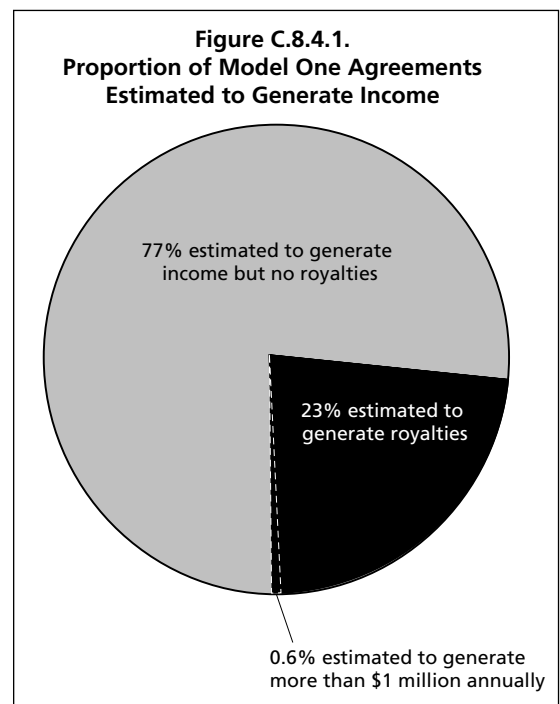


Figure C.8.4.1. Model One estimates that every benefits-sharing agreement could generate some income.

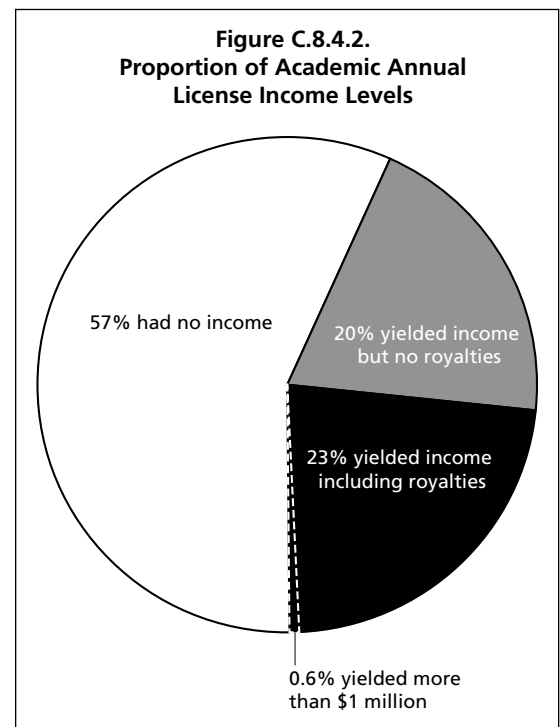


Figure C.8.4.2. Annual licensing income at academic institutions ranged from \$0 for more than half of all licenses to more than \$1 million for 0.6% of licenses in 1999–2002.

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	16	11
U.S. government institutions	3	2
U.S. institutions fitting the description of AUTM members (whether or not actually included in AUTM surveys)	19	8
Non-U.S. institutions ⁴⁴	7	4
Total	45	25

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 11 commercial firms (Model One) and 10 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 DEIS.

C.9 Summary of Potential Monetary Benefits

This section provides an estimated range of potential monetary benefits in each context for this DEIS (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 9.1 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 9.1 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 4.4.1.3-1. It is repeated here as Table 9.1 for reference. The calculations that underlie this summary are presented in Section C.10.4.1-2.

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 DEIS 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 4.4.1.2-2, below. The calculations that underlie this summary are presented in Section C.10.

Table 4.4.1.2-2. Estimated range of potential monetary benefits used to analyze the impacts of a proposed NPS benefits-sharing program on individual parks other than Yellowstone

Duration of potential impact	Potential annual payment	% of agreements likely to yield this average benefits level (see Appendix C, Section C.9.3)	See Appendix C (Sections referenced) for the derivation of this estimate
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 Patenting and Inventing (Calculations for Table C.7.2-1)

The following data and calculated sums and averages were used to develop Table C.7.2-1.

**Table C.10.1. Calculations in support of Table C.7.2-1
(Comparative rate of inventing and patenting in federal laboratories and academic institutions)**

Federal inventions and patents [DOC2004, page 24]							
	FY1999	FY2000	FY2001	FY2002	FY2003	Total reported	Comparative rate*
DOI inventions	8	16	6	not reported	not reported	30	
DOI patents granted	1	4	2	not reported	not reported	7	4.3
HHS inventions	328	375	434	431	472	2,040	
HHS patents granted	180	132	119	116	136	683	3.0
All federal labs inventions	3,649	3,566	3,962	4,135	4,348	19,660	
All federal labs patents granted	1,450	1,444	1,605	1,498	1,607	7,604	2.6

AUTM inventions and patents [AUTM2002, pages 10 and 11]							
	FY1999	FY2000	FY2001	FY2002		Total reported	Comparative rate*
Inventions disclosed	12,324	13,032	13,569	15,573		54,498	
Patents granted	3,661	3,764	3,721	3,673		14,819	3.7

Grand total inventions disclosed	74,158	
Grand total patents granted	22,423	3.3

*The comparative rate (CR) of patenting (P) to inventing (I) is shown as CR=I/P

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 DEIS to estimate potential impacts of Alternative B	\$24,029 (rounded to \$24,000)

*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	\$155,345 (rounded to \$155,000)
% 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 DEIS to estimate potential impacts of Alternative B	\$35,729 (rounded to \$36,000)

*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.							
Active licenses	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
	Totals		3,847	4,257	4,106	5,504	5,991
Total license income	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
	Totals		\$62,367,530	\$73,735,164	\$73,809,600	\$81,993,651	\$87,183,278
Earned royalty income	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	not reported	not reported	not reported	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
	Totals		\$40,645,573	\$49,115,858	\$47,190,465	\$44,517,931	\$47,452,911

Table C.10.3-2. Calculations for Model Two (estimated immediate monetary benefits)*

	FY1999	FY2000	FY2001	FY2002	FY2003	Total
Other license income, federal component						
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
					Total	\$1,061,836,485
Active licenses						
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
					Total	112,313
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 DEIS to estimate potential impacts of Alternative B	\$284 (rounded to \$300)					

*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
Royalty income, federal component						
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
Royalty income, AUTM component						
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
					Total	\$3,457,762,738
Active licenses						
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
					Total	112,313
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 DEIS to estimate potential impacts of Alternative B	\$924 (rounded to \$900)					

*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).⁴⁵ 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)	
Low range, 2 new benefits-sharing agreements per year							
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
Mid-range, 4 new benefits-sharing agreements per year							
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
High range, 9 new benefits-sharing agreements per year							
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
High range plus an annual performance-based payment of at least \$1 million							
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 FY2004 Natural Resource Challenge funding*

Impact definitions (see Chapter 4, Section 4.2)	
Major impact	15% of \$72,963,000
Moderate impact	10% of \$72,963,000
Minor impact	5% of \$72,963,000
Negligible impact	less than 5% of \$72,963,000

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	0.07%	Negligible	\$109,350	0.15%	Negligible			
5	\$121,500	0.17%	Negligible	\$243,000	0.33%	Negligible	\$546,750	0.75%	Negligible			
10	\$269,100	0.37%	Negligible	\$538,200	0.74%	Negligible	\$1,210,950	1.66%	Negligible	\$2,210,950	3.03%	Negligible
20	\$638,100	0.87%	Negligible	\$1,276,200	1.74%	Negligible	\$2,871,450	3.93%	Negligible	\$3,871,450	5.30%	Minor

*CALCULATION: estimated monetary benefits (see Table 4.4.1.3-1) divided by \$8,800,490

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					
		0	Model Two		Model One		\$1 million agreement
			\$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

- ¹ 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).
- ² 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.
- ³ 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

- ⁴ U.S. Department of Commerce (DOC) Technology Transfer Report 2004, page 17, and Association of University Technology Managers (AUTM) Licensing Survey FY2002, 15.
- ⁵ AUTM Licensing Survey FY2002, 7.
- ⁶ DOC Technology Transfer Report 2002, 71.
- ⁷ A. Artuso, *Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing* (Binghamton, New York: The Haworth Press, 1997) 21.
- ⁸ *See* Appendix A, model 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.
- ⁹ Although researchers can realize income related to their research results for a period of time longer than 20 years, this DEIS 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

- ¹⁰ 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.
- ¹¹ 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 DEIS.
- ¹² 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.
- ¹³ 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.
- ¹⁴ AUTM Technology Transfer Report 2002, 15, 18.
- ¹⁵ AUTM Technology Transfer Report 1999, i; AUTM Technology Transfer Report 2000, 1; AUTM Technology Transfer Report 2001, 1; AUTM Technology Transfer Report 2002, 1, 15.
- ¹⁶ 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).
- ¹⁷ 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

¹⁸ 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

¹⁹ 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.

²⁰ DOC Technology Transfer Report 2002, 44.

²¹ J. Spiegel, Senior Advisor for Technology Transfer Operations, Office of Technology Transfer, National Institutes of Health, pers. comm. to A. Deutch, March 19, 2004.

Section C.8 Modeling Potential Monetary Benefits

²² 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.”

²³ 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.

²⁴ *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.”

²⁵ Global market estimates for 1998 unless otherwise noted.

²⁶ 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).

²⁷ *Ibid.*, 188, 27.

²⁸ *Ibid.*, 232.

²⁹ *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).

³⁰ “Other” specifically includes leather, tanning, metals, and oil fields.

³¹ Zedan, “The Economic Value of Microbial Diversity,” 232.

³² *Ibid.*, 232.

³³ *Ibid.*, 42.

³⁴ *Ibid.*, 183.

³⁵ ten Kate, *The Commercial Use of Biodiversity*, 194.

³⁶ DOC Technology Transfer Report, 2004, 74, 82 (Department of Defense, Department of Energy).

³⁷ DOC Technology Transfer Report 2004, 50, 60, 80, 122 (USDA, Department of Commerce, Department of Energy, NASA).

³⁸ AUTM Licensing Survey FY2001, 15.

³⁹ 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.

⁴⁰ 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).

⁴¹ 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).

⁴² *See, e.g.,* M. Milstein, “Firms Milk Park’s ‘Wildlife,’” *High Country News* 25(24) (December 27, 1993).

⁴³ 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).

⁴⁴These patents were assigned to government or private institutions.

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Appendix D

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, 2001.¹ 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, 2002.² 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:³

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.⁴ 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 DEIS

- Genetic engineering
- Intellectual property rights
- Congressional appropriations
- Administration of scientific research activities in the NPS

D.5 Summary of Public Scoping Comments

In this section, public comments are summarized in general terms and the way the NPS incorporated the comments into the DEIS 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.

DEIS: 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.

DEIS: No alternative in the DEIS proposes a new way to authorize collection of any natural resources. Every alternative in the DEIS 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.

DEIS: 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.

DEIS: The administration of scientific research in the NPS is outside the scope of this DEIS (*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.

DEIS: 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.

DEIS: The DEIS proposes mitigation to prevent the research permitting process from being influenced by benefits-sharing considerations (*see* Chapters 2 and 4).

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.

DEIS: 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.

DEIS: 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.

DEIS: Alternative B dedicates all benefits to the conservation of park resources.

Congressional appropriations are outside the scope of this DEIS (*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.

DEIS: These concerns are outside the scope of this DEIS (*see* Chapter 1, Section 1.9.3).

COMMENT: Finally, some respondents had specific advice regarding laws, case law, regulations, and policies that should be kept in mind while preparing the EIS.

DEIS: The legal framework for this DEIS is discussed in Chapter 1.

Notes

Section D.2 Scoping Methodology

¹ 66 Fed. Reg. 33712, 33713.

² 67 Fed. Reg. 18034, 18035.

³ 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

⁴ 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

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

Table E-7. Number of research reports (IAR) submitted servicewide, 1992–2001

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

Table E-8. Chi-square calculation, the number of research reports (IAR) submitted servicewide, 1992–2001, and 1992–1997 compared to 1998–2001

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

Appendix F

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

Background for Benefits-Sharing and Technology Transfer

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Although this DEIS 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 DEIS, 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 1988.¹ 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.”²

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.³ 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.⁴

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 DEIS 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.⁵ 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”⁶ due to the precedent-setting nature of the Yellowstone–Diversa agreement within the NPS.⁷

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.”⁸ The statute also gives federal agencies broad discretion in making laboratory determinations.⁹ 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.”¹⁰

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 with textile processing.¹¹ Diversa’s revenues from Pyrolase 200™ are not known.¹² 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.”¹³

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.¹⁴ 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.¹⁵

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.¹⁶

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.¹⁷ 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.¹⁸ 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.¹⁹

In 1991, the earliest of these agreements was announced between INBio and Merck &

Company.²⁰ 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.²¹

Since 1991, INBio has negotiated many additional agreements with other research firms.²² While INBio has not published the total revenue earned from all such agreements,²³ 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.²⁴ 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.²⁵ 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).²⁶ The importance of non-monetary benefits can often be expected to exceed the importance of monetary benefits.²⁷

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.²⁸ 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>>.²⁹

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.³⁰ 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.”³¹

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).³²

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 FY2003.³⁵

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).³⁶ HHS’s income from licensing was approximately \$55 million in FY2003, accounting for 56% of all federal laboratory licensing

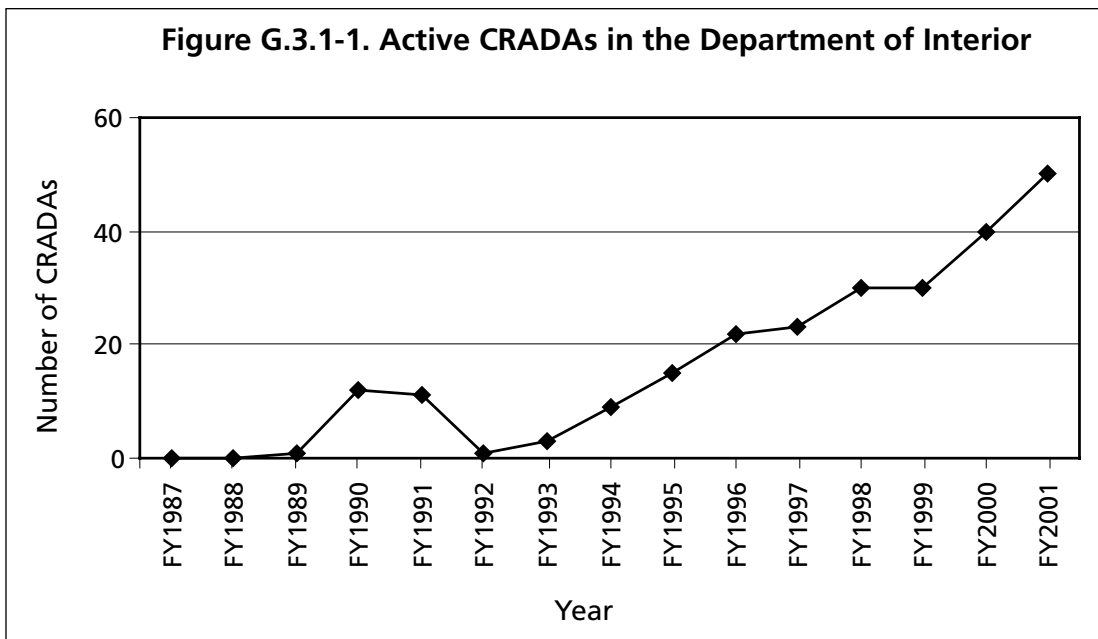


Figure G.3.1-1. The number of active CRADAs managed by the Department of the Interior is increasing.

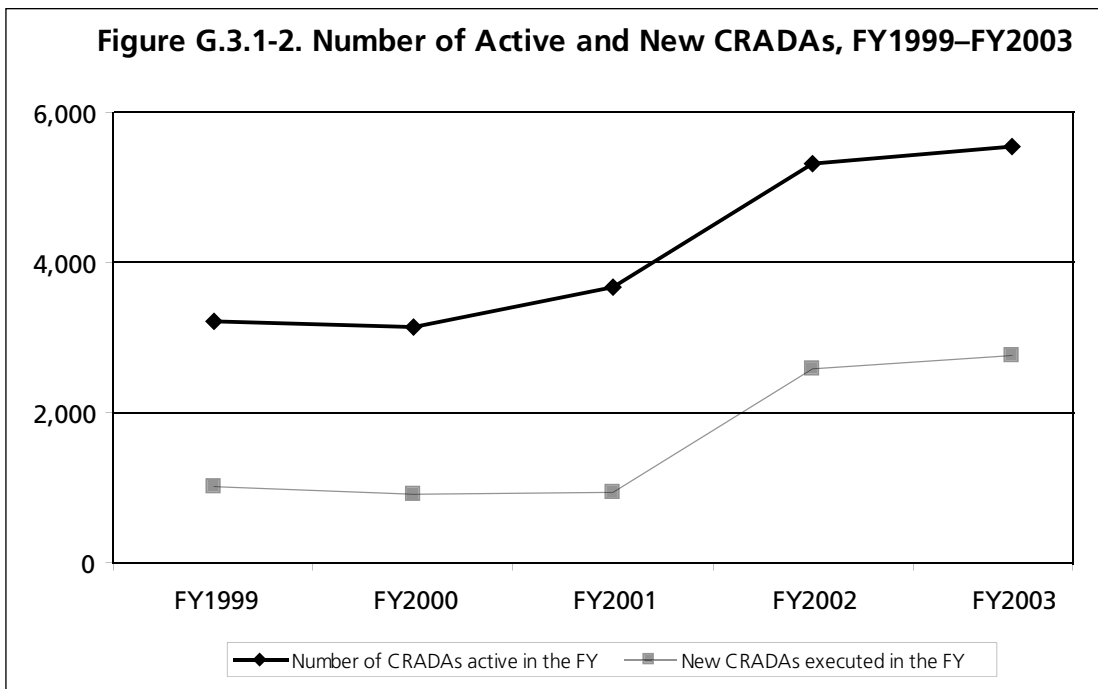


Figure G.3.1-2. Several thousand CRADAs were active annually from 1999 through 2003.

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.”³⁷

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

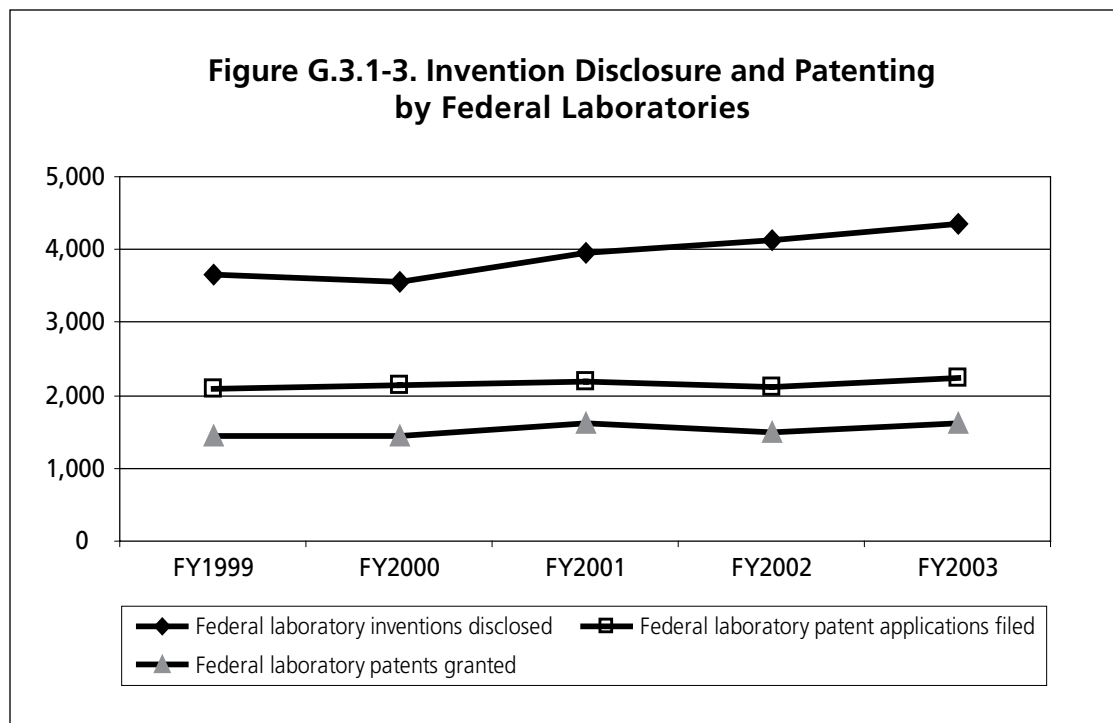


Figure G.3.1-3. During the five-year period FY1999–FY2003, federal researchers reported discovering approximately 3,900 inventions (commercial applications for research results) annually.

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.³⁸

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.³⁹

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.³³ 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).³⁴

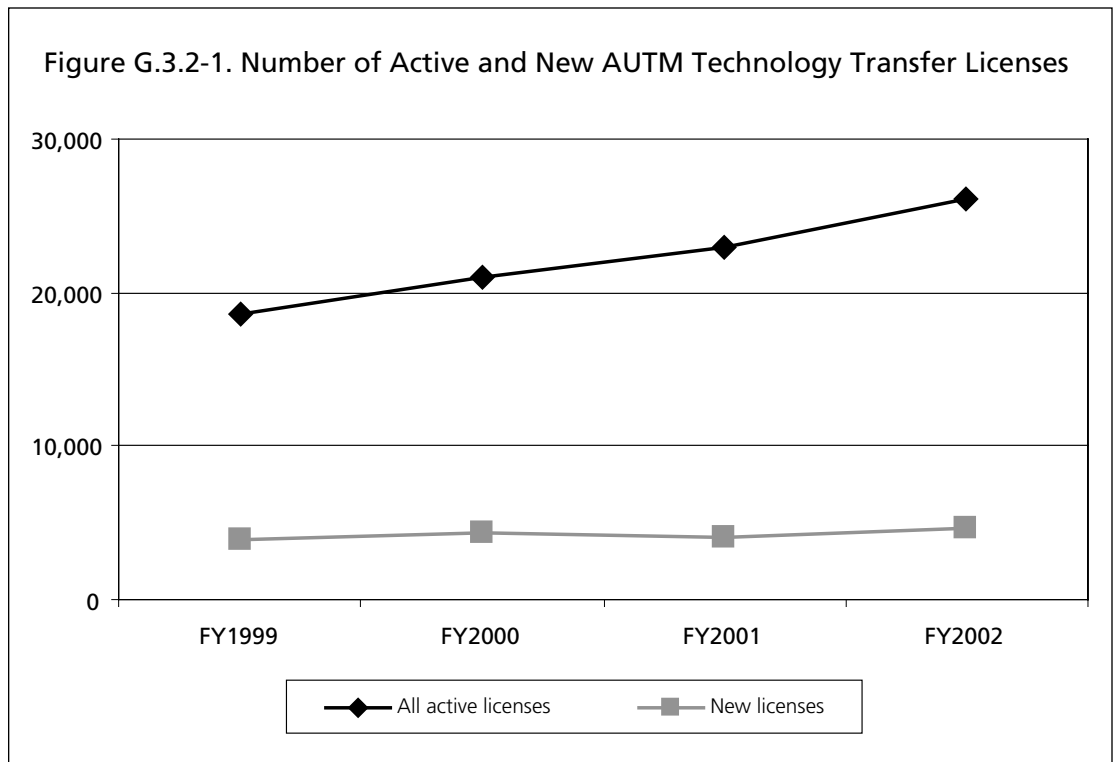


Figure G.3.2-1 On average, more than 22,000 technology transfer licenses were active annually from FY1999–FY2002.

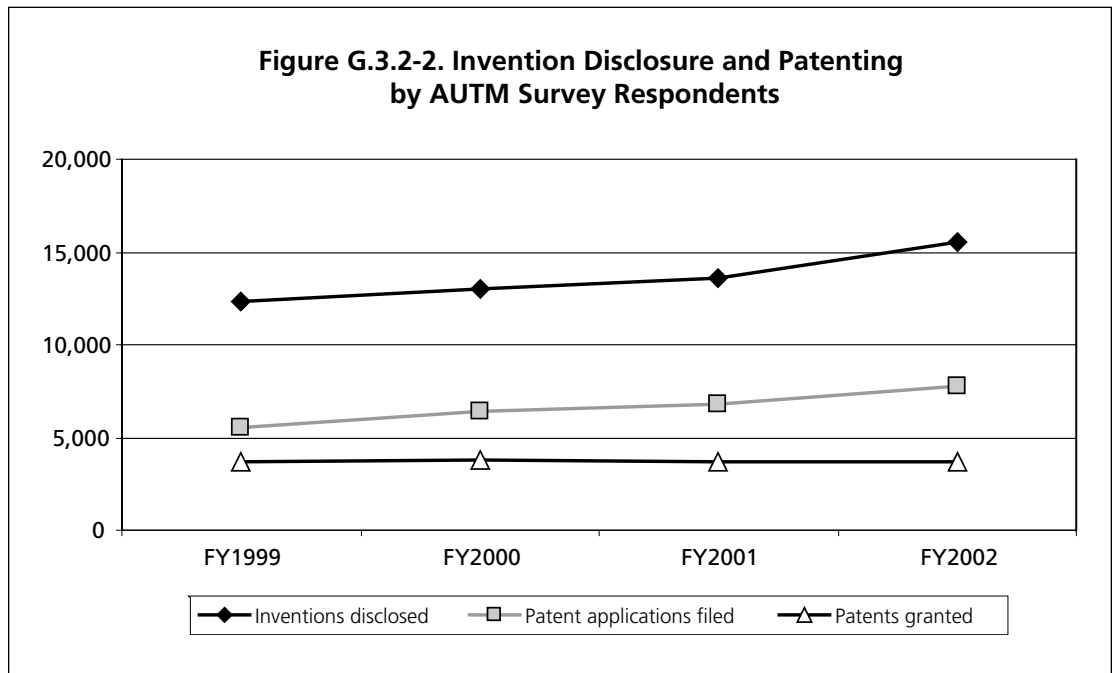


Figure G.3.2-2. During 1999–2002, academic researchers disclosed an average of more than 13,000 inventions (commercial applications for research results) annually.

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 2002, reporting institutions required a total of 846 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).⁴⁰ 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.”⁴¹

Notes

Section G.1 Benefits-Sharing by the U.S. Government

¹ 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.

² See *Gazette Opinion*, “Industries Exploit First Park,” *Billings Gazette*, (December 6, 1994).

³ 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.”)

⁴ 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.

⁵ 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).

⁶ 93 F. Supp. 2d 63, at 72.

⁷ 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).

⁸ 15 USC 3710a(d).

⁹ 15 USC 3710a.

¹⁰ S.Rep. No. 283, 99th Cong., 2d Sess. (1986), at 11.

¹¹ See <<http://www.diversa.com>>. Last accessed April 19, 2006.

¹² 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.

¹³ 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.

¹⁴ *Ibid.*, 14–17.

Section G.2 Benefit-Sharing Around the World

¹⁵ See also *Pharmaceutical Biology* 37 (supplement) (1999) (special edition of case studies resulting from multiple ICBG projects).

¹⁶ See <<http://www.inbio.ac.cr>>, last accessed April 19, 2006.

¹⁷ 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>>.

¹⁸ 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).

¹⁹ 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.

²⁰ 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.”

- ²¹ 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).
- ²² 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.”
- ²³ 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.
- ²⁴ N. Mateo, W. Nader, and G. Tamayo. “Bioprospecting,” in *Encyclopedia of Biodiversity, Volume I* (Philadelphia: Academic Press, 2001), 485–486.
- ²⁵ 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 DEIS is about benefits-sharing only.
- ²⁶ Bonn Guidelines, Appendix II (“Monetary and Non-Monetary Benefits”); *Ibid.*, para. 49.
- ²⁷ 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.”
- ²⁸ 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., *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).

²⁹ 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

³⁰ 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”).

³¹ 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.*).

³² *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.

³³ 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).

³⁴ *Ibid.*, 12, 24, 38, 50.

³⁵ *DOC 2004 Technology Transfer Report*, 37.

³⁶ The proposal under evaluation in this DEIS similarly concerns research results related to the study of (mostly) biological materials.

³⁷ *DOC 2004 Technology Transfer Report*, 11.

³⁸ *Ibid.*, 60, 122.

³⁹ 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.

⁴⁰ *AUTM Licensing Survey, FY2002*, 18, 43.

⁴¹ 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.

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