

Executive Summary

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ES.1 Purpose and Need for Action

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

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

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

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

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

Alternative A: No Benefits-Sharing/No Action;

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

Alternative B1. Always disclose royalty rate and related information;

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

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

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

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

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

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

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

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

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

What are research specimens?

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

What are research results?

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

What are research activities?

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

The important distinction between research specimens (“natural products”) and research results is intended to prevent the marketing or other commoditization of NPS resources, while not interfering with the legitimate development of useful and therefore valuable discoveries from research involving NPS research specimens. For example, NPS regulations and policy provide that specimens collected from a national park area cannot be used as raw material in the manufacture of commercial products.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 if they wish to commercialize their research results. This EIS will clarify the rights and responsibilities of researchers and NPS managers in connection with the use of valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks.

ES.1.2 Public Involvement

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

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

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

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

ES.1.3 Issues and Concerns

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

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

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

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

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

ES.1.4 Issues Not Evaluated Further in this FEIS

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

Genetic engineering

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

Intellectual property rights

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

Congressional appropriations

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

Administration of scientific research activities in the NPS

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

ES.2 Alternatives

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

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

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

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

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

Alternative A: No Benefits-Sharing/No Action.

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

Alternative B1: Always disclose royalty rate and related information;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ES.3 Affected Environment

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

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

ES.3.1 Natural Resource Management

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

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

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

ES.3.2 Visitor Experience and Enjoyment

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

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

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

ES.3.3 Social Resources: The Research Community

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

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

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

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

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

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

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

ES.3.4 Social Resources: NPS Administrative Operations

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

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

ES.4 Environmental Consequences

ES.4.1 Natural Resource Management

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

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

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

ES.4.1.2 Alternative B (Implement Benefits-Sharing)

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

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

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

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

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

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

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

ES.4.2 Visitor Experience and Enjoyment

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

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

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

ES.4.2.2 Alternative B (Implement Benefits-Sharing)

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

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

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

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

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

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

ES.4.3 Social Resources: The Research Community

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

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

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

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

ES.4.3.2 Alternative B (Implement Benefits-Sharing)

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

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

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

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

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

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

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

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

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

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

ES.4.4 Social Resources: NPS Administrative Operations

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

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

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

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

ES.4.4.2 Alternative B (Implement Benefits-Sharing)

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

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

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

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

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

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

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

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

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

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

Table ES-1. Summary of Effects*

Natural Resource Management				
Alternative A No Benefits-Sharing/No Action	Alternative B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
All contexts <ul style="list-style-type: none"> Choosing not to implement benefits-sharing would result in no change in the availability of "science for parks." 	All contexts <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. 		All contexts <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. 	
Servicewide <ul style="list-style-type: none"> No impact. 	Servicewide and Yellowstone <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. 	Servicewide <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. 		Servicewide <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.
Yellowstone <ul style="list-style-type: none"> The return of all monetary benefits provided to Yellowstone by Diversa would have a negligible adverse impact. 		Yellowstone <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. 		Yellowstone <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.
Individual parks <ul style="list-style-type: none"> No impact. 	Individual parks <ul style="list-style-type: none"> Fewer parks would experience the beneficial impacts of Alternative B2. 	Individual parks <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. 		Individual parks <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 B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
All contexts • 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.	All contexts • 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.	All contexts • Increased availability of “science for parks” would have a beneficial impact in all contexts.	All contexts • Increased availability of “science for parks” would have a beneficial impact. • Impacts in all contexts would be the same as for Alternative B2.	All contexts • Decreased availability of “science for parks” could have adverse impacts in all contexts.
	Servicewide and Yellowstone • 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.	Servicewide • At least negligible and possibly minor impacts.		Servicewide • Negligible impact.
		Yellowstone • Negligible-to-minor impacts.		Yellowstone • Negligible-to-minor impacts.
	Individual parks • Fewer parks would experience the beneficial impacts of Alternative B2.	Individual parks • Negligible-to-moderate impacts.		Individual parks • Negligible-to-major impacts.

Table ES-1. Summary of Effects, continued

Social Resources: The Research Community				
Alternative A No Benefits-Sharing/No Action	Alternative B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
	<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. If third-party researcher is a bioprospector, see declared, and inadvertent and undeclared bioprospectors above.
<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 B. Implement Benefits-Sharing			Alternative C Prohibit Specimen Collection for Commercially-Related Research
	Alternative B1 Always Disclose Royalty Rate and Related Information	Alternative B2 Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information	Alternative B3 Never Disclose Royalty Rate or Related Information	
<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 five-year period after the EIS decision is reached.