Chapter 2

Alternatives

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2.1 Introduction

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

This chapter provides a description of the alternatives analyzed in this final environmental impact statement (FEIS), whose purpose is to "examine potential environmental impacts of various methods of implementing the provisions of law that authorize benefits-sharing agreements while ensuring the integrity of resources."[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 FEIS. Specifically, natural products would not be sold (*see also* Chapter 1, Section 1.7.3); all research permit applications would continue to be evaluated under the National Environmental Policy Act of 1969 (NEPA) and other NPS regulations (*see also* Chapter 1, Section 1.7.2); and researchers' discoveries would continue to be eligible for protection under all applicable U.S. intellectual property rights laws.

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

Alternative A: No Benefits-Sharing/No Action (*see* Section 2.2);
Alternative B: Implement Benefits-Sharing (*Environmentally Preferred Alternative)* with the following variations (*see* Section 2.3):

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

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

FEIS objectives

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

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

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

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

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

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

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

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

2.2.1 Prohibition of Commercial Use of Natural Products

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

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

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

What is the NPS benefits-sharing proposal?

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

2.2.2 NPS Research Permit Procedures

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

All permitted researchers would also continue to be required to submit "Investigator's Annual Reports" (IARs), copies of publications, and other materials as agreed, including copies of field notes, databases, maps, photos, and/or other materials (*see* Chapter 1, Section 1.2.3). IARs, in which researchers explain their objectives and findings, would continue to be available over the Internet for access by the public as well as by NPS personnel.[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 under Alternative A. Accordingly, the NPS director would issue an order clarifying the provisions of Section 4.2.4 ("Collection Associated with the Development of Commercial Products") of *NPS Management Policies 2006* to provide that there is no requirement for negotiation of benefits-sharing agreements.

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

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

Under Alternative A, the NPS would continue to issue research permits for the performance of research, including the collection of research specimens, in units of the National Park System to qualified researchers pursuant to 36 CFR 1.6 and 2.5, as well as in compliance with NEPA (*see also* this chapter, Section 2.2.2 and Chapter 1, Section 1.2.3).[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.** Always disclose royalty rate and related information
- **Alternative B2.** Comply with confidentiality laws regarding disclosure of royalty rate or related information (*Preferred Alternative*)
- **Alternative B3.** Never disclose royalty rate or related information

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

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

2.4.1 Necessity for a Benefits-Sharing Agreement

Under Alternative B, if research activities involving research specimens collected from units of the National Park System resulted in useful discoveries, inventions, or other commercially valuable applications, a benefits-sharing agreement would be required to provide the terms and conditions for sharing with the NPS benefits resulting from their further development and use.[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 2006*.

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

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

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

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

2.4.1.1 Parties to an agreement

Under Alternative B, individual parks would negotiate, implement, and monitor benefits-sharing agreements in much the same way that they currently manage a variety of agreements with other institutional entities. Expertise in park-specific concerns, priorities, resource conservation needs, and research-related available park expertise would be provided by the individual park involved in negotiating a benefits-sharing agreement.[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 Sections 2.4.6 through 2.4.6.4, and Section 4.4.5.5.

Under Alternative B, NPS units that are federal laboratories within the meaning of the Federal Technology Transfer Act of 1986 (FTTA) could implement benefits-sharing through negotiation of CRADAs (see Section 2.4.2).[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 FTTA, as the appropriate agreement type for implementing benefits-sharing under Alternative B. While NPS believes that CRADAs are best suited for benefits-sharing, this does not preclude the potential use of other agreement types that the NPS has the authority to use.[9]

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

2.4.2.2 Standardized General Provisions

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

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

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

The NPS would devise and implement an appropriate accounting procedure to ensure that any monetary benefits resulting from implementation of any benefits-sharing agreements would be monitored and accounted for to the high standard called for in existing law, regulation, and policy.[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] In addition, the NPS would report non-monetary benefits generated by CRADAs each year.

2.4.3 Disposition of Benefits

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

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

2.4.4 Variations in Confidentiality: Alternatives B1, B2 and B3

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

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

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

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

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

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

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

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

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

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

Variations in confidentiality: Alternatives B1, B2 and B3

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

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

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

2.4.5 Assurances

2.4.5.1 Resource protection

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

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

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

Alternative B retains the current regulatory prohibition against the sale or commercial use of natural products, including research specimens.[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 FEIS. The NPS would comply with appropriate environmental review requirements under NEPA and any other relevant legislation for any future actions. As part of any such review, the NPS would avoid, minimize, and mitigate adverse impacts or would not take the action.

2.4.6.1 Mitigation: Technical assistance to parks

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

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

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

2.4.6.2 Mitigation: Financial support for administration

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

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

Under Alternative B, the NPS would continue to issue research permits for the collection of research specimens from units of the National Park System to all qualified researchers in compliance with NEPA and pursuant to 36 CFR 1.6 and 2.5.[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 and material originating as an NPS research specimen would continue to be usable for approved research purposes (including research activities that might lead to discoveries that could be commercialized because they were useful in terms of health care, nutrition, agriculture, environmental management, industrial, or other processes with potential commercial or other economic value), whether studied directly by the permitted researcher or studied subsequently by a researcher who obtained them from an authorized third-party source such as a culture collection.

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

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

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

2.4.6.4 Mitigation: Management controls

Management controls would minimize the risk that benefits-sharing might inappropriately influence research permitting decisions.[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 recommended by the regional director and reviewed by the Department of Interior Solicitor's Office and the NPS director before it was signed by the park superintendent and the researcher.

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

would lend a servicewide perspective in implementing benefits-sharing, thereby ensuring that benefits-sharing agreements would be consistent, equitable, and efficient throughout the National Park System. As suggested by the Office of Management and Budget, it would also function as a guard against individuals' exceeding or abusing their assigned authorities.[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 2006*. The order would provide that the collection of specimens for research that is identified or acknowledged by the researcher to have potential for commercial development is prohibited, which would make negotiation of benefits-sharing agreements moot.

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

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

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

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

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

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

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

2.5.1 Alternative C and the Yellowstone–Diversa CRADA

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

2.6 Issues Addressed in the Alternatives

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

Alternative A: No Benefits-Sharing/No Action;

Alternative B: Implement Benefits-Sharing; and

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

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

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 the NPS should prohibit the commercial use of any discovery related to the study of park resources and should deny "commercial bioprospectors" permission to study park resources.

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

2.6.1.2 Criteria for requiring benefits-sharing

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

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

2.6.1.3 Content of benefits-sharing agreements

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

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

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

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

2.6.1.4 Potential confidentiality of benefits-sharing agreements

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

2.6.1.5 Sale or commercial use ("commercialization") of NPS resources

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

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

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

2.6.1.6 Impacts of benefits-sharing on potential consumptive use ("harvesting") of NPS resources

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

Every alternative is consistent with the current regulation prohibiting sale or commercial use of natural products.[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 *(Edmonds Institute, et al. v. Babbitt, et al., 93 F. Supp. 2d 63 (DDC 2000))*.

Research involving NPS specimens could result in discoveries with commercial applications under every alternative, although Alternative C would likely reduce the number of such discoveries.[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 (*see* EIS Sections 2.4.6 through 2.4.6.4, *and* Section 4.4.5.5).

2.7 Alternatives Considered But Not Analyzed Further

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

2.7.1 Prohibit Collection of Research Specimens from NPS Units

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

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

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

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

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

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

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

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

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

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

Any person (including scientists whose research activities involve research specimens lawfully collected from NPS units) is free to protect the valuable results of their research through U.S. patent and other intellectual property rights laws. An absolute prohibition against the development of any commercial use of research results involving specimens collected from NPS units would be contrary to the policies of the United States as expressed through the intellectual property rights and other laws that encourage discovery and technological innovation. The important distinction recognized by the NPS between prohibiting commercial use of research specimens, while permitting development of research results derived from those specimens in ways that may have some valuable commercial application, has been upheld by the federal judiciary.[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 and commercialize their research results for applications that could improve health, safety, and productivity. Alternative B is also expected to result in beneficial impacts to park natural resource management and visitor experience and enjoyment, thus enhancing the NPS's ability to meet this criterion.
- Alternative A also ensures that researchers could develop and commercialize their research results for applications that could improve health, safety, and productivity. However, Alternative A's impact on park natural resource management and visitor experience and enjoyment would be less beneficial than Alternative B. Thus, the NPS's ability to meet this criterion would be less under Alternative A than under Alternative B.
- Alternative C fails to meet this criterion because research that could be expected to lead to discoveries with commercial applications that could improve health,

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

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

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

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

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

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

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

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

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

2.9 Summary of Alternatives and Effects

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

Table 2.9-1. Comparison of Alternatives

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

Table 2.9-2. Summary of Effects*

Natural Resource Management				
Alternative A **No Benefits-Sharing/No Action**	**Alternative B. Implement Benefits-Sharing**			**Alternative C** **Prohibit Specimen Collection for Commercially Related Research**
	Alternative B1 **Always Disclose Royalty Rate and Related Information**	**Alternative B2** **Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information**	**Alternative B3** **Never Disclose Royalty Rate or Related Information**	
All contexts • Choosing not to implement benefits-sharing would result in no change in the availability of "science for parks."	**All contexts** • 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** • 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 • No impact.	**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** • 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** • The loss of a few current and potential future research projects would have negligible adverse impacts to the NPS.
Yellowstone • The return of all monetary benefits provided to Yellowstone by Diversa would have a negligible adverse impact.		**Yellowstone** • 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** • 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 • No impact.	**Individual parks** • Fewer parks would experience the beneficial impacts of Alternative B2.	**Individual parks** • 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** • 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 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), 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 2.9-2. Summary of Effects, continued

<table>
<tr><th colspan="5">Social Resources: The Research Community</th></tr>
<tr><th rowspan="2">Alternative A
No Benefits-Sharing/No Action</th><th colspan="3">Alternative B. Implement Benefits-Sharing</th><th rowspan="2">Alternative C
Prohibit Specimen Collection for Commercially Related Research</th></tr>
<tr><th>Alternative B1
Always Disclose Royalty Rate and Related Information</th><th>Alternative B2
Comply With Confidentiality Laws Regarding Disclosure of Royalty Rate or Related Information</th><th>Alternative B3
Never Disclose Royalty Rate or Related Information</th></tr>
<tr><td rowspan="2"></td><td>Declared bioprospectors
• 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.</td><td>Declared bioprospectors
• The obligation to share benefits would have a long-term negligible adverse impact.</td><td rowspan="4">All contexts
• Impacts in all contexts would be the same as for Alternative B2.</td><td>Declared bioprospectors
• Denial of permission to collect research specimens would have a minor-to-moderate adverse impact.</td></tr>
<tr><td rowspan="3"></td><td rowspan="2"></td><td>Inadvertent and undeclared bioprospectors
• 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.</td></tr>
<tr><td>Third-party researchers
• 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.</td><td>Third-party researchers
• The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.</td><td>Third-party researchers
• The provision of a standard Material Transfer Agreement would have a negligible beneficial impact.
• If third-party researcher is a bioproscpector, see declared, and inadvertent and undeclared bioprospectors above.</td></tr>
<tr><td>All other contexts
• Researchers who make valuable discoveries from research involving NPS specimens would have long-term, negligible beneficial impacts.</td><td>All other contexts
• Impacts to all other researchers would be the same as for Alternative B2.</td><td>All other contexts
• 99% of researchers would experience no adverse impacts.</td><td>Other researchers
• 99% of researchers would experience no adverse impacts.</td></tr>
</table>

Table 2.9-2. Summary of Effects, continued

Social Resources: NPS Administrative Operations				
	Alternative B. Implement Benefits-Sharing			
Alternative A **No Benefits-Sharing/No Action**	**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**	**Alternative C** **Prohibit Specimen Collection for Commercially-Related Research**
Servicewide and individual parks • 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.	**All contexts** • Fewer benefits-sharing agreements would result in less adverse impacts than Alternative B2.	**All contexts** • 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.	**All contexts** • Impacts would be the same as Alternative B2.	**All contexts** • A reduction in the number of submitted research proposals and the institution of Material Transfer Agreements would have negligible beneficial impacts in all contexts.
Yellowstone • 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 five-year period 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://rprs.nps.gov/research/ac/ResearchIndex>, last accessed October 24, 2008.

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://rprs.nps.gov/research/ac/ResearchIndex>, last accessed October 24, 2008.

Section 2.4 Alternative B: Implement Benefits-Sharing

[4] This FEIS 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] 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.

[10] *See* Chapter 1, Section 1.8.1.1 of this document, for a description of federal court review of the Yellowstone–Diversa CRADA.

[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 USC 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] S*ee* 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); s*ee 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 research specimens if researchers identify or acknowledge their proposed specimen collections as being associated with research that has potential for development of commercial applications. However, inadvertent discoveries of commercial applications for research results would still be inevitable.

Section 2.7 Alternatives Considered But Not Analyzed Further

[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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