

Benefits-Sharing Handbook

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Approved:

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NOTE! The information contained in this document is intended only to improve the internal management of the NPS. It is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its departments, agencies, instrumentalities or entities, its officers or employees, or any other person.

When should I use this Handbook?

You should use the Handbook *only* after reading *Director's Order (DO)* #77-10: NPS Benefits Sharing.

You use it when:

- You are evaluating a research permit application that may have research results with commercial potential.
- You are responsible for managing park museum or living collections.
- You have been asked to authorize the transfer or loan of NPS Material.
- A researcher has discovered a potential commercial use for the results of permitted research.
- You are on a negotiating team for benefits sharing.
- You are monitoring an existing agreement that references benefits sharing.
- You need to explain benefits sharing to a permittee, current or potential researcher, superintendent or other NPS staff, the public, and others.
- You have approval, oversight or policy responsibility for NPS benefits-sharing activities.
- You are planning or participating in cooperative research with a partner and that research has the potential for commercial use.

NOTE! *When using the Handbook, be aware that*

- *references to parks and superintendents may be equally interpreted to mean centers/ offices and managers, as applicable*
- references to park curators may apply to other park staff designated responsibility for the park museum collection or park living collection
- acronyms are decoded in Appendix A: Acronyms
- specialized terms are defined in Appendix B: Glossary
- *NPS* Management Policies, *DOs*, and related manuals and handbooks that are referenced in the text are available at <u>https://npspolicy.nps.gov/</u>
- Department of the Interior policies, including the Departmental Manual (DM), that are referenced in the text are available at <u>https://www.doi.gov/elips/browse</u>

How will I know which parts of this handbook are mandatory and which are advisory?

Mandatory instructions are indicated by the words "must" or "will." Advisory guidance is indicated by the words "may," "can," or "should." *DO* #77-10: *NPS Benefits Sharing* establishes requirements and refers to the Handbook for details on certain requirements.

1.0 Background and Purpose

Existing NPS law and policy do not prohibit or authorize commercial use of knowledge and research results derived from collected specimens. *Management Policies 2006* 4.2.4, in requiring "a supplemental written authorization" before using research results for commercial purposes, means that a party proposing a commercial use of research results must first enter into an agreement to share benefits with NPS or an agreement in which NPS declines to share benefits. In the agreement to share or decline benefits, which addresses only benefits-sharing considerations, NPS will state whether or not NPS will expect the other party to provide benefits as a result of the commercial use. A decision on whether to share in benefits will not be based on an opinion as to whether the commercial activity should occur. NPS permits and agreements will 1) include terms and conditions that establish the requirement for an agreement to share or decline benefits prior to commercialization of research results, and 2) state the remedies that NPS may seek in the event the terms and conditions are not met.

Director's Order (DO) #77-10: NPS Benefits Sharing addresses 1) benefits sharing stemming from research results derived from NPS permitted research, and 2) the relationship between benefits sharing and technology transfer resulting from NPS activities. This Handbook expands on these topics and provides additional information on technology transfer, including employee inventions.

1.1 What is NPS "benefits sharing?"

All studies conducted in parks provide the NPS with some type of benefit. Scientific studies support the NPS mission by providing the Service, the scientific community, and the public with an understanding of park resources, processes, and values. Benefits sharing occurs when NPS receives monetary or other benefits from a discovery or invention with a *commercial application* resulting from research originating under an NPS Scientific Research and Collecting Permit, or other permit or authorization. Benefits sharing may result in improved conservation of resources and enhances the public benefits arising from research that occurs in parks. The entity with a proposed commercial use enters into an agreement to share or decline benefits with NPS prior to commercialization.

The commercial use or sale of collected specimens themselves is prohibited by 36 CFR 2.1 and NPS *Management Policies 2006* 4.2.4 (2006).

The overall basis for NPS negotiating benefits sharing is the NPS role in preserving and providing access to the research site and the opportunity to collect specimens. This NPS contribution often represents decades of work. In some cases, NPS also makes available research data, conclusions, or other assistance that informs and supports the research permittee's, or other authorized researcher's, efforts.

1.2 How did NPS get involved in benefits sharing?

In 1997, NPS (Yellowstone National Park) entered into a Cooperative Research and Development Agreement (CRADA) with the biotechnology firm Diversa Corporation. Subsequently, Congress enacted the National Parks Omnibus Management Act, including the authorization for NPS to enter into equitable and efficient benefits-sharing arrangements with the research community and private industry.

In response to a legal challenge, a federal court upheld the NPS-Diversa CRADA but required NPS to complete a National Environmental Policy Act (NEPA) analysis of the CRADA.

Accordingly, NPS prepared a Final Environmental Impact Statement (FEIS) and, in March 2010, issued a Record of Decision (ROD) to implement benefits sharing Servicewide. This guidance document explains how the benefits-sharing program will be conducted. These documents are available through the NPS Electronic Technical Information Center at <u>https://pubs.nps.gov/</u> under the numbers 118039 (FEIS) and 118043 (ROD).

For further background on the history of benefits sharing in Yellowstone, see the "Greater Yellowstone Ecosystem Chapter" on the web page "Yellowstone Resources and Issues" at <u>https://www.nps.gov/yell/learn/resources-and-issues.htm</u>. Yellowstone was the source of the extremophile bacterium, *Thermus aquaticus*, which led to research to improve the functionality of polymerase chain reaction (PCR). PCR was essential to developing the ability to efficiently analyze DNA and remains in use.

1.3 What is NPS's legal authority for benefits sharing?

The National Parks Omnibus Management Act of 1998 authorizes the Secretary of the Interior to "negotiate for and enter into equitable, efficient benefits-sharing arrangements with the research community and private industry" (54 USC 100705(d)). Because the Act does not provide detail on implementation, such as the type of arrangements that NPS should use or the authority to directly retain monetary benefits (rather than conveying them to the U.S. Treasury), NPS relies on the following additional authorities to implement benefits sharing:

• Federal Technology Transfer Act of 1986 (FTTA) and related legislation (15 USC 3710), which focuses on technology transfer and enables federal laboratories, and therefore park units designated as federal laboratories, to enter into CRADAs under which a federal agency may 1) negotiate licenses for patented inventions made at federal laboratories; 2) grant and waive rights to federal laboratory inventions and intellectual property; and 3)

accept, retain, and use funds, personnel, services, and property from a collaborating party and provide personnel, services, and property to a collaborating party.

• The National Park Service Organic Act at 54 USC 100101 *et seq.*, cooperative agreement authority at 54 USC 101702 for park programs and research, cooperative ecosystem study unit authority at 54 USC 100703 and other authorities cited in *DO#20: Agreements*, which collectively authorize NPS to receive and transfer money, property, services, or anything else of value with state, local, and tribal governments, other public entities, educational institutions, and private non-profit organizations to fulfill research, training, information dissemination, and other missions of the NPS.

1.4 What is technology transfer and what is its relationship to benefits sharing?

In general, technology transfer is the process by which technology or knowledge developed in one place, such as in an NPS laboratory, is applied and used in another place. Since 1980, Congress has enacted a series of laws encouraging collaborative research and providing technology transfer mechanisms and incentives to facilitate transfer of technology from federal laboratories to non-federal organizations. Technology transfer activities may include the development of a CRADA between NPS and a partner for a joint research project, and licensing of NPS inventions. Under the FTTA, an NPS employee inventor may share in the monetary benefits of commercialization. Technology transfer activities comprise one component of activities that may result in benefits sharing.

Additional information regarding benefits sharing and technology transfer is in Section 7.0 of this guidance document.

1.5 What are research results that are potentially subject to benefits-sharing arrangements with NPS?

"Research results" means Material (including Material retained in a living collection), modifications, intellectual property, inventions, data, discoveries, and/or other knowledge, processes, products, or applications resulting from research activities of researchers or their institutions or companies. Note: "Research results" excludes collected specimens and museum specimens.

The terms "discovery" and "invention" are both used in a benefits-sharing context. "Discovery" is broadly defined to mean new knowledge gained through search or study. "Invention" means any discovery, thing, method, material, process, or idea that might be patentable or otherwise protected under 35 USC (Patents), 7 USC 2321 *et seq*. (Plant Variety Protection), and 18 USC 1905 (Trade Secrets).

See *Table 2: Examples of Material and Intellectual Property that are Research Results* in Section 3.7.

All kinds of research results are potentially subject to benefits-sharing arrangements. In the short term, the NPS benefits-sharing program will focus on the commercial use of research results originating from permitted scientific research that involved the collection of specimens.

Over the long term, NPS may apply its benefits-sharing authority to the commercial use of research results that did not involve specimen collection. Such research results might derive from research involving social science, archeology, and cultural resources, including museum objects.

NOTE! NPS benefits sharing is consistent with the NPS regulation at 36 CFR 2.1(c)(2)(v), which prohibits the sale or commercial use of natural products. Under this regulation, collected specimens are "natural products" and therefore may not be sold or commercially used. If the researcher slices, polishes, or otherwise prepares or removes a part of the collected specimen, the prepared collected specimen or component remains a "natural product." Substances that are created by people, such as Material, are not natural products and are not subject to the 36 CFR 2.1(c)(2)(v) prohibition on sale or commercial use. Material may include 1) researcher-grown progeny of the collected specimen or 2) researcher-made substances that are exact copies of part of the collected specimen, such as human-made proteins or DNA (termed "unmodified derivatives"). See Appendix B: Glossary for definitions of Material, Progeny, and Unmodified Derivatives. See also Table 1: "Examples of Collected Specimens, Museum Specimens, Living Collection Items, and Material" in Section 3.6.

1.6 Does NPS always seek to share benefits?

No. Once NPS learns about research results that potentially have commercially valuable applications, NPS will evaluate on a case-by-case basis whether to negotiate benefits or decline to negotiate benefits. Based on that evaluation, the NPS will enter into an agreement to share or decline benefits with the institution of the scientist who has identified a proposed commercial use. The agreement will state the NPS decision on benefits and other terms and conditions.

NPS will negotiate benefits with the other party when, based on best available information about the possible commercial use of the research, potential benefits would have some value to NPS resource management and to the general public.

Permittees with proposed non-commercial uses of research results, such as publishing in scientific journals without compensation, do not need to contact NPS prior to such non-commercial activity, provided that such research results do not involve inventions that may be patentable or otherwise protectable.

For permittees who identify a proposed commercial use, NPS does not require the permittee to enter into an agreement to share or decline benefits as required under the Scientific Research and Collecting Permit, General Condition #6, for proposed commercial uses of research results when the NPS determines that the use is primarily educational in nature and would benefit the general public at large. Such educational uses are limited to reporting on research results in: scholarly journals, textbooks, commercial films, other media productions, field guides, photographic

essays, museum exhibits and exhibit catalogs, and other museum publications connected with education, outreach and exhibit. For these limited commercial uses, NPS will not require agreements to share or decline benefits but NPS requires researchers to provide to the appropriate park benefits-sharing coordinator written documentation that the proposed use is educational in nature, would benefit the general public at large, and does not involve inventions that may be patentable or otherwise protectable. Based on this information the superintendent will issue a determination in writing stating whether the proposed commercial use "may occur without an agreement to share or decline benefits." The superintendent will provide the determination to the permittee and place a copy of the permittee's justification and the superintendent's determination in the permit study file. All other proposed commercial uses require the permittee to contact the appropriate park benefits-sharing coordinator to initiate negotiation on an agreement to either share or decline benefits.

NOTE! NPS agreements that include terms and conditions addressing benefits sharing require parties to notify NPS of subject inventions that may be patentable or otherwise protectable prior to any disclosure to the public, within thirty (30) days of an invention disclosure to the person(s) responsible for patent matters in the inventing organization, and within thirty (30) days of filing in the United States or other country any type of application for a patent or other intellectual property claim for the subject inventions. Parties that elect not to file patent applications on such subject inventions must so advise NPS no less than thirty (30) days prior to any disclosure to the public and within (90) days from the date of notifying NPS of the subject inventions.

1.7 With whom may NPS enter into agreements to share or decline benefits?

NPS may enter into agreements to share or decline benefits with institutions of researchers who already have NPS authorization for their research through

- NPS Scientific Research and Collecting Permits,
- NPS loan agreements,
- NPS Material Transfer Agreements (MTAs) or Collected Specimen Transfer Agreements (CSTAs), and/or
- Other NPS research authorizations.

Generally, NPS should enter into only one agreement to share or decline benefits for each commercialization of research results. That agreement usually should be executed with the institution that has primary control over the commercially useful intellectual property (IP), such as a patent. There are three reasons for this approach. First, all revenue derived from the commercialization of research results will be reflected in the agreements between the IP owner and all downstream involved parties. Thus, the NPS agreement to share or decline benefits with the IP owner will take into account all commercialization revenues. Second, that agreement will increase the transparency of the nature of that institution's benefits-sharing obligation and will therefore provide certainty for all downstream entities, thus fostering their efforts to undertake commercialization. Third, entering into one agreement to share or decline benefits per commercial use is more efficient than entering into separate agreements with multiple entities

and is therefore consistent with the NPS's benefits-sharing statutory authority, which mandates efficient benefits-sharing arrangements.

Once notified about a commercial application, NPS determines whether to negotiate or decline benefits sharing.

1.8 What kinds of benefits may accrue to parks through benefits-sharing agreements?

Parks may receive non-monetary and/or monetary benefits. Parks must use these benefits to enhance NPS resource conservation, although some of the benefits may also be used to offset administrative costs associated with the benefits-sharing program.

NPS may receive non-monetary benefits under all types of benefits-sharing agreements, such as a General Agreement, Cooperative Agreement, or a CRADA. See Section 6.0, particularly Section 6.6 Step 5d, for examples of non-monetary benefits.

NPS may receive and retain monetary benefits under a CRADA as authorized by the FTTA (see Section 1.3) and under a Cooperative Agreement authorized by 54 USC 101702. See Section 6.0, particularly Section 6.6 Step 5c, for examples of monetary benefits.

If the NPS does not use a CRADA or a Cooperative Agreement authorized by 54 USC 101702 for benefits sharing, the NPS will not be able to retain any monetary benefits from the agreement. Any monetary benefits received pursuant to agreements under other authorities would be deposited in the U.S. Treasury.

1.9 What information does this benefits-sharing guidance provide?

This guidance document covers the following:

- Identifying responsibilities for benefits sharing;
- Using an issued permit to track collected specimens;
- Using an issued permit to track research results and establish the researcher's obligation to enter into an agreement to share or decline benefits with NPS prior to any commercialization of research results;
- Tracking the results of that research via Investigator's Annual Reports (IARs), cataloging, loan agreements, CSTAs, and MTAs;
- Tracking the commercialization progress of the research results;
- Deciding whether to share in benefits from commercial use of research results and choosing the appropriate type of agreement to share or decline benefits;
- Negotiating an agreement to share or decline benefits;
- Engaging in technology transfer;
- Addressing employee inventions;
- Managing receipt and use of benefits;
- Reporting on benefits sharing and complying with FTTA;

- Addressing ethical concerns and confidentiality; and
- Maintaining awareness of external developments relevant to NPS benefits sharing.

2.0 Responsibilities for Benefits Sharing

The NPS tasks listed under responsibilities are described in detail in Sections 3-13.

2.1 What are the responsibilities of the Department of the Interior?

DOI provides delegation of authority, policy, and other guidance on technology transfer in the Departmental Manual (DM) as follows:

- 207 DM Limited Delegations, Chapter 8 Technology Transfer—delegates to assistant secretaries and bureau directors the authority to negotiate licenses and other agreements related to intellectual property and to enter into Cooperative Research and Development Agreements (CRADAs) with other entities.
- 453 DM Inventions and Patents—covers inventions by employees, inventions by contractor employees, licenses, and unsolicited technical proposals from the public.
- 761 DM Technology Transfer, Chapter 1 Policy and Procedures—addresses policy and standards, requirements and procedures for conducting technology transfer activities.

Under the Federal Technology Transfer Act (FTTA) (15 USC 3710), DOI, because it operates or directs one or more federal laboratories, must:

- Make available sufficient funding to support the technology transfer function at the agency and its laboratories.
- Appoint a representative to the Federal Laboratory Consortium for Technology Transfer (FLC) (see Section 15.4 for a description of the FLC).
- Receive annual reports from the FLC.
- Transfer funds equal to 0.008 percent of the DOI budget to the National Institute of Standards and Technology (NIST) (Department of Commerce) at the beginning of each fiscal year if the amount exceeds \$10,000. NIST will provide these funds to FLC for its activities.
- Submit an annual report to the Office of Management and Budget (OMB).
- Coordinate with bureaus to submit information to NIST for the annual Federal Laboratory (Interagency) Technology Transfer Summary Report to the President and Congress. (See Section 10.0, Reporting on Benefits Sharing.)

NPS provides information to DOI that DOI uses for meeting these obligations.

2.2 What are the responsibilities of the NPS Director?

The NPS Director:

- Delegates the authority for benefits sharing and technology transfer to the Associate Director, NRSS, park superintendents and heads of NPS federal laboratories.
- Determines which NPS entities qualify as federal laboratories and when benefits-sharing revenue will be shared among parks designated federal laboratories. (See Section 9.0, Using Non-Monetary and Monetary Benefits).
- Makes available sufficient funding to support the technology-transfer function in the NPS and its laboratories, consistent with the FTTA (15 USC 3710(b)(2)).

2.3 What are the responsibilities of the Associate Director, Natural Resource Stewardship and Science (NRSS) and other WASO associate directors?

The Associate Director, NRSS:

- Oversees benefits sharing and technology transfer and appoints a WASO Benefits-Sharing Coordinator to administer these activities and provide technical assistance to parks.
- Prepares and maintains current requirements, procedures and information on benefits sharing and technology transfer in *Director's Order (DO)* #77-10, the *Benefits-Sharing Handbook*, and related policies and procedures. Issues the *Benefits-Sharing Handbook*.
- Establishes and oversees servicewide agreements to facilitate benefits sharing and technology transfer.
- Approves proposed negotiations and terms and concurs on final agreements to share or decline benefits.
- May approve reasons to decline benefits sharing that are neither technical nor economic, in consultation with the Regional Director.
- Establishes and oversees the Office of Research and Technology Applications (ORTA) to facilitate technology transfer, as required by the FTTA (15 USC 3710(b) and (c)), and assesses benefits-sharing revenues as needed for operations, consistent with the FTTA.
- Refers benefits-sharing actions to other WASO associate directors for review and concurrence, when applicable.

Overseeing benefits sharing and technology transfer includes responsibility to implement DOI policies on technology transfer in 761 DM 1, including giving high priority and encouragement to these activities, providing incentives for related accomplishments, and providing education and training opportunities for personnel involved in benefits sharing and technology transfer.

Other WASO associate directors are involved in benefits sharing and/or technology transfer when 1) an NPS laboratory or unit that reports to the associate director is involved in benefits sharing and/or technology transfer, and/or 2) the subject of the research in a *park* benefits-sharing and/or technology transfer action falls under their purview. The relevant associate director:

- Reviews and forwards a reporting unit's request for designation as a federal laboratory to the Director.
- Concurs on proposed terms and final agreements to share or decline benefits.
- Prepares and maintains current information on benefits sharing and technology transfer in policies and procedures under his/her purview.

2.4 What are the responsibilities of the regional director?

The regional director:

- Reviews and forwards a park request for designation as a federal laboratory to the Director.
- Concurs on proposed terms and final agreements to share or decline benefits.
- Provides benefits-sharing technical assistance to parks, when available.

2.5 What are the responsibilities of the park superintendent?

The superintendent:

- Approves and issues Scientific Research and Collecting Permits and other authorizations, including the Collected Specimen Transfer Agreement (CSTA), Material Transfer Agreement (MTA), and Loan Agreement. Avoids considering the potential receipt of benefits while making a decision to issue a permit or other authorization.
- Uses permits, CSTAs, MTAs, loan agreements, and cataloging to track collected specimens, museum specimens, living collection items, and Material. Authorizes patent deposits and monitors patent activity relevant to the park.
- Signs licenses for NPS-owned inventions.
- Oversees the park's benefits-sharing program, including appointment of a park benefitssharing coordinator.
- Submits a park request for designation as a federal laboratory through the regional director for the Director's signature.
- Serves as the federal laboratory director in a park designated as a federal laboratory.
- Includes benefits sharing (and technology transfer if the park is a federal laboratory) in the job descriptions, promotion considerations, and performance evaluations for the employees specifically responsible for benefits sharing and technology transfer.
- Sends written notification of the park's intent to enter into benefits sharing to upper management (the regional director, the Associate Director, NRSS, other associate directors as appropriate), and the WASO Benefits-Sharing Coordinator.
- Forms the negotiating team and appoints advisors.
- Reviews proposed negotiations and terms and recommends them to upper management for concurrence and approval.
- Approves agreements to share or decline benefits and submits approved agreements to upper management for final concurrence.
- Approves confidentiality agreements.
- Implements an agreement to share or decline benefits and may delegate responsibility for administration of the agreement to the key official for administration or the agreements technical representative (ATR), as appropriate.
- Receives monetary and non-monetary benefits and approves projects to expend revenue from benefits-sharing agreements.
- Submits park benefits-sharing reports.

- Addresses breaches of benefits-sharing obligations in consultation with the WASO Benefits-Sharing Coordinator and DOI Office of the Solicitor. Details on requirements are in the Benefits-Sharing Handbook.
- Provides benefits-sharing expertise to other parks, when available.

NOTE! Individuals with responsibility for preparing agreements to share or decline benefits and negotiating benefits must not have responsibility for coordinating research permits, CSTAs, MTAs, and loan agreements. To maintain this separation of duties, parks may seek outside assistance to fulfill the benefits-sharing responsibilities. See Section 6.1.1.

2.6 What are the responsibilities of the park benefits-sharing coordinator?

The park benefits-sharing coordinator:

- Avoids any involvement in discussions, negotiations, or any other activity associated with permits, CSTAs, MTAs, and loans for specific cases, but provides information to the staff with responsibility for these authorizations upon request.
- Coordinates the park benefits-sharing program, serves as the administrative point of contact for all park benefits-sharing matters, and oversees all benefits-sharing cases to ensure adherence to this guidance.
- Coordinates with researchers who have identified a commercial purpose or a potentially commercial purpose for their research, and/or disclose an invention, discovery, or patent application to the park to initiate benefits-sharing discussions.
- Monitors the United States Patent and Trademark Office (USPTO) web site at http://www.uspto.gov/patents/process/search/index.jsp to spot relevant applications and patents that may not have been reported and to track the status of known applications or patents.
- Collects background information before benefits-sharing negotiations begin and provides this information to the negotiating team lead.
- Maintains the park's official file on benefits sharing.
- Prepares Park Request for Designation as a Federal Laboratory, if any.
- Keeps WASO Benefits-Sharing Coordinator informed of park benefits-sharing activities on an ongoing basis.
- Prepares park's annual report on benefits sharing.
- Serves as the key official for administration or ATR on a benefits-sharing agreement, as assigned (on a case-by-case basis) by the superintendent.
- Coordinates a park-based ORTA, if established.
- Forwards to the servicewide ORTA documentation on approved permits and research projects that are identified for potential commercial use, if the park is designated a federal laboratory and does not have a park ORTA.
- May serve as the benefits-sharing negotiating team leader.

NOTE! In most parks involved in benefits sharing, the role of park benefits-sharing coordinator will be a collateral duty.

2.7 What are the responsibilities of the negotiating team lead?

The benefits-sharing negotiating team lead:

- Coordinates negotiations and maintains a written record of all negotiation activities.
- Serves as chief negotiator or delegates this responsibility.
- Reviews background information provided by the park benefits-sharing coordinator or other point of contact.
- Consults with an economist for market research and with other advisors, as needed for negotiations.
- Identifies desired monetary and/or non-monetary benefits and develops Request for Approval of Negotiations and Terms for review by the superintendent and upper management concurrence and approval.
- Prepares and shares the Term Sheet (see Appendix J) with the other party and starts negotiations.
- Develops draft agreements to share or decline benefits, shares with the other party (as appropriate), and keeps the superintendent; regional director; Associate Director, NRSS; other WASO associate directors, as appropriate; and park and WASO benefits-sharing coordinators informed of progress.
- Ensures that the agreement to share or decline benefits complies with the National Environmental Policy Act (NEPA) and other legal mandates.
- Prepares signature package for approval of an agreement to share or decline benefits and coordinates NPS surname concurrences, and approvals of both parties. (For a Cooperative Agreement, the contracting officer conveys the document to the other party.)
- Distributes original and scanned copies of executed agreement.
- Provides decision file for benefits-sharing agreements to the key official for administration or the ATR.

2.8 What are the responsibilities of the key official for administration and the agreements technical representative (ATR)?

NOTE! The key official for administration has the following responsibilities for CRADAs and General Agreements. For Cooperative Agreements, the ATR has these responsibilities as well as the responsibilities identified in the Agreements Handbook, Chapter 4.

The key official for administration or the ATR:

- Administers the benefits-sharing agreement.
- Monitors and tracks progress on fulfilling the terms of the benefits-sharing agreement, reporting annually to the superintendent, park benefits-sharing coordinator, and WASO Benefits-Sharing Coordinator.
- Maintains the decision file on the agreement, obtaining the initial decision files from the negotiating team lead.

NOTE! *The key official for administration or the ATR is often the park benefits-sharing coordinator.*

2.9 What are the benefits-sharing responsibilities of the park permit coordinator?

The park permit coordinator:

- Avoids considering the potential receipt of benefits while processing a permit application, CSTA or MTA.
- Avoids any involvement in discussions, negotiations, or any other activity associated with case-specific benefits-sharing arrangements, but provides information to the benefits-sharing team upon request.
- Alerts the park benefits-sharing coordinator, at the time a permit is issued, if the project has a stated commercial or potentially commercial purpose.
- Refers all information or requests for information about research results with potential commercial use to the park benefits-sharing coordinator.
- Issues and tracks CSTAs and MTAs; in coordination with park museum or living collection curator, terminates these agreements if the items become identified for permanent retention and are documented in the park museum or living collection.
- Seeks approval for any changes to the standard template text in a CSTA or MTA from the WASO Benefits-Sharing Coordinator.
- Refers requests to deposit Material in a patent depository to the park living collections curator.
- May perform the duties of the living collections curator in the absence of a living collections curator.

2.10 What are the benefits-sharing responsibilities of the park museum curator?

The park museum curator:

- Avoids considering the potential receipt of benefits while processing loans.
- Avoids any involvement in discussions, negotiations, or any other activity associated with case-specific benefits-sharing arrangements, but provides information to the benefits-sharing team upon request.
- Notifies and assists the WASO Benefits-Sharing Coordinator to facilitate all patent deposits involving research results originating from a museum specimen collected in a park.
- Assists the park permit coordinator to perform the duties of the living collections curator in the absence of a living collections curator.
- Refers to the park benefits-sharing coordinator all notifications from loan recipients about potential commercial uses for research results.
- Seeks approval for any changes to the benefits-sharing terms in the standard template loan agreement from the WASO Benefits-Sharing Coordinator.

2.11 What are the benefits-sharing responsibilities of the park living collections curator?

Note: A DO for living collections is under development.

The park living collections curator:

- Avoids considering the potential receipt of benefits while processing MTAs and loans.
- Avoids any involvement in discussions, negotiations, or any other activity associated with case-specific benefits-sharing arrangements, but provides information to the benefits-sharing team upon request.
- Notifies and assists the WASO Benefits-Sharing Coordinator to facilitate all patent deposits involving research results originating from living collection items.
- Prepares loans and park repository agreements for living collection items in coordination with the WASO Benefits-Sharing Coordinator.
- Prepares MTAs for living collection items.
- Terminates MTAs if Material is identified for permanent retention and documented in the park living collection or park museum collection.
- Tracks MTAs and uses Servicewide tracking system when developed.
- Seeks approval for any changes to the standard template text in an MTA from the WASO Benefits-Sharing Coordinator.

2.12 What are the responsibilities of the WASO Benefits-Sharing Coordinator?

The WASO Benefits-Sharing Coordinator:

- Coordinates the Servicewide benefits-sharing program and related activities under the authority of the FTTA.
- Advises upper management on decisions, concurrences and approvals on benefits-sharing matters.
- Develops and maintains Servicewide electronic systems to track CSTAs, MTAs, and agreements to share or decline benefits.
- Approves changes to the standard template text in an MTA or a CSTA in consultation with the Office of the Solicitor.
- Develops Servicewide repository agreements, and assists parks in developing repository agreements for NPS Material and MTAs for repositories to use in transferring custody to third-party researchers.
- Facilitates all patent deposits involving research results originating from a specimen collected in a park.
- Advises parks on whether to negotiate benefits or decline benefits. Advises parks on type of agreement to use.
- Assists individual parks on development of a Park Request for Designation as a Federal Laboratory.
- Provides technical assistance sources and contacts to facilitate benefits sharing.
- Develops employee training programs on benefits sharing and technology transfer.
- Maintains copies of all park agreements to share or decline benefits.

- Monitors status and content of CSTAs, MTAs, and agreements to share or decline benefits.
- Manages the Servicewide benefits-sharing payment system (such as Pay.Gov) and assists parks to participate.
- Reviews benefits-sharing expenditures and project statements to ensure that they meet the established criteria for resource preservation or benefits-sharing administration.
- Reviews reports from the Accounting Operations Center for the benefits-sharing fund source—Functional Area PROBSBSC4.XZ0000, or its successor.
- Receives annual benefits-sharing reports from parks, compiles the information into an annual report, and submits the report to the DOI Office of Policy, Management and Budget.
- Coordinates the Servicewide ORTA and advises park ORTAs.
- Develops and updates websites with information on benefits sharing and technology transfer, including policies and procedural guidance, templates, and best practices.
- Prepares and submits through the Associate Director, NRSS, to the Office of the Solicitor any requests to contract with outside counsel for legal work in association with benefits sharing and technology transfer activities that cannot be supported by the Office of the Solicitor, in accordance with 456 DM 1, Policy and Procedures for Contracting with Lawyers and Law Firms.

2.13 What are the responsibilities of the Office of Research and Technology Applications (ORTA)?

NOTE! NPS uses the ORTA only when acting under the authority of the FTTA, for example when operating a federal laboratory, developing or using a CRADA, and addressing inventions and discoveries of NPS employees. The purpose of the ORTA is to facilitate technology transfer and use outside the NPS. The establishment and function of the ORTA is described at 15 USC 3710(b) and (c).

NPS has established a Servicewide ORTA, under the Associate Director, NRSS, which performs these functions for all parks designated as federal laboratories unless a park superintendent, as the laboratory director, independently establishes a park ORTA in accordance with 15 USC 3710(b) and in consultation with the Associate Director, NRSS. Park laboratories may establish and staff park ORTAs if the benefits-sharing workload warrants. The WASO Benefits-Sharing Coordinator coordinates the Servicewide ORTA. The park benefits-sharing coordinator manages the park ORTA. Science, technical, and engineering professionals involved in benefits-sharing and technology transfer activities are responsible for supporting the ORTA by identifying opportunities for and facilitating technology transfer, as appropriate, consistent with the NPS mission.

The ORTA:

• Assesses research in designated NPS federal laboratories for potential commercial use by reviewing approved permits and research projects that laboratories identify for potential commercial use and refer to the ORTA for review on an ongoing basis.

- Provides technical assistance to state and local government officials and to programs that transfer technology for the benefit of a region, state, or local jurisdiction.
- Provides and disseminates information on federally owned or federally originated NPS products, processes, and services with potential application to state and local governments and private industry.
- Cooperates with National Technical Information Service (NTIS), FLC, and other organizations to link NPS federal laboratories to potential users in state and local government and private industry.
- Participates, as appropriate, in regional, state, and local programs designed to facilitate or stimulate the transfer of technology for the benefit of the region, state, or local jurisdiction in which the federal laboratory is located.

2.14 What are the responsibilities of the DOI Office of the Solicitor?

An attorney advisor of the DOI Office of the Solicitor:

- Serves as a general legal advisor on all matters concerning benefits sharing.
- Advises the WASO Benefits-Sharing Coordinator on changes to the standard template text in an MTA or a CSTA and reviews proposed changes.
- May serve as a member of the negotiating team for a benefits-sharing agreement.
- Reviews proposed agreements to share or decline benefits prior to finalization, consistent with 761 DM 1.7, E(2).

2.15 What other NPS or DOI offices have review or advisory responsibilities?

NPS managers with direct authority over federal laboratories (other than parks designated as federal laboratories) have all the responsibilities of superintendents in relation to benefits sharing and federal laboratories.

3.0 Research Permits and Benefits Sharing

Research permits and other authorizations that lead to research results are the foundation for benefits sharing, yet consideration of benefits sharing and related negotiations must be kept separate from decisions to issue research permits and other authorizations or deny applications for research permits and other authorizations. This "firewall" helps to make sure that the administration of permits and other authorizations is not influenced by the potential for receipt of monetary or non-monetary benefits under a benefits-sharing agreement. Individuals with responsibility for preparing benefits-sharing agreements and negotiating benefits must not have responsibility for coordinating research permits, Collected Specimen Transfer Agreements (CSTAs), Material Transfer Agreements (MTAs), and loan agreements. Similarly, individuals with responsibility for issuing research permits and other authorizations must not have responsibility for preparing and negotiating benefits.

3.1 What is the link between the NPS research permit and benefits sharing?

The link between the NPS research permit and potential benefits sharing is General Condition #6 of the Scientific Research and Collecting Permit. This condition states that the results of research may be used only for scientific purposes and not for commercial purposes unless the permittee has entered into a "CRADA or other approved benefits-sharing agreement with the NPS." This condition states that specimens collected under permit and any components and research results derived from the collected specimen, including progeny and derivatives, are to be used for science or education. It also establishes that any commercial use of research results derived from NPS-permitted research requires a payment of 20% of gross revenue to NPS absent a "CRADA or other approved benefits-sharing agreement with NPS." See the Permit General Conditions on the NPS Research Permit and Reporting System web site at https://irma.nps.gov/content/RPRS/Index2.aspx.

NOTE! When the Scientific Research and Collecting Permit General Condition #6 refers to "an approved benefits-sharing agreement" it means an executed agreement to share or decline benefits. Otherwise, as described in Director's Order (DO) #77-10: NPS Benefits Sharing, and in this Handbook a "benefits-sharing agreement" applies only to an agreement to share benefits, not an agreement to decline benefits.

3.2 May the park research permit coordinator consider possible benefits sharing when processing a research permit application?

No. The research permit coordinator must not consider past or the potential future receipt of benefits while processing an application and the superintendent must not consider past or potential benefits while making a decision to issue a permit. This "firewall" between permit administration and benefits-sharing activities is necessary to avoid any conflict of interest or appearance of conflict of interest. The park research permit coordinator must not be involved in discussions, negotiations, or any other activity associated with case-specific benefits-sharing arrangements. Just as the research permit coordinator must avoid favoring permit applications that have potential for commercial use of research results and benefits sharing, the coordinator must avoid blanket refusals of a permit application in order to avoid the complexities of commercial use and benefits sharing.

For example, to maintain the firewall, the research permit coordinator must:

- Avoid conducting any examination of potential future commercial applications of possible research results and of future benefits-sharing opportunities while conducting appropriate compliance with the National Environmental Policy Act (NEPA) regarding possible impacts of the research proposed in a permit application.
- Avoid initiating or participating in negotiation of agreements to share benefits or development of agreements to decline benefits.
- Avoid reviewing a description of the precise monetary benefits obligated by an agreement.

- Avoid maintaining copies of licenses or other commercial agreements involving the non-park institution.
- Avoid reviewing, maintaining, or using confidential business information (such as correspondence or other information related to marketing, licensing, or patent prosecution).
- Avoid reading confidential reports required by agreements to share or decline benefits, such as details about a benefits-sharing partner's income related to performance-based payments.
- Avoid accessing files for agreements to share or decline benefits.

3.3 How should the park research permit coordinator treat permit applications for scientific research with a stated commercial or potentially commercial purpose?

The park research coordinator should evaluate such applications in the same way as other research permit applications. The coordinator should make sure that all studies are consistent with park laws and policies and that the research will result in no unacceptable impact to park resources, public enjoyment derived from those resources, or park operations. Whenever a permit is issued for a project with a stated commercial or potentially commercial purpose, the permit coordinator immediately should alert the park benefits-sharing coordinator. The park benefits-sharing coordinator may ask a permitted researcher to provide more information preliminary to developing a benefits-sharing proposal or to contact the park at a particular stage in the project when the nature of the commercial use is better defined.

3.4 Based on the for-profit or non-profit status of a researcher's institution, may I make an assumption about the potential for commercial use of research results?

No. Both types of organizations do research with and without commercial use of research results.

3.5 How should a park address National Environmental Policy Act (NEPA) and related compliance for research permit applications with respect to possible future commercial applications?

Always document NEPA compliance for every research permit in accordance with *DO* #12: *Conservation Planning, Environmental Impact Analysis, and Decision Making.*

The research permit coordinator must not consider potential future commercial uses or past and potential future receipt of benefits while processing an application for a Scientific Research and Collecting Permit and the superintendent must not consider past or future benefits while making a decision to issue a permit. Agreements to share or decline benefits and any associated NEPA compliance for such agreements will be considered separately from the Scientific Research and Collecting Permit issuance process. This "firewall" between permit administration and benefits-sharing activities is necessary to avoid any conflict of interest or appearance of conflict of

interest. The park research permit coordinator must avoid discussions, negotiations, or any other activity associated with case-specific benefits-sharing arrangements.

3.6 How does NPS describe specimens collected under permitted research and substances derived from collected specimens?

For the purposes of benefits sharing, the NPS describes collected specimens and any substances created from them in three categories, depending on their status.

First, a "collected specimen" is the item collected by the permittee under the authority of an NPS permit, and portions thereof. Collected specimens are natural products (see **NOTE!** discussing "natural product" in Section 1.5).

Second, the term Material refers to progeny and unmodified derivatives of collected specimens, museum specimens, living collection items, and multiple generations thereof. The Material does not include a) modifications or b) other substances created by a person through use of the Material that are not modifications, progeny, or unmodified derivatives. Material may be contained/incorporated in modifications. Note: Progeny, unmodified derivatives, and modifications are substances created *ex situ* (outside their natural context) through human ingenuity. They are labeled "created with human intervention" in Figure 1 below.

Third, when collected specimens and Material are permanently retained, they change their status. When collected specimens are permanently retained, they are most often considered part of the park museum collection and are called "museum specimens." When a collected specimen or Material is living or otherwise biologically active and permanently retained *ex situ* for the purpose of generating and providing living or otherwise biologically active material for research, restoration, education or other purposes, it is considered part of the park "Living Collection" and is called a "living collection item." Park living collections are tracked using procedures parallel to park museum collections. (Note: A DO for Living Collections is under development.)

See also glossary definitions for Collected Specimen, Material, Museum Specimen, Living Collection, Living Collection Item, and Culture Collection; *Figure 1: Relationship of Material to Natural Product*; and *Table 1: Examples of Collected Specimens, Museum Specimens, Living Collection Items, and Material.*

NOTE! Management Policies 2006 (4.2.3) states that "natural resource collections include non-living and living specimens...Nonliving specimens ...are managed as museum collections. Living collections will be managed in accordance with the provisions of a park's general management plan, the Animal Welfare Act, and other appropriate requirements."

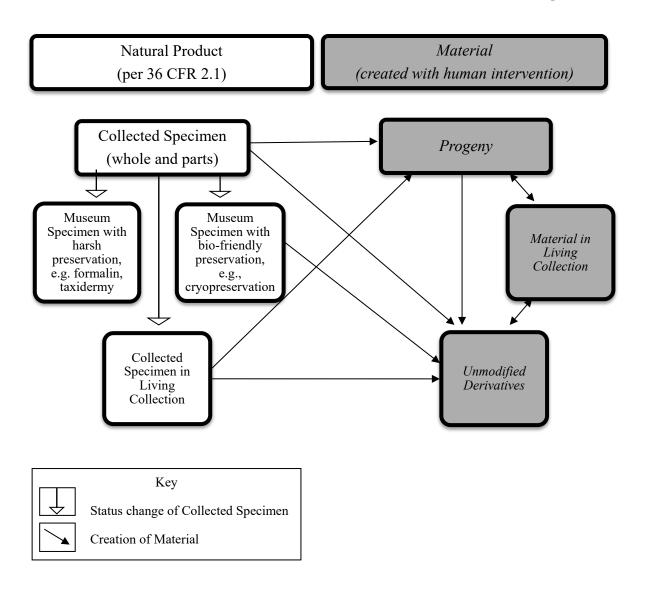


Figure 1: Relationship of Material to Natural Product

Examples of Collected Specimens, Museum Specimens, Living Collection Items, and Material		
Category	Status	Example
Collected specimen	Temporary custody of researcher; may be consumed, discarded, or submitted to park for permanent retention.	 Living and nonliving biological specimens Whole organisms, such as a plant or a beetle Water or soil sample Sweep net sample of insects

Examples of Collected Specimens, Museum Specimens, Living Collection Items, and Material		
Category	Status	Example
		 Fossil in a plaster jacket or removed from its matrix A microorganism, such as the Protozoan, <i>Echinamoeba</i> <i>thermarum</i> Ear punch from <i>Bison bison</i> Sediment collected from water
Museum specimen	Permanently retained in a park museum collection; collected specimens, including geological, paleontological, other physical specimens, and nonliving biological specimens, and components of a collected specimen that are permanently retained, prepared (as needed), and cataloged in a museum collection; may be on loan to non-NPS repository.	 Preserved whole organisms, such as a plant or a beetle Thin section of plant tissue mounted on microscope slide Prepared fossil, such as <i>Rhineura hatchery</i> (legless lizard) Preserved blood or other tissue sample Composite samples that may include multiple undifferentiated organisms or components, such as a sweep net sample
Living collection item	A collected living biological specimen or Material permanently retained in a living collection for the purpose of generating and providing living or otherwise biologically active Material for research, restoration, education or other purposes; may be on loan to non-NPS repository.	 Living whole organisms, such as a plant or a beetle Isolated and cultured microorganisms Seeds Gametes Viable samples, such as cell lines Genes maintained as plasmids in living bacteria

Examples of Collected Specimens, Museum Specimens, Living Collection Items, and Material		
Category	Status	Example
Material — Progeny	Microorganism cultured in laboratory; unmodified descendant from a collected specimen or Material; living organisms produce progeny.	 Isolated microorganism, such as the Protozoan, <i>Echinamoeba thermarum</i> (descendant from collected specimen or from a living collection item) <i>Marasmius capillaris</i>, cell from cell (fungal culture)
Material — Unmodified Derivative	Created in laboratory from collected specimen or Material; unaltered copy of a functional subunit or product.	 Amplified plant or animal DNA Clones of unmodified cell lines Isolated molecules of proteins expressed by DNA/RNA
Material contained in a Modification	Material originating from collected specimens, such as progeny and unmodified derivatives that may be contained/incorporated in modifications.	• DNA incorporated (engineered) into laboratory microbes, such as when <i>E. coli</i> uses incorporated <i>Thermus aquaticus</i> DNA to make Taq polymerase. In this example, the <i>E. coli</i> is a modification incorporating the <i>T. aquaticus</i> DNA, which is Material.

3.7 What are some examples of research results?

For purposes of NPS benefits sharing, the term "research results" means Material (including Material retained in a living collection), modifications, intellectual property, inventions, data, discoveries, and/or other knowledge, processes, products, or applications resulting from research activities of researchers or their institutions or companies. (Note: "Research results" excludes collected specimens and museum specimens.) "Discovery" is broadly defined to mean new knowledge gained through search or study. "Invention" means any discovery, thing, method, material, process, or idea that might be patentable or otherwise protected under 35 USC (Patents), 7 USC 2321 *et seq.* (Plant Variety Protection), and 18 USC 1905 (Trade Secrets).

Table 2 provides examples of research results. Also see Section 1.5.

Examples of Material and Intellectual Property that are Research Results		
Example	Material	Intellectual Property
A pure laboratory-grown culture of <i>Thermus</i> <i>aquaticus</i> developed from a bacterium found in a water sample collected in a park	Х	
Knowledge of how to grow a culture of <i>Thermus aquaticus</i>		X
Development of a new C-14 date calculation method using charred corn from an archeological site		X
Taq polymerase, an enzyme purified in the researcher's laboratory from progeny of <i>Thermus aquaticus</i> .	Х	
Polymerase Chain Reaction (PCR), a patented invention and process often using Taq polymerase that facilitates widespread uses of DNA analyses		X
Copyright for photograph of plant cell structure		X
A viable (reproducing) culture of microorganisms, such as the Protozoan <i>Cyrtolophosis acuta,</i> developed from a collected specimen and maintained by a culture collection (repository)	Х	
Improved method to prepare genes for sequencing using an enzyme first discovered in a park-sourced microorganism.		X

Table 2: Examples of Material and Intellectual Property that are Research Results

4.0 NPS Specimen and Material Management Procedures that Underpin Benefits Sharing: Permits, Cataloging, Loan Agreements, and Transfer Agreements

Note: Some of the information in this section will be moved to a new Director's Order (DO) and handbook on living collections. Until that DO and handbook are available, the information will remain in this Handbook.

Park resources may be preserved *in situ* or collected under permit and become collected specimens. With appropriate authorization, collected specimens may then be shared within the research community, discarded or destroyed in analysis, used in the laboratory to create Material, or retained in park collections and preserved in park or partner repositories. Each step in this process requires authorization, documentation, and tracking of movement. The Scientific Research and Collecting Permit authorizes collecting. The Collected Specimen Transfer Agreement (CSTA) authorizes the movement of collected specimens when a determination has not been made regarding final disposition. The Material Transfer Agreement (MTA) authorizes the movement of Material (derived from the collected specimen) that a researcher has created in a laboratory, and the loan agreement authorizes the movement of permanently retained museum specimens or living collection items. See Appendix B: Glossary for definitions of Scientific Research and Collecting Permit, CSTA, MTA, and loan agreement.

NOTE! NPS issues Scientific Research and Collecting Permits for scientific and educational purposes only. NPS decides to issue research permits and deny permit applications without regard to whether the permit applicant is, was or might become a party to an agreement to share or decline benefits. Likewise, NPS issues, renews, and denies requests for CSTAs, MTAs, loan agreements and any other similar agreements or authorizations without regard to negotiation or existence of an agreement to share or decline benefits.

4.1 How does NPS manage collected specimens, museum specimens, and Material?

Parks must use research permits, CSTAs, cataloging records, loan agreements, and MTAs, as applicable, to track collected specimens, museum specimens, and Material. Tracking collected specimens, museum specimens, and Material is critical to monitoring commercial use of research results and eventual benefits sharing.

NOTE! Individuals with responsibility for preparing agreements to share or decline benefits and negotiating benefits must not have responsibility for coordinating research permits, CSTAs, MTAs, and loan agreements. To maintain this separation of duties, parks may seek outside assistance to fulfill the benefits-sharing responsibilities.

4.1.1 Research Permits

Through the permit application, permit, and Investigator's Annual Report (IAR), the permit system tracks information critical to benefits sharing, including:

- Scientific description of specimens permitted for collection, sample sizes and quantities authorized for collection
- Designated repository for permanently retained specimens
- Status of collected specimens and Material while in custody of permittee

For further guidance consult the park research permit coordinator and visit the NPS Research Permit and Reporting System website (<u>https://irma.nps.gov/Content/RPRS/</u>). Permits for archeological research and collecting under the Antiquities Act and Archaeological Resource Protection Act may be revised in the future to address benefits sharing. For further guidance on archeological permits see <u>http://www.nps.gov/archeology/npsGuide/index.htm</u>.

4.1.2 Collected Specimen Transfer Agreements (CSTAs)

CSTAs authorize researchers other than researchers designated in the permit to take custody of collected specimens. NPS also uses the CSTAs to track the specimens. A permittee must have prior NPS authorization when the permittee wants another researcher's institution to take custody of the collected, but uncataloged, specimen, or a part of the collected specimen. In response to the permittee's request, NPS enters into a CSTA with the other researcher's institution to authorize that institution to receive the collected specimen. For example, if a collected specimen is no longer needed by the permittee, it could be studied by a different researcher under a CSTA. Guidance on CSTAs is not available elsewhere, and is therefore discussed in detail below. Use the template in Appendix C to create a CSTA or, as described in Section 4.1.5, an MTA. Both the researcher receiving the specimen and a responsible official of the receiving institution must sign the CSTA.

4.1.3 Cataloging

An NPS catalog record identifies and describes a museum specimen or living collection item and includes a unique catalog number for tracking. Catalog records provide information such as collector, collection date, locality, museum specimen or living collection item identification, current location, condition, and analysis. For further information about museum collections, see the park museum curator and the Interior Collections Management System (ICMS) guidance at http://www.nps.gov/history/museum/publications/ICMS.html. Guidance on living collections is under development.

4.1.4 Loan Agreements

An NPS loan agreement is a contractual arrangement between a lender and a borrower of museum or living collections, specifying the items lent and the terms, conditions, and responsibilities and liabilities of each party. The NPS uses outgoing loan agreements to track loans of cataloged museum specimens and living collection items to other institutions, such as research laboratories or repositories. NPS does not loan to individuals, only to institutions. Loans may be short-term, for example a loan to a laboratory for analysis, or long-term, such as to a

repository or culture collection. A culture collection offers highly specialized storage environments, such as cryogenic storage at extremely low temperatures, such as -130°C and lower for cells and microorganisms.

For further information on museum specimen loans see the park museum curator and the ICMS guidance at <u>http://www.nps.gov/history/museum/publications/ICMS.html</u> and NPS Museum Handbook, Part II, Chapter 5, Outgoing Loans, at <u>http://www.nps.gov/history/museum/publications/handbook.html</u>. Information on living collection loans is under development, but will have a structure similar to museum loans.

4.1.5 Material Transfer Agreements (MTAs)

An NPS MTA is an agreement that establishes the terms by which NPS authorizes a change in custody of Material. For example, an MTA may authorize an institution or researcher currently assigned custody of the Material to send a portion of the Material to another institution for research use. The MTA also tracks disposition of the Material when the researcher's use concludes. Guidance on NPS MTAs is not available elsewhere, and is therefore discussed in detail below. Use the template in Appendix C to create an MTA or as discussed above in Section 4.1.2, a CSTA. Both the researcher receiving the specimen and a responsible official of the receiving institution must sign the MTA.

Use a	to
Permit	Authorize research and collection of specimens. Park may amend a permit to include additional researchers or to authorize research that is an extension of the permitted study, as needed.
Collected Specimen Transfer Agreement (CSTA)	Authorize change in custody of collected specimen from permittee to institution of researcher not named in permit.
Catalog Record (Form 10-254 for museum specimens; a new form is under development for living collection items)	Identify and describe a museum specimen and assign a unique catalog number for tracking. Guidance on cataloging living collection items is under development.
Loan Agreement (Form 10-127 for museum specimens; a new form is under development for living collection items) or equivalent repository agreement	Authorize loans and track 1) museum specimens and living collection items in temporary custody of institutions and organizations for research or other purposes, and 2) museum specimens and living collection items in the long-term custody of repositories, such as culture collections. Loan conditions may authorize third-party loans, destructive analysis, and related reporting requirements, as needed. In addition, loan agreements may authorize repositories to distribute Material to third parties using an NPS MTA.
Material Transfer Agreement (MTA)	Authorize custody and track Material, other than permanently retained Material, that parks and authorized non-NPS repositories provide to institutions and organizations for research and temporary custody. Generally, the Material will be consumed or discarded after use. If a researcher generates Material that is recommended for permanent retention, it must be cataloged in the park living collection. Other Material that is not consumed must be returned or destroyed.

4.1.6 Comparison of Choices for Managing Specimens and Material

4.2 Why is the correct use of permits, Collected Specimen Transfer Agreements (CSTAs), loan agreements, and Material Transfer Agreements (MTAs) to account for the collected specimens and Material important?

Using permits, CSTAs, loans, MTAs, and museum or living collection access agreements correctly is important because these documents accountably track the specimens and Material and also contain terms and conditions that obligate the signatories to discuss and, as appropriate, develop agreements to share or decline benefits with NPS. These terms and conditions provide that the:

- Permittee, borrower, user, or recipient (henceforth "researcher") agrees not to use the collected specimens, museum specimens, Material, or research results for commercial purposes without first entering into an agreement to share or decline benefits with NPS.
- Researcher agrees not to provide the collected specimens, museum specimens, or Material to third parties without prior written NPS authorization.
- Sale or commercial use of natural products, such as collected specimens, is prohibited (36 CFR 2.1).
- NPS may seek specific remedies in the event terms and conditions are not met.

In addition, CSTAs and MTAs require recipients to:

- Abide by the terms and conditions of the permit that authorized collection of the original specimen,
- Provide NPS with copies of reports and publications, and
- Notify NPS before filing a patent or intellectual property claim

NOTE! When users study collections in NPS or non-NPS repositories, or borrow collections from non-NPS repositories without specific, case-by-case NPS authorization, users must agree in writing to the conditions in this section.

See Table 3 for examples of how to authorize and track collection and use of collected specimens and Material upon request from a researcher, permittee, or other user.

Examples of How to Authorize and Track Collection and Use of Collected Specimens and Material		
If a/an	proposes to	a park may authorize by
Permit Applicant	Collect in a park,	Issuing a permit.
Permit Applicant	Have the collected specimens be retained in a museum collection,	Issuing a permit that identifies the proposed repository (making the permittee responsible for ensuring that the collected specimens are cataloged in ICMS), and authorizing a

 Table 3: Examples of How to Authorize and Track Collection and Use of Collected Specimens and Material

Examples of How to Authorize and Track Collection and Use of Collected Specimens and Material			
If a/an	proposes to	a park may authorize by	
		loan of the resulting museum specimens to a non-NPS repository, if applicable.	
Permit Applicant	Consume in analysis or discard collected specimens,	Issuing a permit that authorizes consumption or discard.	
Permittee	Permanently retain live collected specimens or Material,	Working with the permittee to catalog the collected specimen or Material into the park living collection and deposit it in a repository (on loan, if a non-NPS repository).	
Researcher	Study museum specimens or living collection items at an NPS repository,	Documenting the research and nature of the study and providing access. Park may authorize destructive analysis.	
Researcher	Study museum specimens or living collection items at a non-NPS repository,	Including in the repository loan agreement a provision for researcher access to and reporting on NPS museum specimens and living collection items. Park may also authorize repository to allow destructive analysis.	
Researcher	Send a museum specimen or a living collection item from an NPS repository to another researcher or laboratory,	Completing a loan agreement to the other researcher's institution or the laboratory. Park may authorize destructive analysis.	
Researcher	Send a museum specimen or a living collection item from a non-NPS repository to another researcher or laboratory,	Including in the repository loan agreement authorization for the repository to make third-party loans. Be sure to indicate if loans for certain purposes or types of material	

Examples of How to Authorize and Track Collection and Use of Collected Specimens and Material			
If a/an	proposes to	a park may authorize by	
		must be specifically approved by the park.	
Permittee	Send collected specimens to a non-NPS repository for long- term storage,	Completing a loan agreement with the non-NPS repository after the permittee has worked with the park to catalog the collected specimens in the museum or living collection.	
Permittee	Send collected specimens or Material that is authorized for consumption or discard to a <i>commercial</i> laboratory for a specific analysis needed by the permittee,	Allowing this portion of the permitted research to proceed under the research permit.	
Permittee	Send collected specimen or Material that is to be permanently retained to another researcher or laboratory,	Working with the permittee to catalog the collected specimen or Material and completing a loan agreement with the other researcher's institution or the laboratory.	
Permittee	Send collected specimens or Material that is authorized for consumption or discard to a researcher not associated with the permitted project,	Issuing a CSTA for a collected specimen or an MTA for Material to the non- permitted-researcher's institution.	
Permittee	Send collected specimens or Material to a colleague not named in the permitted study to do related work that extends beyond the purpose of the permitted study,	Issuing a CSTA for collected specimens or MTA for Material to the colleague's institution.	
Researcher authorized by an NPS CSTA or MTA	Send collected specimens or Material to a colleague not named in the researcher's CSTA or MTA,	Issuing a CSTA for collected specimens or MTA for Material to the colleague's institution.	

Examples of How to Authorize and Track Collection and Use of Collected Specimens and Material			
If a/an	proposes to	a park may authorize by	
Non-NPS Repository	Provide Material that the repository has created from NPS specimens or Material to another researcher or laboratory,	Including in the repository loan agreement for the NPS specimens or Material authorization for the repository to provide Material that it creates using an NPS MTA.	

4.3 How should parks use Collected Specimen Transfer Agreements (CSTAs) and Material Transfer Agreements (MTAs)?

Parks use a CSTA for collected specimens or an MTA for Material when researchers, other than permittees, want custody of collected specimens or Material for scientific research, and the collected specimens or Material are expected to be consumed in analysis or discarded after analysis. If researchers subsequently recommend that collected specimens or Material should be permanently retained, then parks work with the researchers to catalog them as museum specimens or living collection items and deposit them in an NPS repository or on loan to a non-NPS repository (unless parks reject the recommendation and require destruction or discard).

NOTE! Do not use a CSTA or an MTA for museum specimens, or for living collection items that are permanently retained. Refer instead to the appropriate park curator for help with using loan agreements.

4.3.1 How should a park use a CSTA or an MTA to authorize a change in custody?

Use the NPS CSTA/MTA template in Appendix C to authorize custody of collected specimens (CSTA) or Material (MTA) by entities other than permittees. If the park proposes any changes to the template text, even a single word, the park must send the proposal to the WASO Benefits-Sharing Coordinator, who will consult with an attorney advisor in the DOI Office of the Solicitor, before deciding whether to approve the requested changes.

Only NPS may authorize use of NPS collected specimens and Material. Non-NPS repositories may not use their institution-specific agreements with third parties to authorize use of NPS collected specimens and Material without specific NPS approval and customization of terms, as needed.

The park research permit coordinator is responsible for issuing CSTAs for collected specimens and MTAs for Material to change custody of some or all of the collected specimens or Material from the permittee to a third party. In addition, the park living collections curator or repository manager is responsible for issuing MTAs that apply to Material originating from a museum specimen or living collection item and held in an NPS or non-NPS repository. In the absence of a living collections curator, the park research permit coordinator performs these tasks with the assistance of the park museum curator.

4.3.2 How should a park authorize repositories to use MTAs for transfers to third parties?

Under the terms of a repository agreement, NPS may authorize a repository that distributes NPS Material to a third party to act as an NPS agent and issue an NPS MTA that has been customized for that specific repository's use. Refer to the WASO Benefits-Sharing Coordinator for help with establishing an MTA for a repository to use with third parties.

4.3.3 What should a park do if a researcher says the collected specimen or Material should be permanently retained?

If a researcher notifies the park that a collected specimen received under a CSTA or Material received under an MTA should be permanently retained, refer the researcher to the park museum curator or park living collections curator, as appropriate. The curator will work with the researcher to accession and catalog the collected specimen in the museum or living collection or the Material in the living collection and deposit the cataloged item in an NPS repository or loan it to a non-NPS repository (for museum collections see DO # 24; the DO for living collections is under development). The curator then works with the permit coordinator to terminate the CSTA or MTA or with the living collections curator to terminate MTAs originating with living collections.

If the researcher wants to maintain custody and use of the cataloged museum specimen or living collection item, the responsible curator will loan the museum specimen or living collection item to the researcher's institution.

4.4 How should parks track microbiological specimens and related Material?

Parks should track collected microbiological specimens and Material originating with those specimens as outlined in Section 4.3. Tracking microorganisms can be challenging. Like many museums and universities involved in the study of microbiology, NPS manages microorganisms that are permanently retained as living collections using a tracking system similar to the museum collection system. A researcher who develops a culture of NPS Material suitable for deposit in a culture collection should contact the park living collections curator to arrange a loan of the living collection culture to the recommended culture collection. NPS has a Servicewide repository agreement with the American Type Culture Collection. See the *NPS Museum Handbook*, Appendix H, for further guidance. Guidance on living collections is under development.

Generally accepted standards in microbiology require that newly identified species and inventions that involve microorganisms be published and that types be deposited in a culture collection so that others may access the type strains to verify or expand upon the research. Some standards require deposit of types in two culture collections in two different countries. See Section 5.3.1.

5.0 Developments that Trigger Benefits-Sharing Actions

The Scientific Research and Collecting Permit obligates researchers to inform the park about any proposed commercialization of research results.

When a permit applicant or a permitted researcher states an intention to commercialize research results or a permitted researcher discloses an invention, discovery, or patent application to the park permit coordinator or other park staff, the park staff member must alert the park benefits-sharing coordinator immediately. Once notified, the benefits-sharing coordinator assumes responsibility for all discussions regarding benefits sharing and the permit coordinator focuses only on permit, Collected Specimen Transfer Agreement (CSTA), and Material Transfer Agreement (MTA) issuance and compliance.

The CSTA and MTA conditions also require recipients to notify NPS of every discovery or invention that relates in any respect to research results, including modifications, derived from study of provided items prior to any public disclosure, within thirty (30) days of making an invention disclosure to the person(s) responsible for patent matters in the inventing organization, and within thirty (30) days of filing any type of application for a patent or other intellectual property claim in the United States or other country.

When a park independently discovers information about proposed commercial uses for a permitted researcher's research results, including a researcher's invention disclosures or patent applications, the park benefits-sharing coordinator must promptly evaluate that information for its potential for benefits sharing. If the evaluation identifies a possible commercial use, the benefits-sharing coordinator assumes responsibility for all discussions regarding benefits sharing.

When NPS receives notification or otherwise confirms a researcher's potential or contemplated commercialization, NPS must confirm the development stage of the commercialization, monitor development, and, when proposed commercialization is definite, but before commercialization occurs, initiate development of an agreement to share or decline benefits. See exception noted in Section 1.6 regarding commercial applications for certain educational products. See Section 6.0 for guidance on developing agreements to share or decline benefits.

5.1 When is the use of research results considered commercial?

NPS considers the transfer, use, or study of research results in return for value received to be a commercial use of research results. Commercial use is defined as use of Material or modifications or other research results in a product, service, or process resulting in a product or service that is sold, leased, licensed, or otherwise transferred for value received. Table 4 shows examples of research results that became products that were sold or licensed.

Examples of Commercial Use of Research Results		
Research Results	Commercial Use	
Polymerase Chain Reaction (PCR), a patented invention and process that facilitates widespread uses of DNA analyses. PCR sometimes uses the enzyme Taq polymerase, originally isolated from a bacterium first collected in a national park.	Business applications of PCR range from rapid diagnosis of disease to forensic medicine. (Note: This product was developed prior to any NPS benefits-sharing obligation).	
Enzymes from thermophilic microorganisms resulted in trademarked product Pyrolase 200	Pyrolase 200 had an industrial application in oil and gas recovery. (Note: This product is no longer for sale.)	

Table 4: Examples of Commercial Use of Research Results

5.2 How do parks learn of potential commercial use of research results?

Most often, as required in the permit, CSTA, loan agreement, or MTA, the researcher will directly notify the park of a potential commercial use by phone, email, or in the Investigator's Annual Report (IAR). Sometimes park employees who are diligent in monitoring reports, publications, the press, and other communications in the relevant research community will learn of imminent commercialization from an indirect source. Always confirm with the researcher any information from indirect sources.

Once you learn about a potential commercial use of research results, refer the researcher or forward the information to the park benefits-sharing coordinator. If you are the park benefits-sharing coordinator, see Sections 5.7 and 6.0 of this guidance to evaluate whether benefits sharing is desirable and, if so, which benefits-sharing agreement would be appropriate.

5.3 What should a park do when a researcher applies for a patent involving research results originating from a specimen collected in a park?

The park does not need to take any specific action when a researcher applies for a patent involving research results originating from a specimen collected in a park, *unless* the United States Patent and Trademark Office (USPTO) requires the applicant to deposit (in a culture collection or other repository) Material, such as microbes. (This deposit is called a "patent deposit.") A researcher who needs to make a patent deposit should contact the park permit coordinator or the park living collections curator. The park living collections curator coordinates the deposit and notifies the WASO Benefits-Sharing Coordinator, who can also provide assistance in facilitating the deposit.

Inventions derived from research results originating from a specimen collected in a park may be patented in the United States and/or in other countries. In the United States, a patent is an

intellectual property right that the federal government grants to an inventor "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited time in exchange for public disclosure of the invention when the patent is granted. Any new, useful, and non-obvious discovery or invention that satisfies applicable statutory requirements may be patented. Collected specimens are natural products and cannot be patented—only inventions may be patented.

CSTAs and MTAs require the recipient to notify NPS within thirty (30) days of filing an application for a patent. Nevertheless, the park benefits-sharing coordinator should monitor the USPTO web site at <u>http://www.uspto.gov/patents/process/search/index.jsp</u> to spot relevant applications and patents that may not have been reported and to track the status of known applications or patents.

The USPTO grants patents to inventors, who may assign the patent rights to their institutions or other entities. The owner of patent rights controls who uses the invention. Institutions generally require or encourage employees and associated researchers to disclose their inventions and discoveries to the institution and assign any patent rights to the institution. Institutions also have the option of waiving the patent rights in favor of the employee inventor.

A patent application or a patent does not necessarily mean that commercialization will occur. Patent activity does not necessarily trigger initiation of benefits-sharing negotiations, but it does suggest that the park should be alert to possible future commercial use. Patents have no effect on the ownership of the park collected specimen or anything in the park.

5.3.1 How does a park living collections curator authorize a biological Material patent deposit?

For patents involving biological Material, including microbial Material, USPTO requires deposit of a sample of the Material in an approved depository. Such biological Material includes Material that is capable of self-replication (directly or indirectly), for example bacteria, fungi, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living Material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living Material.

If the researcher needs to deposit biological Material in an approved depository (repository) as part of the patent application process, a customized NPS living collection loan agreement (repository agreement) is necessary (see Section 4.1.4 Loan Agreements). The park living collections curator notifies and involves the WASO Benefits-Sharing Coordinator for all patent deposits.

A patent deposit generally follows these steps (procedures may vary slightly by repository):

• NPS establishes an agreement with a repository that will accept NPS loans for the purpose of a patent deposit. Consult with the WASO Benefits-Sharing Coordinator for assistance as NPS may already have a Servicewide agreement with the repository. The park living collections curator works with the researcher to accession and catalog the Material in the park living collection.

- The park superintendent sends a letter to the researcher with instructions to provide the following source information on the repository's deposit form (for example, the Budapest Treaty Deposit Form):
 - o "National Park Service"
 - Name of the park
 - NPS permit number
 - NPS living collection item catalog number
- The researcher submits the form and the NPS Material to the repository with a copy to the park living collections curator.
- Park living collections curator completes a living collection loan record for the deposit so that the Material may be tracked as a loan. Note: Because the repository has a customized repository loan agreement with NPS, the repository does not sign the loan agreement that NPS generates specifically for the deposit. Instead, cite the repository agreement in the signature block of the loan agreement.
- Repository periodically tests viability of the deposit. If the deposit is not viable, and no additional Material is available, NPS directs the repository to dispose of the living collection item and deaccessions it.

Requirements for public availability of patent deposits are determined by the rules in the country in which the patent application is filed. In the United States, generally the Material is distributed freely without NPS restrictions during the time a patent is in effect.

For a researcher, a patent may represent the culmination of years of research and the first public announcement of an invention. NPS needs to facilitate expeditious patent deposits.

NOTE! The USPTO decides which culture collections (repositories) may receive patent deposits in the United States. The USPTO follows the requirements of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. Deposits made according to these requirements are internationally recognized. The inventor may apply for a patent in one or more countries.

5.4 What should a park do when research results developed under a park research permit are to be licensed?

Patent holders license (allow) other parties to use their patented invention or discovery, usually in return for a fee or royalty payment. Licensing generally occurs because the licensee envisions a commercial use for the invention. (Note: See Section 7.5 for examples of when NPS may hold rights to a patent.)

Licensing generally triggers NPS benefits-sharing negotiations because commercialization is involved. If you learn about a license involving research results, you should immediately contact the WASO Benefits-Sharing Coordinator, who will help the park develop an agreement to share or decline benefits with appropriate terms and conditions.

NPS becomes involved in licensing activities either directly or indirectly, as follows:

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- Direct involvement—NPS holds rights to a patent and licenses another party to use the patented invention or discovery. (If the NPS inventor was a co-inventor with a non-NPS party, the rights are shared between the co-inventors. If another federal agency transfers a partial interest in a federally owned invention to NPS, NPS would share rights with the other federal agency.)
- Indirect involvement—A permittee or researcher, or the researcher's institution, holds a patent that is subject to NPS permit, loan agreement, or MTA terms and conditions and proposes to license a third party to use the patented invention. As part of negotiated benefits, a researcher patentee could name NPS in a license agreement with a third party. NPS might then receive benefits, such as milestone payments or royalties, directly from the third party.

5.4.1 How does a park determine appropriate compensation for benefits sharing involving a license?

In determining a reasonable compensation figure, either for a license that NPS issues directly or for benefits that would accrue to NPS as a result of a permittee or researcher licensing use of NPS Material and/or research results, NPS considers:

- Type of license being granted
 - Non-exclusive—allows the licensor to grant the same rights to other licensees; licenses are non-exclusive by default.
 - Exclusive—prohibits the licensor from granting the same rights to other licensees within defined geographic areas, media, languages, or industries, or combination of these parameters.
- Investment of the NPS, any non-NPS inventor(s), and the licensee.
- Associated risks in commercializing the invention.
- Market sector for the invention.
- Potential value of the anticipated products.

See Section 6.0 for further information on negotiating benefits. Only a park designated as a federal laboratory has authority to retain income from licensing.

5.5 Do copyright and trademarks have any relevance for NPS benefits sharing?

Yes. Copyrights provide legal protection for works of authorship that are produced in tangible expressions, such as writings, paintings, movies, sculpture, and computer software. Although government employees may not copyright their own works prepared as part of their official duties, NPS may acquire copyright or licenses to use works produced by others. NPS may acquire copyright as part of negotiated benefits and thereafter license the same to other entities. NPS will most likely learn of copyrights relative to a particular invention and their potential usefulness to NPS as part of benefits-sharing negotiation.

In acquiring documents as a condition of a permit or under negotiated benefits, NPS should obtain either copyright to the documents or the right to copy and publish them. Rights and permissions must be documented in writing. For further information on NPS acquisition and

management of copyrights see *NPS Museum Handbook, Part II*, Chapter 2, Section E. Acquiring Copyrights, and Part III, Chapter 2: Legal Issues at

<u>http://www.nps.gov/history/museum/publications/handbook.html</u>. To search for registered copyrights, see <u>http://www.copyright.gov/records/</u>.

Trademarks protect any word, symbol, or combination thereof that is used on goods to indicate their source. The owner of a trademark can exclude others from using a similar mark on similar goods that would be likely to confuse consumers as to the source of the goods. For example, NPS has a trademark for the NPS Arrowhead. When NPS is not directly involved in research but the researcher has a benefits-sharing agreement with NPS then, under that agreement, NPS may acquire a trademark to a product, license to use a trademark, and/or the right to license others to use the trademark.

See Table 5 for examples of copyright and trademarks. Information on searching trademarks is available at <u>http://www.uspto.gov/main/profiles/acadres.htm</u>.

	Examples of Copyright and Trademarks
Copyright	A permitted researcher collects a water sample from a thermal pool, isolates a new enzyme, and creates a digital image of it. The researcher notifies NPS that this enzyme has potential commercial use for production of biofuels. As part of benefits-sharing negotiations, NPS does not obtain the copyright but gets unlimited right to use the image for NPS scientific and educational purposes.
Trademark	Under a Cooperative Research and Development Agreement (CRADA), an NPS historic preservation laboratory is co-inventor of a substance to consolidate stone. Under the terms of the agreement, if the product goes to market, the parties will trademark it and jointly license use of the trademark to manufacturers.

Table 5: Examples of Copyright and Trademarks

5.6 Does a researcher's use of traditional knowledge trigger benefits-sharing considerations?

Yes. In the event that the commercial application of research results uses traditional knowledge from groups traditionally associated with the park and/or with the resources under study, the researcher (including an NPS researcher) is responsible for engaging such individuals or groups in any benefits-sharing negotiations. See Appendix B: Glossary, for definition of traditional knowledge.

The World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore provides information on traditional knowledge, intellectual property, access to genetic resources, and benefits sharing. See <u>http://www.wipo.int/tk/en/</u>.

5.7 How should the park respond when research results could be commercialized?

Once the park learns of imminent commercialization, the park must decide whether to seek benefits and the type of agreement to use. Make this decision on a case-by-case basis using economic forecasting and other information to assess relative levels of foreseeable:

- Administrative costs
- Monetary benefits
- Non-monetary benefits
- Other relevant factors

The flow chart in Figure 2 explains this decision-making process.

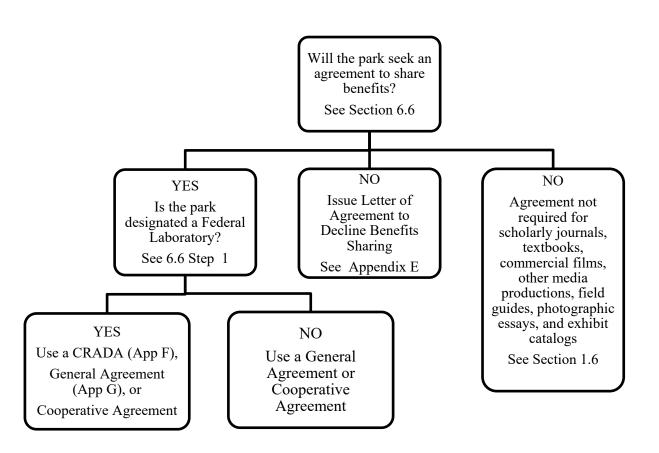


Figure 2: Decision Making Process for Benefits Sharing

5.8 Whom should a park contact for technical assistance when making decisions about benefits sharing?

The park may contact the WASO Benefits-Sharing Coordinator, who will work with the park to identify technical assistance sources and contacts based on the identified need. Parks, regions, and Washington offices with specialized benefits-sharing expertise will be available, as resources

allow, to park superintendents and others upon request to provide technical assistance with benefits sharing. Such expertise may be provided on a case-by-case basis depending on the nature and duration of technical assistance for each request.

Also see informational and training resources in Section 15.0 and Appendix D.

5.9 What should a park do if an entity proceeds with commercialization without an agreement to share or decline benefits?

Confirm that commercialization has occurred by contacting the entity that is proceeding with commercialization. If the park confirms that an entity that is obligated (through permit, CSTA, MTA, loan, or other agreement conditions) to enter into a benefits-sharing arrangement with NPS prior to commercialization of research results has, in fact, commercialized research results, the park will offer that entity an opportunity to correct its deficiency.

If the other party wishes to correct its deficiency, then the superintendent, in consultation with the WASO Benefits-Sharing Coordinator and the DOI Office of the Solicitor, must immediately send a letter of agreement that the other party counter signs stating that the other party

- a. is in breach of the cited agreement(s) (such as the permit, CSTA, MTA or loan);
- b. will agree to seek an agreement to share benefits as a remedy;
- c. will pay NPS 20% of gross revenues received prior to the execution date of this letter of agreement and will make the payment within sixty (60) days of such execution;
- d. will cease further commercialization until an agreement that NPS will share or decline benefits is in force, or will continue to pay NPS 20% of gross revenues following the date of execution of the letter of agreement on a schedule that NPS sets (generally annually on October 1) until the required agreement in which NPS shares or declines benefits is in force;
- e. acknowledges that the letter of agreement does not constitute the required agreement in which NPS shares or declines benefits; and
- f. acknowledges that NPS may seek other damages, including but not limited to injunctive relief, if the other party does not meet the terms of this agreement.

After the relevant letter of agreement is signed by all parties, the park should immediately begin the process of negotiating an agreement to share or decline benefits (see Section 6.0).

If the other party does not seek a remedy by negotiating the required agreement in which NPS shares or declines benefits, the superintendent, in consultation with the WASO Benefits-Sharing Coordinator and the DOI Office of the Solicitor, must send a letter to the other party stating that the other party

- a. is in breach of the cited agreement(s), and
- b. must pay NPS 20% of past and future gross revenues on a schedule that NPS establishes (generally annually on October1) until such time as the required agreement in which NPS shares or declines benefits may be executed.

The letter will also state that NPS may seek other damages, including but not limited to injunctive relief.

The superintendent will provide copies of such letters to the regional director, Associate Director, NRSS, other WASO associate directors as appropriate, the WASO Benefits-Sharing Coordinator, and the Office of the Solicitor. On a case-by-case basis, the Office of the Solicitor will provide guidance on further actions.

6.0 How to Enter into Agreements to Share or Decline Benefits

This section addresses agreements to share benefits in 6.1-6.4 and agreements to decline benefits in 6.5. Procedures to establish all agreements are in 6.6.

NOTE! Upon notification of planned commercial use for research results, NPS must develop an agreement to share or decline benefits, except as noted in Section 1.6 regarding commercial applications for certain educational products. In situations where NPS learns of planned commercial use for research results from sources other than the permittee, see Section 5.2.

6.1 If a park decides to seek benefits, what kinds of agreements should be used?

Three primary agreement instruments are available for parks to implement benefits sharing:

- Cooperative Research and Development Agreement (CRADA)
- General Agreement
- Cooperative Agreement

Other agreement types may also apply in certain circumstances. Consult with the WASO Benefits-Sharing Coordinator before selecting other types of agreements.

The factors to help choose the appropriate agreement type to use are described below, followed by Table 6, which highlights their characteristics and differences. Together, these different descriptions should help you decide which agreement type is best for the specific commercialization effort and the park. Parks may contact the WASO Benefits-Sharing Coordinator for help at any point in the benefits-sharing process.

In order to retain monetary benefits, parks that are eligible usually will choose a CRADA as authorized under the Federal Technology Transfer Act (FTTA) because the CRADA offers the broadest authority to retain monetary benefits; however, NPS may also retain monetary benefits under a Cooperative Agreement that uses the authority of 54 USC 101702 regarding cooperative research with a public or private educational institution, state, or a political subdivision of a state. Under a General Agreement, monetary benefits must go to the U.S. Treasury. NPS receives the funds and deposits them in the U.S. Treasury.

NPS may receive and provide non-monetary benefits under all agreement types. Agreement types that allow monetary benefits may also be used for solely non-monetary benefits.

Under a CRADA, the park may provide personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement but may not provide funds to the non-federal partner. CRADAs may also be used for traditional technology transfer if a park employee scientist works closely with another institution on a mutual research goal (see Section 7.4). A park may use a CRADA for benefits sharing only if the NPS Director has determined that the park is a federal laboratory as defined by the FTTA.

A Cooperative Agreement may be used if a park expects to have substantial involvement in a research project with potential to develop a commercial use that qualifies as a public purpose. Cooperative Agreements will likely be the least-used agreement type for benefits sharing because commercial uses for research results most commonly arise from independent studies authorized by park research permits rather than cooperative projects.

A General Agreement may be used when the park is not designated as a federal laboratory and the park does not anticipate substantial involvement.

If you begin negotiating one type of agreement and then determine that the situation warrants another type of agreement, you may switch agreement types and apply the information already gathered to the process for the new agreement type. In addition, after operating under one agreement type for a period of time, the parties may decide to negotiate new terms using a different agreement type. Because circumstances change, parties generally make multiple amendments or even use a different instrument during the life of a project. Use Table 6 to evaluate the various agreement types and their characteristics.

	Selected Characteristics of Agreements				
Agreement Type	Cautions	NPS may partner with	Who may provide non- monetary benefits?	Who may receive monetary benefits from the other party?	What does NPS contribute?
CRADA	Park must be deemed a federal laboratory.	Any non-federal institution or organization. Note: Other federal agencies may participate but cannot provide monetary benefits.	NPS and other parties	NPS may receive monetary benefits from non-federal partners	NPS should commit to facilitate current or future research efforts
General Agreement	Several types of General Agreements exist. For benefits	Federal and non- federal entities (institutions and	NPS and other parties; NPS may request reimbursement for supplies and	If the other party is non- federal, the U.S. Treasury benefits. (NPS	As mutually agreed by the parties

Table 6: Selected Characteristics of Agreements

Selected Characteristics of Agreements					
Agreement Type	Cautions	NPS may partner with	Who may provide non- monetary benefits?	Who may receive monetary benefits from the other party?	What does NPS contribute?
	sharing, use the template in Appendix G.	organizations, not individuals).	rental equipment provided to federal and non-federal entities (54 USC 100901).	receives the funds and deposits them in the U.S. Treasury.) Federal entities may not provide monetary benefits to NPS, but may grant interests in inventions leading to monetary benefit from separate licensing. Only parks designated as federal laboratories could retain the monetary benefit.	
Cooperative Agreement	Cannot be used with a for-profit institution, with an individual, or with another federal agency. The project must have a public purpose above and beyond fulfilling an NPS Mission. The agreement must have a certified Agreements	Public or private educational institutions, states, and their political subdivisions.	Both parties.	Both parties, based on 54 USC 101702.	NPS must have substantial involvement in th project by law.

Selected Characteristics of Agreements					
Agreement Type	Cautions	NPS may partner with	Who may provide non- monetary benefits?	Who may receive monetary benefits from the other party?	What does NPS contribute?
	Technical Representative. The park must work through its contracting officer.				

NOTE! Any agreement may identify NPS actions to provide operational support or participate in the work. Any such actions that may impact the environment are subject to compliance with applicable laws and regulations, including the National Environmental Policy Act (NEPA). This compliance may occur before or after signing the agreement. If compliance occurs after signing the agreement, then the agreement must state that NPS performance is subject to such future compliance.

6.1.1 May NPS have an arrangement with an outside party to assist with benefits-sharing negotiations?

Yes. On a park or Servicewide basis, NPS may enter into an agreement with another agency or a contract with a non-federal entity to provide consultation services as part of agreement negotiations. NPS must, however, have oversight for the negotiations, remain involved in the negotiation, make all decisions, and be the approving authority for the negotiated agreement. For example, NPS may contract with a culture collection that maintains NPS Material to provide market research and advise on CRADA negotiations involving commercial uses of that Material.

6.2 What is a Cooperative Research and Development Agreement (CRADA)?

A CRADA is "any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory..." (15 USC 3710a(d)(1)) (see Appendix F for NPS CRADA template). A CRADA is not a federal contract, grant or Cooperative Agreement (as defined in 31 USC 6303 *et seq.*).

6.2.1 When should I use a CRADA for benefits sharing?

You may use a CRADA for benefits sharing if the Director has determined in writing that your park is a "federal laboratory" and your park wants to receive monetary benefits and/or non-monetary benefits and keep any monetary benefits.

6.2.2 Who may enter into a benefits-sharing CRADA with NPS?

Virtually any organization may enter into a CRADA with NPS, including federal, state and local governments, universities, and the private sector, but each CRADA must involve at least one non-federal partner (15 USC 3710a(a)(1)).

6.2.3 Since a benefits-sharing CRADA is for "cooperative research" between a researcher and a federal laboratory, what cooperation does NPS provide?

Parks determined to be federal laboratories may contribute personnel, equipment, facilities, services, and intellectual property to the non-federal partner. Parks that permit researchers under the Scientific Research and Collecting Permit often contribute personnel, facilities, and services when providing the permittee with access to the park's resources. Park facilities may include, but are not limited to, built research centers, roads and other infrastructure that provide access to, protection of, or data about research sites; virtual (for example, web-based) research centers, collections management facilities and databases, geographic information systems (GIS) facilities, remote sensing facilities maintaining environmental data from satellites and aircraft, and inventory and monitoring databases. Parks preserve the resources and values of protected areas that are the source of unique research opportunities. NPS cooperation under a CRADA may not involve providing funds directly or indirectly to the non-federal party. For example, the NPS may not accept from the non-federal partner proprietary software when that acceptance would indirectly obligate NPS to pay a software maintenance fee to the partner.

6.2.4 What types of resources may CRADA partners contribute to NPS?

The cooperating partner may agree, in the benefits-sharing CRADA, to provide funds, personnel, services, facilities, equipment and/or other resources for the conservation of resources protected and managed by the NPS.

6.3 What is a General Agreement for Benefits Sharing?

A General Agreement for Benefits Sharing documents a wide range of mutually agreed-to policies, procedures, objectives, understandings and/or relationships between the NPS and non-federal parties (institutions and organizations, not individuals), and between NPS and other federal agencies. A General Agreement for Benefits Sharing provides for non-monetary benefits that can be shared between the parties. In addition, non-federal parties may provide monetary benefits that the NPS receives and deposits in the U.S. Treasury, and federal parties may grant interests in inventions to NPS, leading to income to NPS from separately negotiated licenses

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with third parties. For a complete description of General Agreements, see *Director's Order (DO)* #20: Agreements (https://npspolicy.nps.gov/DOrders.cfm).

6.3.1 When and how should the park use a General Agreement for Benefits Sharing?

All parks may use the General Agreement for Benefits Sharing, regardless of whether they have been determined to be federal laboratories. Under a General Agreement for Benefits Sharing, the NPS may receive non-monetary benefits from the other party. NPS may provide non-monetary benefits and may furnish supplies and rental equipment on a reimbursable basis pursuant to 54 USC 100901. NPS may use a General Agreement to arrange for a non-federal partner to pay the negotiated monetary benefits to NPS, which deposits the funds in the U.S. Treasury. In addition, if the other party is federal, it may grant to NPS right, title, or interest in its federally owned invention (35 USC 207) (a non-monetary benefit), which entitles the park to seek monetary benefits from separately negotiated licenses with third parties (35 USC 209). Such monetary benefits that NPS receives must be deposited in the U.S. Treasury. (See 5.4.1.)

A General Agreement for benefits sharing should be entitled "General Agreement for Benefits Sharing" to help distinguish it from other General Agreements. See the template in Appendix G.

6.3.2 Who may enter into a General Agreement for Benefits Sharing with NPS?

Federal and non-federal entities (institutions and organizations, not individuals) may enter into a General Agreement for Benefits Sharing with the NPS.

6.3.3 How should the park enter into a General Agreement for Benefits Sharing?

The park should follow the steps for developing a benefits-sharing agreement in Section 6.6, but skip those steps that apply only to CRADAs or Cooperative Agreements.

6.4 What is a Cooperative Agreement for Benefits Sharing?

A Cooperative Agreement for Benefits Sharing, under the authority of,54 USC 101702 is a legal instrument that establishes a relationship between NPS and public or private educational institutions, states, and their political subdivisions, when, as required by law, the NPS will have substantial involvement in cooperative research (which may involve training) concerning NPS resources and the cooperative effort has a public purpose. Cooperative Agreements are described in detail in the NPS *Agreements Handbook*. Whereas under a General Agreement, NPS provides exclusively non-monetary contributions, under a Cooperative Agreement NPS may provide and receive monetary and non-monetary benefits and must be substantially involved.

NOTE! 54 USC 101702 provides authority for Cooperative Agreements as follows: *"The Secretary may...*

(j) Cooperative research and training programs. Enter into cooperative agreements with public or private educational institutions, States, and their political subdivisions, for the purpose of developing adequate, coordinated, cooperative research and training programs concerning the resources of the National Park System, and, pursuant to any such agreements, to accept from and make available to the cooperator such technical and support staff, financial assistance for mutually agreed upon research projects, supplies and equipment, facilities, and administrative services relating to cooperative research units as the Secretary deems appropriate; except that this paragraph shall not waive any requirements for research projects that are subject to the Federal procurement regulations."

6.4.1 When and how should I use a Cooperative Agreement for Benefits Sharing?

Under the provisions of 54 USC 101702, NPS may use a Cooperative Agreement for Benefits Sharing when NPS receives from or provides to a cooperator a monetary benefit (money and/or property, services with an assigned monetary value, or anything else of monetary value) and has substantial involvement in the project, which must have a public purpose. Although most benefits-sharing Cooperative Agreements will fall under the provisions of 54 USC 101702, other cooperative agreement authorities may apply in certain circumstances for receipt of non-monetary benefits but do not allow NPS to receive monetary benefits. Consult the WASO Benefits-Sharing Coordinator.

6.4.2 Who may enter into a benefits-sharing Cooperative Agreement with NPS?

Under 54 USC 101702, cooperators must be public or private educational institutions, states, and their political subdivisions. Under other cooperative agreement authorities, additional non-governmental organizations may be cooperators.

6.4.3 Since a Cooperative Agreement for Benefits Sharing requires "substantial involvement" by the NPS, what involvement does NPS provide?

Examples of NPS substantial involvement include NPS involvement in program management decisions, NPS collaboration in the accomplishment of the activity, or NPS operational involvement or participation during the project. The NPS *Agreements Handbook* provides additional guidance on determining substantial involvement.

6.4.4 What benefits may be exchanged in a Cooperative Agreement for Benefits Sharing?

Under a benefits-sharing Cooperative Agreement, as authorized by 54 USC 101702, NPS may provide and receive monetary and non-monetary benefits.

6.4.5 How does a park enter into a Cooperative Agreement for Benefits Sharing?

The park's Benefits-Sharing Coordinator should first contact the park's servicing contracting office to explain the decision to enter into a Cooperative Agreement for Benefits Sharing and to gain input about the necessary NPS substantial involvement and the public purpose of the project. Entering into a Cooperative Agreement for Benefits Sharing requires significant involvement of personnel with specific training for Cooperative Agreements.

The park should generally follow the steps for developing a benefits-sharing agreement in Section 6.6, but skip those steps that apply only to CRADAs or General Agreements and integrate the steps with the requirements for Cooperative Agreements as outlined in *DO #20: Agreements* and the *Agreements Handbook*, Chapter 4, Cooperative Agreements. In the event of a conflict between the steps in this guidance and the instructions on Cooperative Agreements in the *Agreements Handbook*, follow the *Agreements Handbook* available at https://npspolicy.nps.gov/DOrders.cfm. Cooperative Agreements generally do not exceed five years, but are renewable.

6.5 What should a park do if it decides not to seek benefits?

When, after careful consideration, the park decides to decline benefits sharing, the park must draft a letter of agreement, or other agreement, signed by the parties wherein the park declines to share in benefits and states any other terms and conditions that may apply. Parks may decline benefits sharing based on technical and/or economic reasons, not on an opinion as to whether the commercial activity should occur. If technical and economic reasons to decline benefit sharing do not apply, the Associate Director, Natural Resource Stewardship and Science (NRSS), in consultation with the Regional Director, may approve other reasons on a case-by-case basis.

Upon deciding not to seek benefits, the park superintendent develops an agreement to decline benefits by following Steps 2-4, 9 and 10 in Section 6.6. The agreement includes both a statement declining to share in any benefits that might result from the proposed commercialization and also appropriate terms and conditions. The terms and conditions explicitly state that the other party must return to the park for a separate agreement if commercialization beyond that described in the current agreement is later proposed. The agreement must be signed by both parties. The example letter of agreement in Appendix E contains a model statement declining to share benefits and typical terms and conditions for such an agreement.

6.6 How does my park enter into an agreement to share or decline benefits?

The following steps show the process of developing agreements to share or decline benefits.

Use CRADAs, General Agreements, and Cooperative Agreements to share benefits.

Some steps apply to only certain agreement types and are so marked. In addition, for Cooperative Agreements also use the *Agreements Handbook*, which takes priority over this guidance in the case of conflict.

To decline to share benefits, use a Letter of Agreement to Decline Benefits Sharing (see Appendix E) or equivalent document and follow Steps 2-4, 9 and 10 only.

The park may start the agreement process intending to share or to decline benefits and later switch to the other option. In any case, the park must make sure that it has completed and documented the steps required for the ultimate agreement type.

The following steps may happen sequentially or simultaneously.

Step 1: Obtain the NPS Director's designation of the park as a federal laboratory. (CRADA only)

The term "federal laboratory" means "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(d)(2)(A)). Units of the National Park System that satisfy the FTTA definition of a "federal laboratory" are eligible to enter into CRADAs as a benefits-sharing arrangement. If a park does not satisfy the FTTA definition of a "federal laboratory," that park will not be able to use a CRADA; instead it should use a General Agreement or a Cooperative Agreement as the benefits-sharing instrument.

The superintendent should submit a Request for Designation as a Federal Laboratory through the regional director for the Director's signature. The superintendent will collaborate with the WASO Benefits-Sharing Coordinator who will review the justification and make any suggestions for clarification. In the justification, explain how the performance of research is a substantial purpose of the park by succinctly providing the following information:

- 1. Describe the park's research function as found in the park mission statement. (Cite the document where this mission statement is found.)
- 2. List the park's research facilities. (See description of facilities in Section 6.2.3 for guidance.)
- 3. Summarize the scientific research occurring at the park by park employees and others. Include number of research studies by each group over prior three years. Include Cooperative Ecosystem Studies Unit (CESU) research in the park, Inventory and Monitoring (I & M) Network activities, issuance of Scientific Research and Collecting Permits and other research permits, and all other research. Separately state how many NPS employees and non-NPS scientists are doing inventory, monitoring, and research in the park.

Follow the format of the example justification in Appendix H. Contact the WASO Benefits-Sharing Coordinator if you have questions about the justification. **NOTE!** Designation of a park as a federal laboratory triggers certain FTTA requirements. Per 15 USC 3710(a), the NPS complies with those requirements as consistent with the NPS mission. These requirements are explained throughout this document. See Section 10.0 for reporting requirements. The FTTA requires the DOI to make sufficient funding available to support the technology transfer function at the agency and its laboratories.

Step 2: Notify upper NPS management of the park's intent to develop an agreement to share or decline benefits.

The superintendent must send written notification of the park's intent to enter into an agreement to share or decline benefits to the regional director, the Associate Director, NRSS, other associate directors as appropriate, and the WASO Benefits-Sharing Coordinator. Include the following information:

- 1. Names of institution and researcher/inventor planning the proposed commercial use.
- 2. Brief description of the proposed commercial use, while excluding proprietary and confidential information.
- 3. Identification of permit (number and study title, parties involved), CSTAs and MTAs (provide a description of the collected specimens for a CSTA and the Material for an MTA, CSTA/MTA number, parties involved, and date), loan agreement (number, description, parties involved, date) obligating the researcher to notify NPS of a potential commercial use, if applicable.
- 4. Justification for choice of proposed agreement type. Reference the anticipated benefits that each party will provide, unless the park is declining to share in benefits.
- 5. Identification of park benefits-sharing coordinator.

Compiling all of these documents together, at the beginning of the process, is critical for consistency among these documents and the eventual agreement. Working together, the park and the WASO Benefits-Sharing Coordinator should establish the park decision file for the agreement and assign an agreement number. For example, PARK-2014-1.0 would be the assigned number for a park's first agreement in 2014. (See Section 8.4.)

Step 3: Form a negotiating team.

The negotiating team researches decisions on whether to share or decline benefits, recommends appropriate agreement types, and negotiates agreements.

For each proposed agreement, the superintendent forms the negotiating team, which must include one or more WASO members and an attorney advisor of the DOI Office of the Solicitor. The superintendent will consult with the WASO Benefits-Sharing Coordinator regarding the nonpark members. The superintendent also names a team lead, and appoints advisors as appropriate. The team lead may be from a park, region, or WASO program office, but should possess the knowledge, skill, and time to handle the complex task of negotiations. In order to maintain a "firewall" between research permit decisions and benefits sharing, the park research permit coordinator must not participate in agreement negotiations, either as a team member or as an advisor. The research permit coordinator may provide factual information to the benefits-sharing team.

Step 4: Collect background information.

The park benefits-sharing coordinator assembles and provides to the negotiating team lead the following information in electronic (generally scanned) format, as applicable:

- 1. Copies of research permits, study plans, and annual reports that apply to the research results.
- 2. Copies of NEPA and National Historic Preservation Act (NHPA) Section 106 and any other relevant compliance documentation for the relevant permits.
- 3. Copies of relevant field notes, maps, photographs, and other documentation that the permittee submitted in compliance with a condition of the permit or voluntarily.
- 4. Copies of correspondence; notes; publications; notifications regarding patent applications, invention disclosures, and potential commercial use of research results; and other relevant documentation from the applicable study and other files.
- 5. Copies of applicable CSTAs, loan agreements, culture collection documents, and MTAs and a compiled list showing current locations of collected specimens, museum specimens, living collection items, and Material. For each item, provide contact information for the permittee or institution with custody.
- 6. Clearly identify any documents that the other party has marked in writing as confidential or proprietary.
- 7. Current contact information for the researcher and the point of contact in the researcher's institution responsible for benefits-sharing negotiations. The institutional contact is generally in the institution's technology development/transfer office.
- 8. Public record of any patents or patent applications resulting from disclosure of this researcher's technology.
- 9. Relevant information obtained from the researcher's web site or the researcher's institution's web site. Any other available and relevant background information, such as documentation on similar inventions, markets, or research efforts.
- 10. Other background documentation that the team lead requests.

Step 5: Begin the benefits-sharing negotiation process.

The following tasks may occur sequentially or simultaneously. Keep a written record of all negotiation activities (see Section 8.4 for more information on decision files).

Step 5a: Initiate a dialog with the other party.

The team lead should initiate the first face-to-face or conference-call meeting between the two parties. After this initial meeting, NPS team member involvement in dialogues between the two parties will occur as directed by the negotiating team lead.

Goals of the initial meeting are to confirm mutual interest in developing an agreement, share expectations regarding outcome and time frame for negotiations, understand roles and responsibilities of both parties and their team members, explore the kinds of benefits that could materialize, and facilitate exchange of documents that may inform the agreement development process.

Examples of useful documentation that NPS might request include:

- Market analysis
- Business plan
- Revenue analysis
- Development analysis
- Marketing plan

NOTE! Negotiate each benefits-sharing agreement on a case-by-case basis, taking into account the relative importance of the NPS collected specimen and related contributions to the research and development for the technology. Approach the negotiations as a collaborative and interactive process that results in a fair agreement for both parties.

Step 5b: Complete market research.

The team should consult with an NPS economist or may contract with an outside economist to provide market research, as needed.

In determining a reasonable negotiating position for benefits that would accrue to NPS as a result of a benefits-sharing partner commercializing its technology, NPS considers:

- Investment of the NPS, the non-NPS inventor(s), and any licensees
- Associated risks in commercializing the invention
- Market sector for the invention
- Potential value of the anticipated products

Step 5c: Identify desired monetary benefits. (If seeking only non-monetary benefits, proceed to Step 5d.)

There are several kinds of monetary payments that the NPS could seek in a benefits-sharing agreement. These include, but are not limited to, an upfront payment, an annual maintenance payment, and performance-based payments. Contact the WASO Benefits-Sharing Coordinator for assistance in setting upfront and annual maintenance payments. A performance-based payment is based on income from the product that is produced and sold, on the relative

contributions towards commercialization by the parties to the agreement, on the general cost of bringing the new technology into the specific market sector, and on available information about worldwide practices. For example, commercialization of a new industrial enzyme might result in a higher performance-based payment rate to NPS than commercialization of a new medicine because usually the cost of research and development is substantially lower for an enzyme than for a medicine, which would make the NPS contribution a greater proportion of the overall effort to bring the enzyme to market.

Seek a fair benefit. Avoid overwhelming the partner with benefit requirements that may contribute to failure of the commercialization effort.

NOTE! These same monetary payment types apply to licenses that NPS may negotiate, separate from a benefits-sharing agreement, based on its right, title, or interest in a federally owned invention. NPS may issue licenses pursuant to 35 USC 207 and 209. The FTTA allows an NPS federal laboratory to retain funds received from licensing; parks that are not designated federal laboratories may not retain such funds. (See 5.4.1 and 7.6.)

These payments types are described in Table 7.

Payment Types				
Туре	Description	Advantages	Challenges	
Upfront Payment	A one-time payment made right after the agreement is signed.	An upfront payment can be considered as assurance that the partner takes the commercialization effort seriously.	As the NPS gains benefits-sharing experience, a suitable range of up-front payment levels will be developed.	
Annual Maintenance Payment	A payment due once every year that the agreement is active.	Use of this payment type makes sure that both parties will pay attention to the agreement and its obligations.	In some cases, NPS might find that administering a small annual payment could be cumbersome.	
Performance-based Payments	Most often, performance-based payments are defined as a percent of the revenue stream from the commercialization of the product.	This payment provides a fair return to the NPS with regard to the income enjoyed by the commercial entity.	This payment obligation must be fair to both parties. If the company has no revenue, it will make no performance-based payments. As the NPS gains benefits-sharing experience with benefits-sharing agreements, a suitable	

Table 7: Payment Types

Payment Types				
Туре	Description	Advantages	Challenges	
			range of payment levels will be	
			developed.	
Milestone payments	A payment that occurs at a defined stage of research and development—not calendar-based	Non-NPS party can predict timing of obligations as development occurs	Delays in meeting milestone will delay benefits to NPS	

As the NPS gains experience in benefits sharing, other types of payments may be identified. See examples of these monetary payment types in Table 8.

Table 8: Examples of Monetary Benefits

	Examples of Monetary Benefits		
Upfront Payment	In a CRADA between a park and Company X selling industrial enzymes, the company agrees to provide an upfront payment of \$50,000, payable in 5 yearly installments of \$10,000, to be offset against any future performance-based payments received by the park under the agreement.		
Annual Maintenance Payment	Company Y pays a set amount annually that may/or may not be off-set by future performance-based payments.		
Performance- based Payment	In a CRADA with Company Z, the performance-based payment is based on stated percentages of gross revenue for different categories of product.		
Milestone payments	A biopharmaceutical company working on developing a vaccine using an enzyme that originated with a park-collected specimen agrees in a CRADA to make specific payments at the conclusion of each development phase as described in a development plan.		
	In exchange for an exclusive license on an invention related to biofuels, Company X provides a park with specified payments as it reaches identified sales milestones (products sold).		
Other	When NPS has a joint interest in a patent that is the subject of a CRADA, the co-owner could pay the full patent maintenance fees.		

Step 5d: Identify desired non-monetary benefits.

As applicable, the negotiating team identifies non-monetary benefits, or contributions, that could be provided by the other party and by NPS. The team should consult with experts in disciplines relevant to the technology involved.

The NPS has identified four types of non-monetary benefits that could be included in benefitssharing agreements: knowledge and research relationships, training and education, researchrelated supplies and equipment, and special services such as laboratory analyses. See examples of these four types of non-monetary benefits in Table 9.

	Examples of Non-Monetary Benefits
Knowledge and research relationships	Intellectual Property (IP)—Another federal agency owns an invention based on research results from NPS-permitted research and grants the park a partial interest in the invention. (A park designated a federal laboratory could receive future monetary benefits from subsequently licensing the IP, jointly with the other agency, to a third party.)
	A company that made an invention based on toxins from ants agrees to participate in the park's ongoing inventory of insects for 6 years.
Training	In a benefits-sharing agreement between a park and a company, the company agrees to train park staff in some molecular biology techniques.
Supplies and equipment	In a benefits-sharing agreement between a park and a company, the company agrees to give the park DNA extraction kits and DNA "primers."
Special services	A company that invented an ungulate disease vaccine, in part by studying NPS Material, agrees to administer the vaccine to the historic park's diseased goat population and monitor the animals for two years.

Table 9: Examples of Non-Monetary Benefits

Step 5e: Develop the Term Sheet.

The negotiating team develops a draft Term Sheet to represent the NPS's initial negotiation position. The draft Term Sheet is a document that lists in a table or bullet-point format proposed principal terms for an agreement that is to be negotiated. Upon upper management's approval of the proposed NPS terms, the park will present the Term Sheet to its benefits-sharing partner to initiate negotiations.

Use of a Term Sheet speeds the negotiations process by focusing the initial negotiations on the fundamental aspects of the project. Term Sheets may include, for example:

• Purpose of the benefits-sharing agreement

- Proposed collaborative research activities
- Commercial use of the research results
- Current status of Material originating as a collected specimen
- Current status of licenses and research and development
- Parties to benefits sharing
- Proposed monetary benefits
- Proposed non-monetary benefits

After developing the draft Term Sheet, the team lead will submit the team's proposed terms, benefits, and negotiation ranges to the superintendent using a draft Request for Approval of Negotiations and Terms. The superintendent reviews and signs the Request for Approval of Negotiations and Terms and sends it through the regional director and, if applicable, to other WASO associate directors with related oversight, for concurrence; and to the Associate Director, NRSS, for approval. Only after receiving approval should the park complete development of the Term Sheet and schedule and initiate negotiations. See Appendix I: Template for a Request for Approval of Negotiations and Terms, and Appendix J: Template for a Term Sheet.

NOTE! *Remember that the Term Sheet is just the NPS starting point and that some of the provisions may change as negotiations lead to a benefits sharing agreement.*

Step 6: Share the Term Sheet with the other party and start negotiating.

After the Associate Director, NRSS, approves the Request for Approval of Negotiations and Terms, the negotiating team lead should complete the Term Sheet to show the proposed benefits, send it to the prospective partner, and initiate negotiations. The negotiating team lead manages the negotiations on behalf of the park, serves as the park point of contact, and makes sure that the remaining team members are involved. Negotiations may be face-to-face, by conference call, or by written correspondence using formal letters or email. The team lead will keep detailed and dated notes on all negotiations.

Negotiations are generally considered confidential. Either party may require both sides to sign confidentiality agreements, as needed. Parks must get approval of the DOI Office of the Solicitor attorney advisor before NPS employees sign any confidentiality agreement.

Step 7. Develop the draft agreement and continue negotiating.

Once the parties agree upon the key provisions of the Term Sheet, the NPS negotiating team should draft an agreement based on the templates in Appendix F (CRADA) or G (General Agreement) or the *Agreements Handbook*, Chapter 4 (Cooperative Agreement), incorporating the provisions of the Term Sheet into the draft agreement. Certain standard wording in the draft agreement must not be changed from the templates in Appendices F and G without prior concurrence of the team's attorney advisor. If you are developing a Cooperative Agreement, refer to example Cooperative Agreements in the *Agreements Handbook* at

<u>https://npspolicy.nps.gov/DOrders.cfm</u> and check all changes to standard wording with the contracting officer.

Share the draft agreement with the partner and continue negotiating the remaining details.

All team members will periodically report to their managers on the status of negotiations. The negotiating team lead should share the agreement with the superintendent, regional director, WASO Benefits-Sharing Coordinator, and appropriate WASO associate directors at critical points during the negotiating process.

The negotiating team lead should make sure that the other party is likewise reporting to its management on the status of negotiations during the negotiating process, to avoid any last-minute delays in signing the final agreement.

Step 8: Comply with NEPA and all other legal mandates.

Both parties must document in writing that the work described under the agreement has been analyzed appropriately and will comply with all legal mandates, including NEPA for NPS.

The following agreement types are federal actions that usually do not have the potential to impact the human environment. Therefore, these actions will usually qualify for a categorical exclusion under the DO #12 Handbook, Section 3.3:

- Agreement to share or decline benefits (categorical exclusion 3.3C),
- CSTA, MTA, loan agreement (categorical exclusion 3.3Y).

Please note however, that if the criteria in Section 3.5 of the DO #12 Handbook apply, or if for any other reason you believe the actions above may have an impact on the human environment, procedures described in the DO #12 Handbook Section 3.2 should be followed.

Projects, activities, or programs proposed to be conducted in connection with a benefits-sharing agreement will receive separate, site-specific environmental review, as appropriate, in compliance with NEPA and other applicable laws.

The agreement does not substitute for NEPA compliance or any other permit or compliance requirements.

Step 9: Seek final review and approval of NPS officials and partner officials.

The negotiating team lead prepares the signature package for final review and approval by NPS officials. The signature package includes two original copies of the agreement to share or decline benefits with all appendices, and a *briefing paper* summarizing:

- The statement of work (omit if declining benefits).
- Benefits [if declining benefits, provide 1) the agreement terms and conditions, and 2) the justification describing the technical and/or economic reasons for the decision or a copy of the written approval from the Associate Director, NRSS, authorizing a reason that is neither technical nor economic].

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- Relationship of the commercial product to the originally collected specimen.
- NEPA compliance documentation for the Agreement and underlying permit(s).
- Other pertinent background information.

All members of the NPS negotiating team and the attorney advisor must surname the signature package as proof of agreement with its terms. The superintendent will sign two copies of the agreement as the approving official followed by concurrence from the regional director, the Associate Director, NRSS, and other applicable associate directors. Original signatures are required on both copies of the agreement. For Cooperative Agreements, follow the approval process in the *Agreements Handbook*, and obtain superintendent approval and upper level management concurrence on a signature page.

The negotiating team lead then sends both copies of the signed agreement, with concurrences, to the other party for approval (without the other documents from the signature package). The other party will sign both copies, keep one original, and return the other to the negotiating team lead. For a Cooperative Agreement, the contracting officer generally conveys the document to the other party.

Step 10: File original agreement in park and distribute copies.

The negotiating team lead will scan the original executed agreement, send the original agreement to the superintendent, and distribute the scanned copies to:

- Office of the Solicitor negotiating team attorney advisor
- Associate Director, NRSS
- WASO Benefits-Sharing Coordinator
- Regional director
- Superintendent
- Park benefits-sharing coordinator
- Other NPS officials named in the agreement, including the park employee delegated responsibility for administration of the agreement, if not the park benefits-sharing coordinator

A statement on the cover of the agreement notifies users regarding any confidentiality requirements (in addition to the agreement term on confidentiality, see Section 13.0).

See Section 8.0 for guidance on tracking agreements and providing and receiving benefits.

For Cooperative Agreements, share copies with the above list, but follow the procedures in the *Agreements Handbook*.

7.0 NPS Research and Technology Transfer in the Context of Benefits Sharing

7.1 What is technology transfer?

Technology Transfer is the process by which technology or knowledge developed in one place is made available for use in another place. Federal technology transfer is the transfer of federally owned or federally originated technology to state and local governments and the private sector.

NPS may, for example, become involved in technology transfer when it 1) enters into a Cooperative Research and Development Agreement (CRADA) to do collaborative research and development and then transfers the developed technology to a non-federal entity for further development and/or use, or 2) holds the rights to license or patent an invention and makes the invention available to the public through the marketplace.

Examples of possible NPS technology transfer projects include collaboration between NPS and a non-federal researcher or company to develop a new substance to preserve stone in historic structures, a more efficient solar collector, or a bear-resistant container.

Technology transfer activities are authorized and described in the Federal Technology Transfer Act of 1986 (FTTA) and related legislation (15 USC 3710). See Section 1.3. See Departmental Manual (DM) at 207 DM 8 for delegations of authority related to technology transfer and 761 DM 1 for policy and standards, requirements and procedures for conducting technology transfer activities.

7.2 Which aspects of NPS benefits sharing overlap with technology transfer?

NPS benefits sharing overlaps with technology transfer when NPS units are determined to be federal laboratories, pursuant to the FTTA. Under the FTTA, federal laboratories are to promote technology transfer consistent with agency missions and NPS may receive benefits from technology transfer activities. The FTTA authorizes CRADAs, which provide the broadest authority for NPS to accept and retain monetary benefits.

7.3 Why should the NPS engage in technology transfer?

Engaging in technology transfer channels the creativity of NPS employees for the public good, while also benefitting NPS and the NPS employee inventor.

7.4 How should an NPS unit initiate technology transfer when it is not triggered by another party's proposed commercialization of research results derived from a collected specimen?

There are two opportunities for NPS to initiate technology transfer. The first opportunity occurs when NPS wishes to embark on collaborative research and development. NPS should enter into a

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CRADA before the project starts. The CRADA describes the collaborative work. For example, NPS could enter into a CRADA that authorizes NPS scientists to work closely with outside researchers to invent a new way to preserve stone cemetery markers. Remember that only NPS units that are federal laboratories may enter into CRADAs. Use the CRADA template in Appendix F.

The second opportunity occurs when NPS holds the rights to an invention and distributes it to the public. NPS may license the invention to a company with the ability to commercialize it, or NPS may place the invention in the public domain.

7.5 When NPS research and development leads to a patent opportunity, who gets the patent rights–NPS or the employee?

If an NPS employee makes a patentable invention or discovery as part of official duties or using information gained through official duties or with a government contribution, such as funds, facilities, equipment, materials, or information, or the time or services of another government employee, the employee may apply as inventor for a patent, but the patent rights would belong to NPS (the "assignee"), unless NPS waives its rights. The DOI Office of the Solicitor makes determinations on rights in inventions. When NPS retains its rights as assignee, NPS is likely to perform the work and pay the fees required for the employee to file the patent application.

In similar circumstances, an NPS employee, working with a non-NPS researcher, may be identified in a patent application as a co-inventor with the non-NPS researcher, but the patent rights of the NPS employee would belong to NPS, unless NPS waives its rights. NPS would hold rights jointly with the other co-inventor(s).

If NPS waives its rights to the patent, NPS would retain the right to freely use the invention for governmental purposes. If the Office of the Solicitor determines that the NPS contribution is insufficient to justify a requirement of assignment of the rights, the NPS inventor may retain all rights.

Any NPS employee who develops an invention may be identified as an inventor in a patent, and may have patent rights as described above; however, an employee inventor in an NPS unit that is a federal laboratory could receive financial benefits even if the patent rights are assigned to NPS. In accordance with the FTTA (15 USC 3710c(a)(1)(A)(i)), when an NPS unit that is determined to be a federal laboratory receives royalties or other payments from the licensing and assignment of inventions under CRADAs, the NPS unit:

- 1. Shall pay each year the first \$2,000, and thereafter at least 15 percent of the royalties or other payments, other than payments of patent costs as delineated by a license or assignment agreement, to the inventor or co-inventors, if the inventor's or co-inventor's rights are assigned to the United States.
- 2. May provide financial incentives from royalties or other payments to park employees who are not the inventor or co-inventor but who substantially increased the technical value of patented research results.

If an NPS employee makes an invention that is unrelated to official duties and does not involve any government contribution, then the employee may independently apply as inventor, or coinventor, and retain the patent rights.

For further guidance on patents, see Departmental Manual, Part 453, Inventions and Patents (453 DM 1-3).

7.6 May the NPS license federally owned inventions?

Yes. A license is a legal instrument authorizing the licensee to use the licensor's patent or other intellectual or other property.

When NPS holds the patent rights to an invention, NPS may grant non-exclusive, exclusive or partially exclusive licenses subject to NPS terms and requirements of 35 USC 207 and 209. See Section 5.4.1.

Only parks designated as federal laboratories may retain income from licensing.

7.7 May the NPS obtain a trademark as part of the commercialization of the collaborative research?

Yes. When NPS is a co-inventor with a non-NPS party, the negotiated benefits under the joint research project may assign NPS as the owner or co-owner of a trademark in the event of commercialization of the research results. In this case, NPS will be a party to the decision to trademark a product resulting from the collaborative research.

8.0 Accountability: Tracking Agreements and Providing and Accepting Benefits

The tracking of agreements is standardized, but each agreement type has certain unique requirements regarding accepting and providing benefits as described in this section.

8.1 Is there a Servicewide register of all agreements to share or decline benefits?

Yes. The WASO Benefits-Sharing Coordinator maintains a Servicewide list of all agreements to share or decline benefits and copies of the agreements. The Servicewide annual reports, which are based on park reports, also list all current agreements. The WASO Benefits-Sharing Coordinator posts the Servicewide annual reports on the web.

8.2 Who is responsible for ensuring that the terms of an agreement to share or decline benefits are met for the duration of the agreement?

The superintendent is responsible for meeting the terms of the Cooperative Research and Development Agreement (CRADA), General Agreement, Cooperative Agreement, or Letter of Agreement to Decline Benefits Sharing, although the superintendent may delegate responsibility for administration of the agreement to the key official for administration or the agreements technical representative (ATR) as appropriate, who may be the park benefits-sharing coordinator or another employee.

8.3 Who tracks benefits that were negotiated in the Cooperative Research and Development Agreement (CRADA), General Agreement, or Cooperative Agreement?

The key official for administration or the ATR, as appropriate, monitors and tracks progress on fulfilling the terms of the agreement. These employees account for monetary and non-monetary benefits received and annually report these benefits, for each agreement, to the park benefits-sharing coordinator, who compiles a report for the superintendent to send to the WASO Benefits-Sharing Coordinator. (See Section 10.0 on reporting.)

8.4 Who maintains the decision file and what is included in it?

Decision files document NPS's decision-making process and record the basis and rationale for making a decision. The key official for administration or the ATR, as appropriate, maintains the decision file on each agreement. (Note: For Cooperative Agreements, the contracting officer maintains the official contracting file with original documents.) The decision file includes, but is not limited to:

- Permit and associated conditions
- NEPA and any other compliance documentation
- Results of consultations
- CSTAs
- List of cataloged specimens
- Loan agreements
- MTAs
- Invention disclosures and/or patent application notifications
- Original CRADA or General Agreement, or a copy of the Cooperative Agreement
- General correspondence
- Documents showing receipt and distribution of monetary and non-monetary benefits
- Documents showing use of benefits (monetary and non-monetary)
- Annual and other reports
- Other relevant material

Copies of the above documents are acceptable unless the original is specified. Other information ordinarily kept in the research permit files should continue to be kept in those files. Copies of

relevant information from the research permit file should also be kept in the benefits-sharing decision file.

Maintain the decision file as a permanent record consistent with Director's Order (DO) #11D: Records and Electronic Information Management.

8.5 Who documents and accounts for non-monetary benefits?

CRADAs and General Agreements: Upon receipt of non-monetary benefits, the key official for administration signs and sends a letter of acknowledgement to the other party's designated point of contact. For benefits that are ongoing, the key official for administration will acknowledge benefits on a regular schedule, but no less frequently than annually. The key official for administration will maintain a chronological log of all benefits received. See Section 8.6.

Cooperative Agreements: The ATR is responsible for administering the Cooperative Agreement, documenting receipt of deliverables, and recommending payments to the other party. Follow the instructions in the *Agreements Handbook*, Chapter 4.

8.6 Is there a Servicewide tool for tracking receipt of benefits and due dates?

No, not at this time. The park key official for administration or the ATR, as appropriate, sets up a workbook, for example in Excel, with spreadsheets to describe monetary benefits by type (such as, upfront, annual maintenance, performance-based, milestone and other payments, see Table 7) and non-monetary benefits by type (such as knowledge and research relationships, training, supplies and equipment, special services, see Table 9), due dates, and dates of receipt, as well as expenditures of monetary benefits. The park will submit this record as part of an annual report on benefits sharing (see Section 10.1).

See spreadsheet template in Appendix K.

8.7 How does the non-federal partner make monetary payments?

The partner uses the Pay.Gov system to make electronic payments using the Automated Clearing House (ACH) system, a credit card, or PayPal. To make a payment, the partner goes to <u>https://www.pay.gov/paygov/</u>.

Upon completion of a park's first CRADA that will generate monetary payments and, separately, upon completion of a park's first General Agreement that will generate monetary payments, the park must work with the WASO Benefits-Sharing Coordinator to add a park-specific Benefits-Sharing CRADA payment site and a separate park-specific Benefits-Sharing General Agreement payment site in Pay.Gov. The WASO Accounting Operations Center liaison to Pay.Gov will facilitate the process, provide sample payment forms for the park to consider in designing its payment forms (one for CRADAs and one for General Agreements), and connect the park with

Pay.Gov staff for final form design, testing of the form and system reports, and implementation of the park-specific payment site.

When making a payment, the payer opens the appropriate park-specific CRADA or General Agreement payment site and completes the payment form to document the payment. The WASO Accounting Operations Center uploads or enters the data into the Financial and Business Management System (FBMS).

The information that the U.S. Department of the Treasury collects on behalf of parks on Pay.Gov is exempt from Office of Management and Budget (OMB) approval under the Paperwork Reduction Act. Managing the Personally Identifiable Information (PII) and establishing the system of records is the responsibility of the U.S. Department of the Treasury. The designated park staff, the WASO Accounting Operations Center liaison to Pay.Gov, the WASO Benefits-Sharing Coordinator, and others the park designates will have access to reports from the system. Such reports may contain protected confidential information such as PII and/or, depending on the terms of the benefits-sharing agreement, other information, such as payment amount and type.

The U.S. Department of the Treasury does not charge a fee to either the payer or the payee for use of Pay.Gov.

Parks would follow procedures similar to the procedures for CRADAs if payments were to be received under a Cooperative Agreement, as authorized by 16 USC 1a-2(j). Contact the WASO Benefits-Sharing Coordinator before proceeding.

8.7.1 What requirements are specific to the park's CRADA payment site on Pay.Gov?

The park must name the form to collect CRADA payments in the following format:

PARK [for park acronym] B-S [for benefits-sharing] CRADA. For example, PARK_B-S_CRADA.

The park must include the following data fields on the CRADA payment form that it designs:

- Agreement Number
- Agreement type (CRADA only)
- Partner's name and acronym (XYZ)
- Payment amount

Parks have the option of collecting additional information.

8.7.2 What requirements are specific to the park's General Agreement payment site on Pay.Gov?

The park must name the form to collect General Agreement payments in the following format:

PARK [for park acronym] B-S [for benefits-sharing]GenAgmt. For example, PARK_B-S_GenAgmt.

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The park must include the following information on the General Agreement payment form that it designs:

- Agreement Number
- Agreement type (General Agreement only)
- Partner's name and acronym (XYZ)
- Payment amount

Parks have the option of collecting additional information.

8.8 What accounting procedures apply to funds that NPS receives under a Cooperative Research and Development Agreement (CRADA)?

All standard NPS accounting and procurement procedures apply to receipt and expenditure of the funds, except that:

- The Federal Technology Transfer Act (FTTA) requires that all funds received under CRADAs be obligated within two fiscal years after the end of the fiscal year in which the funds were received.
- The funds must be spent to enhance resource protection or to offset costs of administering benefits sharing.

When expecting a payment through Pay.Gov, the park runs a Pay.Gov report for benefits-sharing CRADA payments. Such reports may contain protected confidential information, depending on the terms of the benefits-sharing agreement, and parks should take appropriate steps to prevent inadvertent disclosure.

Once the payment is received in Pay.Gov, the park contacts the WASO Accounting Operations Center to arrange for the funds to be transferred to a park account with a Functional Area designation of PROBSBSC4.XZ0000, or its successor. (See Section 9.1 for further guidance.) The park may elect to have Pay.Gov automatically send notification of payments to email addresses that the park specifies.

The park maintains a record of payments received by type of payment. (See Section 10.1.)

8.9 What accounting procedures apply to funds that NPS receives under a General Agreement and must be deposited in the U.S. Treasury?

When expecting a payment through Pay.Gov, the park runs a Pay.Gov report for benefits-sharing General Agreement payments in order to ensure that the terms of the agreement are met and to collect this information for annual reporting. Such reports may contain protected confidential information, depending on the terms of the benefits-sharing agreement, and parks should take appropriate steps to prevent inadvertent disclosure.

The WASO Accounting Operations Center will assign the funds to Fund X with a Functional Area designation of PSS00OCXL.XB0000, or its successor, and ensure that the funds are deposited in the U.S. Treasury. Parks do not need to take any action regarding disposition of these funds.

8.10 Who processes refunds?

Parks and WASO Accounting Operations Center process refunds as described (for NPS users) at <u>https://comp.sharepoint.nps.gov/AOC/SitePages/ RDMT_DOC.aspx</u> regardless of whether the refund is due from funds received under a CRADA and held by the park or from funds received under a General Agreement and deposited (or designated for deposit) in the U.S. Treasury. The WASO Accounting Operations Center liaison to Pay.Gov and the Receipts and Debt Management Team can guide parks through this process (contact: aoc_refunds@nps.gov).

9.0 Using Non-monetary and Monetary Benefits

Except as noted below in relation to certain monetary benefits, parks must use the majority of monetary benefits received to enhance NPS resource protection, although some of the benefits may also be used for NPS administrative costs associated with the benefits-sharing program. The funds may not be used to pay permanent employees. Receipt and use of non-monetary and monetary benefits must be reported in the annual report. See Section 10.1.

When an NPS employee is an inventor named in a patent developed through a Cooperative Research and Development Agreement (CRADA), the Federal Technology Transfer Act (FTTA) provides for a required annual payment to the employee from any licensing royalties received (see Section 7.5). In addition, the park may provide appropriate incentive payments from such royalties or payments to employees who are not inventors or co-inventors but who substantially increased the technical value of such inventions. For example, NPS may provide a cash award to an employee who makes procedural changes that make production of a patented invention more economical. In accordance with the FTTA, the balance of the revenue should be used by the receiving park, unless the NPS Director determines, in special cases, that the revenue should be shared with other parks that are designated federal laboratories, in which case the receiving park will be authorized to expend the majority share of the revenue. For further guidance see 15 USC 3710c.

9.1 What responsibilities does the park have in expending benefits-sharing revenue?

The park will:

1. Maintain the funds in an account with a Functional Area designation of PROBSBSC4.XZ0000, or its successor.

- 2. Obligate funds received under a CRADA within two fiscal years after the fiscal year of receipt.
- 3. Ensure appropriate environmental compliance for funded actions that may affect the environment.
- 4. As part of the Servicewide Comprehensive Call (SCC), in the Project Management Information System (PMIS), or other project management system that the Associate Director, NRSS, designates, propose projects and annually update plans for expenditure of the funds, taking into account anticipated revenue and the time limit for expenditure. In PMIS, select "Benefits Sharing" as a fund source. The superintendent approves these projects.
- 5. Annually report accomplishments and project status in PMIS (or designated alternate system) until the project is completed.
- 6. Track Benefits-Sharing revenue and expenditures using the standard NPS accounting systems.

NOTE! In negotiating CRADAs, the park should carefully schedule to receive payments in order to facilitate the expenditure of funds. For example, if the park receives funds in October of Fiscal Year 1, those funds must be expended by September 30 of Year 3—35 months later. If, however, the park receives funds in September of Fiscal Year 1, the funds must be expended by the same date, September 30 of Year 3, which is only 24 months later.

9.2 What responsibilities does the region have in expending benefits-sharing revenue?

The region has oversight for the park expenditure of benefits-sharing revenue and monitors benefits-sharing project expenditures using PMIS (or designated alternate system).

9.3 What responsibilities does WASO have related to expending benefits-sharing revenue?

The WASO Accounting Operations Center is responsible for generating reports on income and expenditures, including such reports for benefits sharing.

The WASO Benefits-Sharing Coordinator is responsible for reviewing:

- benefits-sharing project expenditures in PMIS (or a designated alternate system) to ensure that they meet the established criteria for resource protection or benefits-sharing administration, and
- reports from the WASO Accounting Operations Center for the benefits-sharing fund source (Functional Area PROBSBSC4.XZ0000, or its successor).

10.0 Reporting on Benefits Sharing and Technology Transfer

10.1 Does the park prepare an annual report on benefits-sharing activities?

Yes. The park submits the information below to the WASO Benefits-Sharing Coordinator, using templates in Appendix L, according to a schedule that the Coordinator establishes.

All parks involved in benefits sharing must provide for the preceding fiscal year:

- Summary of park benefits sharing (template section 2), including:
 - o Number of active agreements
 - Number of newly executed agreements
 - Total monetary benefits received from all agreements
 - o Total monetary benefits received and deposited in the U.S. Treasury
 - o Examples of key non-monetary benefits received
 - Identification of current permitted research activities that are likely to lead to commercial application in future years
 - o Number of new agreements to decline benefits sharing
 - Any other relevant and similar information
- Data for each agreement (template section 3), including:
 - Agreement type (Cooperative Research and Development Agreement [CRADA], General Agreement, Cooperative Agreement) and assigned agreement number (for example, PARK-2014-1.0)
 - o Brief summary of agreement, listing major milestones
 - Summary of the activities during the year, including
 - disclosures of inventions and related patents filed and granted (to NPS and/or other party)
 - non-monetary benefits received and used
 - monetary benefits received (by type, such as upfront, annual, performance, and other payments) and used
 - monetary benefits that NPS received under an NPS General Agreement and deposited in the U.S. Treasury
 - lapsed monetary benefits (unobligated during period available)
 - List of associated permits, CSTAs, MTAs, and loan agreements applicable to the agreement

In addition, parks that are federal laboratories must provide for the preceding fiscal year the following technology transfer information on licenses and inventions (template section 4):

- *Licenses.* For each patent or other licensable form of intellectual property (IP) that NPS owns and for which NPS has active licenses, report details shown in Appendix L for each license, including:
 - o License title
 - Year of execution
 - o Status as exclusive, partially exclusive, non-exclusive

- o Whether the license is for an invention or other IP
- Whether the license provides for income to NPS
- Total income for the fiscal year
 - Income from inventions for the fiscal year
 - Income from other IP for the fiscal year
- Earned royalty income represented as part of total income from inventions and other IP for the fiscal year
- o License issuance fee (if any)
- Other payments [Describe]
- Time elapsed from the date on which the licensee requested the license in writing to the date NPS executed the license
- o Earned royalty income obligated and how used
- o Income, other than earned royalty income, obligated and how used
- Whether license was terminated for cause or other reasons
- *Inventions.* Report on each NPS employee invention disclosed this fiscal year, and on all patent applications pending at any time during the fiscal year. Report using the template in Appendix L:
 - Name of employee
 - o Date invention disclosed
 - Invention summary (non-confidential)
 - Date patent application filed, if applicable
 - Patent application serial number
 - Date patent granted, if applicable
 - o Patent number, if applicable
 - o Date patent denied, if applicable

10.2 Does WASO prepare an annual Servicewide report on benefits-sharing and technology transfer activities?

Yes. The WASO Benefits-Sharing Coordinator compiles the information that parks provide into a report required by the Federal Technology Transfer Act (FTTA) (15 USC 3710(f)) and the Departmental Manual (DM) at 761 DM 1, Technology Transfer Policies and Procedures. The report summarizes NPS benefits sharing and technology transfer for the year, outlines future plans, highlights selected case studies, and provides required non-confidential performance metrics. (NPS chooses to report on all NPS benefits sharing, not just the activities of NPS federal laboratories.) Upon DOI request, the WASO Benefits-Sharing Coordinator also provides information on any licenses and employee inventions from parks that are not designated federal laboratories.

NPS submits its annual report to the DOI Assistant Secretary, Policy, Management and Budget, who compiles the DOI report and submits it to the Office of Management and Budget (OMB) with copies to the Attorney General and Secretary of Commerce. The Secretary of Commerce in consultation with the Attorney General and the Commissioner of Patents and Trademarks, uses this report to prepare and submit an annual Federal Laboratory (Interagency) Technology

Transfer Summary Report to the President, the Office of the United States Trade Representative, and Congress.

The WASO Benefits-Sharing Coordinator posts a summary of the compiled NPS nonconfidential information on the Internet for public benefit. Federal Laboratory (Interagency) Technology Transfer Summary Reports for previous years are available at <u>http://www.nist.gov/tpo/publications/index.cfm</u>.

11.0 Funding Administration of the Benefits-Sharing Program

Administration of the benefits-sharing program may be funded through:

- Appropriations (for parks, regions, WASO),
- Funds received under a Cooperative Research and Development Agreement (CRADA) (for certain NPS expenses, see Section 9.0), and
- Funds received under a Cooperative Agreement (for NPS expenses at parks, see Section 6.4).

The Federal Technology Transfer Act (FTTA) requires each agency that operates one or more federal laboratories to make available sufficient funding, either as a separate line item or from the agency's research and development budget, to support the technology transfer aspects of benefits sharing at designated federal laboratories (15 USC 3710(b)(2)). This support may be provided centrally in WASO or at the region or park. Each unit is individually responsible for submitting funding requests for its technology transfer activities.

12.0 International Perspective

12.1 How is benefits sharing addressed in the international arena?

NPS benefits-sharing is generally consistent with the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, which were adopted in 2002 by the parties to the United Nations Convention on Biological Diversity (CBD). These voluntary guidelines identify general steps that may be established, in appropriate circumstances, for obtaining access to genetic (non-human) resources, seeking prior informed consent of providers, and determining the basis for benefit-sharing. The United States is not a party to the Convention or its protocols. For further information see <u>https://www.cbd.int/convention/</u> and <u>https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf</u>.

In addition, the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (ABS) is an international agreement under the CBD adopted in 2010. It entered into force October 12, 2014. The United States is not a signatory to the Nagoya Protocol. Many countries' rules are evolving regarding access to, and use of, genetic resources. Countries' domestic regimes implementing the Nagoya Protocol and the CBD may seek to impose restrictions on research, use, or resulting commercialization with respect to genetic resources in those countries. For further information see http://www.cbd.int/abs/about/.

12.2 Does NPS negotiate agreements to share or decline benefits with park-permitted researchers from outside the United States?

Yes. Subject to limited exceptions, NPS must negotiate an agreement to either share or decline benefits to fulfill the terms of the permit or other subsequent agreement, such as an MTA. NPS may negotiate benefits-sharing agreements for monetary or non-monetary benefits with researchers from outside the United States, provided that the other party agrees to comply with U.S. law. The U.S. government may not accept funds from foreign governments, including universities and laboratories and other entities that the foreign government owns or operates, but may accept funds from non-governmental foreign entities. The U.S. government may accept non-monetary benefits from foreign governments and non-governmental foreign entities. Parks and the WASO Benefits-Sharing Coordinator will coordinate with the NPS Office of International Affairs on all agreements with foreign entities. The Office of International Affairs will confer with the Department of State, Office of the United States Trade Representative, and other federal agencies, as appropriate.

12.3 Should parks use NPS loan agreements, Collected Specimen Transfer Agreements (CSTAs), and Material Transfer Agreements (MTAs) for specimens and Material housed in repositories outside the United States?

Yes. Loan, CSTA, and MTA provisions apply to specimens and Material whether they are in U.S. or foreign repositories.

13.0 Ethical Concerns and Confidentiality

Every park must ensure that there are no conflicts of interest related to any agreement to share or decline benefits and that confidentiality provisions are upheld.

13.1 What conflicts of interest may arise relative to benefits sharing?

As already noted in Sections 2.9-2.11 and 3.0, NPS employees who issue permits and other authorizations, such as Collected Specimen Transfer Agreements (CSTAs), Material Transfer Agreements (MTAs), and loans, are considered to have an inherent conflict of interest and the benefits-sharing program maintains a "firewall" between these employees and benefits-sharing agreements. In addition, NPS employees who administer grants and contracts may have an

inherent conflict of interest that would preclude their participation in the development of an agreement to share or decline benefits if the other party is eligible for or a recipient of a grant or contract that the NPS employee administers. NPS scientists may have conflicts of interest if they serve as project officers on a contract or have authority over funding decisions in the course of their research that could affect an arrangement to share or decline benefits. Employees may have financial interests that would be affected by a proposed agreement. Therefore, any conflict of interest—actual or apparent—must be addressed in the process of developing, negotiating, reviewing, approving and implementing agreements to share or decline benefits.

NOTE! Employees active in developing and managing agreements to share or decline benefits and both employees and former employees involved in research covered by an agreement or involved in negotiating agreements, licenses or assignments of inventions with federal agencies are subject to ethics laws and regulations and must consult their servicing ethics officer for guidance. The ethics officer may require the employee to complete an Annual Confidential Financial Disclosure Report (OGE Form 450). Every park must ensure that there are no conflicts of interest related to any agreement to share or decline benefits. Cooperative Agreements require a "Conflict of Interest and Confidentiality Certificate" as an attachment to the agreement in certain circumstances (see Agreements Handbook, Chapter 4). The DOI Ethics Guide, other information on ethics, and contact information for the Servicewide NPS ethics officer, who can provide contact information for all NPS ethics officers, are at <u>http://www.doi.gov/ethics/index.cfm</u>.

13.2 Must current and former employees seek permission to privately participate in commercial development and share in benefits?

Yes. NPS employees must consult the ethics officer if they propose to privately participate in commercial development in job-related subject areas regardless of whether they share in benefits. Providing that NPS has determined that there is no conflict of interest, NPS may grant permission or waive the requirement for permission to participate in commercial development and share in benefits. See Section 7.5, which describes certain circumstances in which an NPS employee may acquire rights to intellectual property and/or share in benefits. Also see DOI policy on ethics and conflict of interest relative to technology transfer in the Departmental Manual (DM) at 761 DM 1.6, C.

13.3 When must the park keep research results, business plans, and other benefitssharing matters confidential?

The park must keep information confidential when the other party informs the park in writing that information received and accepted by NPS is confidential. Confidential information may be provided to the NPS at the time of research permit application, during the development of research results, at the time of invention or patent application disclosures, upon notification of intent to commercialize, in the process of negotiations, or after an agreement to share or decline benefits has been signed.

Government employees are bound by 18 USC 1905, known as the Federal Trade Secrets Act, not to disclose confidential and proprietary information disclosed to them in the conduct of their official duties. NPS employees may share confidential information with other NPS employees when necessary for the performance of the recipient's duties. The NPS employee providing the information must state in writing or verbally that the information is confidential. If NPS has a need to disclose confidential, sensitive, or proprietary information to an outside party, NPS must obtain permission from the owner of the confidential information and obtain a signed confidentiality agreement from the recipient before such information is disclosed. If disclosure is required under the Freedom of Information Act or other applicable law, a subpoena, a court order, or a federal audit, NPS must follow the respective procedures prior to disclosure. Consult the Office of the Solicitor for matters involving subpoenas or court orders.

NPS is required to maintain confidentiality of any information marked by another party as either confidential or proprietary indefinitely, or for an agreed upon period of time, or until the owner of the information agrees that the NPS may release it, or when such information becomes available to the public through no action of the government. Trade secrets and financial information from a non-federal entity must be kept confidential permanently or for the period indicated by the non-federal entity.

Federally created information that would have been a trade secret or confidential had it been developed by a non-federal entity may, but is not required to, be kept confidential for up to five years.

Each CSTA, MTA, and agreement to share or decline benefits must state the kinds of information that are to be kept confidential, including NPS information, such as locality data, that is confidential. The benefits-sharing agreement will include a confidentiality clause and may include a prescribed format for confidentiality agreements.

Consistent with *Management Policies 2006* 1.9.2.3, information will be withheld when disclosure would be harmful to an interest protected by an exemption under the Freedom of Information Act (FOIA). Information will also be withheld when NPS has a written agreement, such as a benefits-sharing agreement or a confidentiality agreement, to withhold information. Such information will not be provided unless required by the Freedom of Information Act or other applicable law, a subpoena, a court order, or a federal audit.

A sample confidentiality agreement is in Appendix M. Prior to signature, all confidentiality agreements must be reviewed by a DOI Office of the Solicitor attorney advisor.

13.4 May park employees who negotiate benefits develop or approve NPS projects that expend benefits-sharing revenue or use non-monetary benefits?

Yes. There is no conflict of interest when a park employee both negotiates a benefits-sharing agreement and determines how the park will use the benefits, providing that the employee is not an inventor or co-inventor or otherwise personally a party to the benefits sharing.

14.0 Research Equipment

14.1 What special provisions apply to excess equipment under the Federal Technology Transfer Act (FTTA)?

The superintendent of a park that is designated a laboratory may loan, lease, or give research equipment that is excess to the needs of the laboratory and NPS to an educational institution or nonprofit organization for the conduct of technical and scientific education and research activities. See FTTA 15 USC 3710(h)(3)(i).

15.0 Informational Resources and Training Opportunities

Because Congress provided NPS with benefits-sharing authority that is specific to NPS, the experience of other federal agencies in stimulating research and implementing technology transfer under the Federal Technology Transfer Act (FTTA) has limited application to NPS benefits sharing. Providing that NPS employees understand the differences between NPS benefits sharing and other agencies' technology transfer activities, the following key informational and training resources may be helpful. Additional resources are in Appendix D.

15.1 What NPS resources are available to park employees responsible for benefits sharing?

The following NPS resources may be useful to those individuals responsible for benefits sharing:

- Park benefits-sharing coordinator (in your park or another park with benefits-sharing experience)
- WASO Benefits-Sharing Coordinator, NRSS
- Economists with the social science program, NRSS
- Technical staff of the NRSS and other associate directorates
- Attorney advisor, Office of the Solicitor (accessed through the WASO Benefits-Sharing Coordinator, or as an appointed member of a park negotiating team)
- Ethics official
- Contracting officer (for Cooperative Agreements)
- See also Section 5.8.

15.2 What DOI information resources might be useful to individuals responsible for benefits sharing?

DOI does not currently have a technology transfer office. The WASO Benefits-Sharing Coordinator works closely with the DOI Office of Policy, Management and Budget, which is responsible for coordinating and submitting annual agency reports on technology transfer activities required by the FTTA (15 USC 3710(f)). (See Section 10.2.) The Departmental Manual (DM) includes the following guidance:

- 207 DM Limited Delegations, Chapter 8 Technology Transfer—delegates to assistant secretaries and bureau directors the authority to negotiate licenses and other agreements related to intellectual property and to enter into Cooperative Research and Development Agreements (CRADAs) with other entities.
- 453 DM Inventions and Patents—covers inventions by employees, inventions by contractor employees, licenses, and unsolicited technical proposals from the public.
- 454 DM Copyright—covers use of copyrighted material and rights in government-funded copyrightable materials.
- 761 DM Technology Transfer, Chapter 1 Policy and Procedures—addresses policy and standards, requirements and procedures for conducting technology transfer activities.

DOI provides technology transfer information and resources at <u>http://www.doi.gov/techtransfer/index.cfm</u>.

The WASO Benefits-Sharing Coordinator can provide contact information for other DOI bureaus that are involved in technology transfer, such as Bureau of Reclamation and U.S. Geological Survey.

15.3 What kinds of technical assistance are provided by the Department of Commerce?

Under the FTTA, the Secretary of Commerce has the responsibility to:

- Provide to federal agencies expertise regarding the commercial potential of inventions and methods and options for commercialization.
- Develop and disseminate to federal agencies model provisions for use in cooperative research and development arrangements.
- Provide advice and assistance, upon request, to federal agencies regarding cooperative research and development programs and projects.

15.4 What is the Federal Laboratory Consortium for Technology Transfer (FLC)?

Congress chartered the FLC under the FTTA to work with federal laboratories and the private sector to rapidly move federal technology research and development from federal laboratories into the mainstream of the U.S. economy. The FLC offers technology transfer services and resources, including:

- Training courses
- Reference materials, publications, newsletters, website
- National and regional meetings with a training component
- Technology Locator Service that connects potential partners with appropriate federal resources

The FLC is a volunteer organization with members from federal research laboratories and agencies with technology transfer functions. Each member agency or laboratory appoints one voting representative. Although the FLC has a small staff in Washington, DC, the FLC committees manage the organization, including coordination of issues and policies and training activities. Some FLC training and discussion topics are of particular interest to NPS.

Under FTTA, federal agencies with federal laboratories and technology transfer activities, including DOI, are required to contribute a percentage of their budgets to the National Institute of Standards and Technology (NIST) for the purpose of funding the FLC.

For further information see the FLC web site at http://www.federallabs.org/.

15.5 May NPS use Federal Laboratory Consortium for Technology Transfer (FLC) services?

Yes. In establishing the NPS benefits-sharing program, NPS consulted FLC and several of the member agencies. Park staff involved in benefits sharing should take advantage of the technical information, conferences, and training that FLC provides.

15.6 What information and services does the Association of University Technology Managers (AUTM) provide?

The AUTM is a non-profit member-based association of technology managers and business executives who manage intellectual property. Although its roots are in the university community, its membership is now much broader. Its web site provides useful background and technical information on technology transfer. AUTM provides the results of an annual licensing survey, other research results, annual and regional meetings, training, and publications.

AUTM manages the documentation for the Universal Biological Material Transfer Agreement (UBMTA), an MTA template that over 400 universities and other organizations have agreed to use. The NPS MTA is consistent with the UBMTA.

AUTM technology transfer resources are at <u>https://autm.net/about-tech-transfer</u>.

Appendices

NOTE! Templates and example formats are available to NPS users in Word or Excel at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

- Appendix A: Acronyms
- Appendix B: Glossary
- Appendix C: Template for a Collected Specimen Transfer Agreement or a Material Transfer Agreement
- Appendix D: Information and Training Resources
- Appendix E: Example NPS Letter of Agreement to Decline Benefits Sharing
- Appendix F: Template for a Cooperative Research and Development Agreement for Benefits Sharing
- Appendix G: Template for a General Agreement for Benefits Sharing
- Appendix H: Example of a Park Request for Designation as a Federal Laboratory
- Appendix I: Template for a Request for Approval of Negotiations and Terms
- Appendix J: Template for a Term Sheet
- Appendix K: Example of a Record of Benefits Received
- Appendix L: Template for a Park Benefits-Sharing Annual Report
- Appendix M: Example of a Confidentiality Agreement
- Appendix N: Summary of Laws on Benefits Sharing and Technology Transfer

Appendix A: Acronyms

ABS—Access and benefit sharing ATCC—American Type Culture Collection ATR—Agreements Technical Representative AUTM—Association of University Technology Managers CBD—Convention on Biological Diversity CESU—Cooperative Ecosystem Studies Unit CFR—Code of Federal Regulations CRADA—Cooperative Research and Development Agreement CSTA—Collected Specimen Transfer Agreement DM—Department of the Interior Departmental Manual DNA— Deoxyribonucleic acid DO—Director's Order (see https://npspolicy.nps.gov/) DOI—Department of the Interior **EIS**—Environmental Impact Statement FBMS—Financial and Business Management System (see http://www.doi.gov/pmb/fbms/index.cfm) FEIS—Final Environmental Impact Statement FLC—Federal Laboratory Consortium for Technology Transfer FTTA—Federal Technology Transfer Act of 1986 GIS—Geographic Information System GMO-Genetically modified organism GPS—Geographical Positioning System IAR—NPS Investigator's Annual Report I & M Network—NPS Inventory and Monitoring Network ICMS—Interior Collections Management System IP—Intellectual property LES-Licensing Executives Society (USA and Canada) LESI-Licensing Executives Society International, Inc. MTA-Material Transfer Agreement NEPA-National Environmental Policy Act, (see DO #12 and its Reference Manual for guidance) NHPA—National Historic Preservation Act NIH—National Institutes of Health NIST-National Institute of Standards and Technology (Department of Commerce) NPOMA—National Parks Omnibus Management Act of 1998 NPS—National Park Service NRSS-the NPS directorate of Natural Resource Stewardship and Science OGE-U.S. Office of Government Ethics OMB—Office of Management and Budget ORTA—Office of Research and Technology Applications PCR—Polymerase chain reaction PMIS—Project Management Information System R & D—Research and development RNA— Ribonucleic acid **ROD**—Record of Decision RPRS—NPS Research Permit and Reporting System

August 18, 2014, Updated October 16, 2018

SCC—Servicewide Comprehensive Call

SSTI—State Science and Technology Institute

T2S—Technology Transfer Society

UBMTA—Universal Biological Material Transfer Agreement

UN—United Nations

USC—United States Code

USPTO—United States Patent and Trademark Office

WASO—Washington Office (NPS headquarters office)

WIPO—World Intellectual Property Organization

Appendix B: Glossary

Note: Provided definitions are as used in the NPS benefits-sharing context.

Agreement to share or decline benefits—A contractual agreement established prior to a researcher's commercialization of research results from studies authorized by an NPS Scientific Research and Collecting Permit or other permit or authorization. The agreement states the rights and responsibilities of researchers and NPS managers and agreement terms and conditions. NPS uses different agreement types depending on whether NPS will share or decline to share in benefits resulting from the commercialization. To share benefits, see Section 6.0 for information on Cooperative Research and Development Agreements (CRADA) (6.2), General Agreements (6.3), and Cooperative Agreements (6.4). To decline to share benefits see Section 6.5 for guidance on a Letter of Agreement to Decline Benefits Sharing.

American Type Culture Collection—A private, not-for-profit biological resource center focused on the acquisition, authentication, production, preservation, development and distribution of standard reference microorganisms, cell lines and other materials for research in the life sciences.

Annual Confidential Financial Disclosure Report (OGE Form 450)—A federal employee files this form when the duties and responsibilities of the employee's position require filing to disclose financial interests and affiliations of the employee. The purpose of the report is to assist employees and their agencies in avoiding conflicts and apparent conflicts of interest between official duties and private financial interests or affiliations.

Benefits, monetary—Currency-based payments and income to either party. For the purpose of this guidance, NPS monetary benefits include, but are not limited to, upfront payments, annual maintenance payments, performance-based payments, and milestone payments.

Benefits, non-monetary—Benefits that accrue to either party and are not currency-based, including knowledge and research relationships, training and education, research-related supplies and equipment, and special services.

Benefits sharing—Occurs when NPS receives monetary or other benefits from a discovery or invention with a commercial application resulting from research originating under an NPS Scientific Research and Collecting Permit, or other permit or authorization.

Bioprospecting—The search for useful scientific information from genetic or other biological resources.

Biotechnology—Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure—This treaty recognizes specific culture collections as international microorganism depository authorities. A deposit made with any one of these culture collections is recognized as valid for patent purposes by all the contracting parties (countries) in which protection for the relevant invention is sought. The United States is a party to this Treaty.

Catalog Record—A record that identifies and describes a museum specimen or living collection item and lists a unique catalog number for tracking. The NPS museum catalog record is Form 10-254.

Collected specimen—The item collected by the permittee under the authority of an NPS Scientific Research and Collecting Permit, and portions thereof. Collected specimens are natural products. See also museum specimen, living collection item, and Material, which originate from a collected specimen.

Collected Specimen Transfer Agreement (CSTA)—An agreement to provide custody of collected specimens to organizations and their researchers, other than researchers identified in the Scientific Research and Collecting Permit, for purposes of research when a determination has not yet been made on whether the specimens will be permanently retained and incorporated into an NPS museum or living collection.

Commercial application—See commercial use.

Commercial purpose—See commercial use.

Commercial use—Use of Material or modifications or other research results in a product, service, or process resulting in a product or service that is sold, leased, licensed, or otherwise transferred for value received. Also referred to as "commercial application" and "commercial purpose." [Note: Collected specimens, including collected specimens that are permanently retained in museum and living collections, may not be used commercially.]

Commercial use agreement—A type of contract, such as a benefits-sharing agreement, that pertains to commercial activity.

Compensable interest—A legal share in physical or intellectual property that is entitled to compensation when others use that share of the property.

Confidential information—Any information or material in tangible form that is marked as confidential or proprietary by the furnishing party at the time it is delivered to the receiving party, and information that is furnished orally if the furnishing party identifies such information as confidential or proprietary when it is disclosed and promptly confirms such designation in writing after such disclosure. Confidential information does not include:

- 1) information that is publicly known or available from other sources who are not under a confidentiality obligation to the source of the information; or
- 2) information that has been made available by its owners to others without a confidentiality obligation; or

- 3) information that is already known by or available to the receiving party without a confidentiality obligation; or
- 4) information that relates to potential hazards or cautionary warnings associated with the handling, use or disposal of NPS specimens; or
- 5) information that is required by other applicable law or by an agreement to be disclosed.

Confidentiality agreement—A written agreement that contains a promise not to disclose trade secrets, other proprietary information, or information restricted by law or regulation learned in the course of a relationship with another party.

Conflict of interest—A real or perceived incompatibility between one's private interests and one's public or fiduciary duties.

Cooperative Agreement—A legal instrument that establishes a relationship between NPS and public or private educational institutions, states, and their political subdivisions, when the NPS will have substantial involvement in cooperative research (which may involve training) concerning NPS resources and the cooperative effort has a public purpose.

Cooperative Research and Development Agreement (CRADA)—An agreement between one or more federal laboratories and one or more non-federal parties under which the government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-federal parties) and the non-federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts that are consistent with the missions of the laboratory.

Copyright—A divisible bundle of rights given to creators (for example, authors, artists, photographers, and architects) granting them exclusive rights to their creative work, from the moment the work is in fixed form.

Culture—As used in this guidance, microorganisms and cell lines grown in a laboratory. See culture collection.

Culture collection—An organization that collects, authenticates, maintains, and distributes cultures of microorganisms and cells.

Deaccessioning—The process of permanently removing NPS museum collections from an NPS unit's ownership (title) and custody. Similarly, permanently removing an item from an NPS living collection.

Derivative—A creation, other than progeny, that is based on a collected specimen or Material.

Derivative, modified—See "modification"

Derivative, unmodified—See "unmodified derivative"

Discovery—New knowledge gained through search or study.

Economic rent—The value of research and development attributable to study of the collected specimen, Material, museum specimen, and/or living collection item, excluding the input costs associated with research, development, and marketing.

Environmental Impact Statement (EIS)—A detailed National Environmental Policy Act document that is prepared when a proposed action or alternatives have the potential for significant impact on the human environment.

Enzyme—A protein that catalyzes (i.e., increases the rate of) a chemical reaction.

Ex situ—Off site. Refers to the location and maintenance of a collected specimen outside its place of collection.

Federal laboratory—As defined under the FTTA, "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."

Federal Technology Transfer Act of 1986 (FTTA) and related legislation (15 USC 3710) focuses on technology transfer and enables federal laboratories, and therefore park units designated as federal laboratories, to 1) enter into Cooperative Research and Development Agreements (CRADAs); 2) negotiate licenses for patented inventions made at federal laboratories; 3) grant and waive rights to federal laboratory inventions and intellectual property; and 4) accept, retain, and use funds, personnel, services, and property from a collaborating party and provide personnel, services, and property to a collaborating party.

General Agreement for Benefit Sharing—A generic instrument used to document a wide range of mutually agreed-to policies, procedures, objectives, understandings and/or relationships with federal and non-federal entities. This agreement provides for non-monetary benefits that can be shared between the parties. For a complete description of General Agreements, see *Director's Order (DO) #20: Agreements* at https://npspolicy.nps.gov/.

Genetic material—Any material of plant, animal, microbial, or other origin containing functional units of heredity.

Investigator's Annual Report (IAR)—A report that researchers who hold NPS Scientific Research and Collecting Permits submit. It is available to the public at https://irma.nps.gov/rprs/IAR/Search.

In situ—On site. Refers to natural and cultural resources that are in their original location.

Intellectual Property (IP)—Creations of the mind for which a set of exclusive rights may be recognized by law. Intellectual property includes, but is not limited to, inventions, discoveries,

copyright, patents, trademarks, trade secrets, certain forms of traditional knowledge, and other forms of comparable knowledge.

Interior Collections Management System (ICMS)—An automated system for documenting and tracking museum specimens in DOI bureaus. Guidance at http://www.nps.gov/history/museum/publications/ICMS.html.

Invention—Used in a benefits-sharing context to mean any discovery, thing, method, material, process or idea that might be patentable or otherwise protected under 35 USC (Patents), 7 USC 2321 *et seq.* (Plant Variety Protection), and 18 USC 1905 (Trade Secrets).

License—A permission to commit an act that would otherwise be illegal, including an agreement between the owner of a patent or intellectual property and another party interested in using the owned property or protected invention. Licenses may be

1) Non-exclusive—allowing the licensor to grant the same rights to other licensees; licenses are non-exclusive by default.

2) Exclusive—prohibiting the licensor from granting the same rights to other licensees within defined geographic areas, media, languages, or industries, or combination of these parameters.

Living collection—Biological material that is permanently retained *ex situ* for the purpose of generating and providing living or otherwise biologically active material for research, restoration, education or other purposes. Living collections are retained in an NPS or non-NPS repository, documented, and tracked. Items in a living collection may be the collected specimen, or may originate directly from a collected specimen, from Material, or from other biological material in the living collection.

Living collection item—An organism, component from an organism, or Material maintained in a living collection.

Loan agreement—A contractual arrangement between a lender and a borrower of museum specimens or living collections, specifying the items lent and the terms, conditions, and responsibilities and liabilities of each party. The NPS uses outgoing loan agreements to track loans of cataloged museum specimens and living collections to other institutions, such as research laboratories or repositories.

Material (when capitalized)—Progeny and unmodified derivatives of collected specimens, museum specimens, living collection items, and multiple generations thereof. The Material does not include a) modifications or b) other substances created by a person through use of the Material that are not modifications, progeny, or unmodified derivatives. See also definition for modification.

Material Transfer Agreement—An agreement that establishes the terms by which one party both provides Material to another party for research use and tracks disposition of the Material.

Microbial—Related to microorganisms

Microorganism—An organism that is microscopic or submicroscopic, such as a bacterium or protozoan.

Modification—A human-created substance that contains or incorporates Material (progeny and/or unmodified derivatives).

Monetary payments—See benefits, monetary.

Museum specimen—A collected specimen that is permanently retained in a park museum collection. A museum specimen is non-living.

Natural products—Naturally occurring items collected from a park. Collected specimens are natural products. Natural products from parks may not be sold or commercially used. Note: If the researcher slices, polishes, or otherwise prepares or removes a part of the collected specimen, the prepared collected specimen or component remains a "natural product."

Nondisclosure agreement—A contract or contractual provision containing one party's promise not to disclose any information shared by or discovered from the other party, such as information about trade secrets, procedures or other internal or proprietary matters. Also termed a confidentiality agreement.

Patent (U.S.)—An intellectual property right granted by the federal government to an inventor to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States for a limited time in exchange for public disclosure of the invention when the patent is granted.

Patent application (U.S.)—Formal submission to the United States Patent and Trademark Office to request award of a patent.

Pay.Gov—A web-based system for making electronic payments to the federal government.

Permitted research—research that is allowed or authorized through permits or other authorizations.

Polymerase Chain Reaction (PCR)—A scientific technique in molecular biology to amplify a single or a few copies of genetic material across several orders of magnitude, generating thousands to millions of copies of a particular genetic sequence.

Progeny—Unmodified descendant from a collected specimen or Material, such as virus from virus, cell from cell, or organism from organism.

Proprietary information—Information that embodies trade secrets or that is confidential technical, business, or financial information provided that such information:

1) is not generally known or available from other sources without obligations concerning its confidentiality;

2) has not been made available by the owners to others without obligations concerning its confidentiality; and

3) is not already available to the Government without obligations concerning its confidentiality.

Record of Decision (ROD)—The document that is prepared to substantiate a decision based on an EIS. It includes a statement of the decision made, a detailed discussion of decision rationale, and the reasons for not adopting all mitigation measures analyzed, if applicable.

Repository—A location to provide storage and management for and access to museum or living collections according to professional standards.

Repository agreement—A long-term loan agreement between NPS and another party qualified to manage the loaned collections, wherein the other party agrees to manage NPS museum or living collections for a defined period consistent with NPS standards. The repository agreement states terms and conditions that are more detailed than the terms of a standard loan agreement.

Research results—Material (including Material retained in a living collection), modifications, intellectual property, inventions, data, discoveries, and/or other knowledge, processes, products, or applications resulting from research activities of researchers or their institutions or companies. Note: "Research results" excludes collected specimens and museum specimens.

Royalties—A payment made to an author, inventor, or rights holder for each use or copy of a work or article sold under a copyright or patent, such as royalties from licensing inventions.

Scientific Research and Collecting Permit—NPS authorization to conduct scientific research and collecting in an NPS unit, often referred to as an NPS "research permit." A Scientific Research and Collecting Permit is required for most scientific activities pertaining to natural resources or social science studies in National Park System areas that involve fieldwork, specimen collection, and/or have the potential to disturb resources, visitors, or park operations.

Specimen—A collected specimen or a museum specimen. See definitions for Collected specimen and Museum specimen.

Taq polymerase—A heat-stable enzyme originally isolated in the 1980s from the bacterium *Thermus aquaticus* and often used in the PCR process.

Technology transfer—The process by which technology or knowledge developed in one place is made available for use in another place. Federal technology transfer is the transfer of federally owned or federally originated technology to state and local governments and the private sector.

Term sheet—A document that lists, for negotiation purposes, certain principal terms of a proposed agreement.

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Third party—An entity or person who is not involved in the subject NPS transaction or contractual agreement.

Trade Secrets Act—An Act that prohibits federal employees from disclosing trade secrets and related confidential and proprietary information that is disclosed to them in the conduct of their official duties, unless authorized by law. A violation of this Act can result in a fine, imprisonment up to one year, or both, and removal from office or employment. (18 USC 1905)

Trademark—Legal protection for any word, symbol, or combination thereof that is used on goods to indicate their source. The owner of a trademark can exclude others from using a similar mark on similar goods that would be likely to confuse consumers as to the source of the goods.

Traditional knowledge—Knowledge that reflects recognizable cultural patterns transmitted by a group across at least two successive generations. For example, knowledge of plants used for medicinal purposes by one's cultural group.

Universal Biological Material Transfer Agreement (UBMTA)—A template agreement developed with public participation by the National Institutes of Health (NIH) that simplifies exchanges of biological materials among institutions. See Federal Register/Vol. 60, No. 45/Wednesday, March 8, 1995/Notices under Health and Human Services Department at http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR.

Unmodified derivative—A human-created substance that is not a portion of the collected specimen and, instead, constitutes an unaltered copy of a functional subunit or of a product expressed by the collected specimen or Material. Some examples include: copies of cells of the collected specimen, purified or fractionated subsets of the Material, proteins expressed by DNA/RNA extracted from the collected specimen or Material.

Appendix C: Template for a Collected Specimen Transfer Agreement or a Material Transfer Agreement

NOTE! This template is available to NPS users as a Word document at <u>https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx</u>

NATIONAL PARK SERVICE

COLLECTED SPECIMEN TRANSFER AGREEMENT (CSTA #____)

MATERIAL TRANSFER AGREEMENT (MTA #____)

Caution:

Before using these agreements with recipients outside the United States, perform an Export Control check. Consult the WASO Benefits-Sharing Coordinator for more information.

For *collected specimens incorporated into a museum or living collection*, do not use this form—instead, *use an NPS loan agreement*.

Instructions:

Check the **Collected Specimen Transfer Agreement box** when providing collected specimens, or parts thereof, for research *when a determination has not yet been made on whether the collected specimens will be permanently retained* and incorporated into an NPS museum or living collection.

Check the **Material Transfer Agreement box** when providing *Material, which is not the collected specimen* but is progeny or a derivative of the collected specimen. Use an NPS Material Transfer Agreement (MTA) to provide Material that is not the collected specimen but is progeny or a derivative of the collected specimen.

NOTE! Delete cautions and instructions in [brackets and italics] before using the Template.

I. Definitions and Identifications:

1. PROVIDER: NPS unit supplying the PROVIDED ITEMS(S). The Provider is "National Park Service [Enter full name of NPS unit]." [Also enter point of contact name, title, address, telephone and email.]

2. PROVIDER SCIENTIST: [Enter name of the permittee/scientist who will be supplying the *PROVIDED ITEMS(S)*, together with the scientist's title, permittee/scientist's institution/organization name and address, telephone number, and email.]

3. RECIPIENT ORGANIZATION: Organization receiving the PROVIDED ITEMS(S). The name of this party is: *[Enter institution/organization name, address, telephone.]*

4. RECIPIENT SCIENTIST: [Enter name, title, address, telephone, and email of recipient scientist, who must be affiliated with the Recipient Organization.]

5. RECIPIENT ORGANIZATION/SCIENTIST: The RECIPIENT ORGANIZATION and the RECIPIENT SCIENTIST.

6. PROVIDED ITEM(S):

[Choose the appropriate paragraph for the PROVIDED ITEM, either COLLECTED SPECIMEN for a CSTA or MATERIAL for an MTA, and delete the other paragraph.]

COLLECTED SPECIMEN: [See definition #7 for COLLECTED SPECIMEN.] The COLLECTED SPECIMEN(S) provided to the RECIPIENT ORGANIZATION is/are: [Enter scientific name, container type and size/volume, quantity (e.g., three 5 ml glass vials). For multiple taxa and containers, reference here and attach a list as Attachment 2. For each entry of a Collected Specimen, provide the associated Scientific Research and Collecting Permit Number. Enter locality where collected, and, as applicable, collection number. If not applicable, enter N/A.]

MATERIAL: [See definition #8 for MATERIAL.] The MATERIAL provided to the RECIPIENT ORGANIZATION is: [Enter scientific name, container type and size/volume, quantity (e.g., three 5 ml glass vials). For multiple taxa and containers, reference here and attach a list as Attachment 2. For each entry of Material, provide the associated Scientific Research and Collecting Permit Number. Enter locality where the Collected Specimen (from which the Material derived) was collected, Collection Number of the Collected Specimen if any, and, if applicable, the NPS museum or living collection catalog number, repository/culture collection catalog number, and any other catalog number. If not applicable, enter N/A.]

NOTE! Identify in writing information that is confidential, such as NPS locality data that qualifies for exemption under FOIA.

Scientific Name or description:

Container type, size/volume, quantity:

NPS Scientific Research and Collecting Permit number:

Locality where COLLECTED SPECIMEN was collected:

Collection Number for COLLECTED SPECIMEN (field number that the collector assigns to the specimen):

NPS Museum or Living Collection Catalog Number:

Other non-NPS catalog number:

7. COLLECTED SPECIMEN—The item collected by the permittee under the authority of an NPS Scientific Research and Collecting Permit, and portions thereof. COLLECTED SPECIMENS are natural products.

8. MATERIAL: PROGENY and UNMODIFIED DERIVATIVES of COLLECTED SPECIMENS, museum specimens, living collection items, and multiple generations thereof. The MATERIAL does not include a) MODIFICATIONS or b) other substances created by a person through use of the MATERIAL that are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.

9. PROGENY: Unmodified descendant from the COLLECTED SPECIMEN or MATERIAL, such as virus from virus, cell from cell, or organism from organism.

10. UNMODIFIED DERIVATIVE: A human-created substance that is not a portion of the COLLECTED SPECIMEN and, instead, constitutes an unaltered copy of a functional subunit or of a product expressed by the COLLECTED SPECIMEN or MATERIAL. Some examples include: copies of cells of the COLLECTED SPECIMEN, purified or fractionated subsets of the MATERIAL, proteins expressed by DNA/RNA extracted from the COLLECTED SPECIMEN or MATERIAL.

11. MODIFICATION: Substance created by the RECIPIENT ORGANIZATION that contains or incorporates MATERIAL.

12. COMMERCIAL PURPOSE: Use of MATERIAL or MODIFICATIONS or RESEARCH RESULTS in a product, service, or process that results in a product or service that is sold, leased, licensed, or otherwise transferred for value received. [Note: COLLECTED SPECIMENS, including COLLECTED SPECIMENS that are permanently retained in museum and living collections may not be used for COMMERCIAL PURPOSES.]

13. RESEARCH RESULTS: MATERIAL (including MATERIAL retained in a living collection), MODIFICATIONS, intellectual property, inventions, data, discoveries, and/or other knowledge, processes, products, or applications resulting from research activities of the RECIPIENT ORGANIZATION.

II. Terms and Conditions of this Agreement

1. The RECIPIENT ORGANIZATION/SCIENTIST agree that PROVIDED ITEMS and MATERIAL:

(a) are to be used solely for non-commercial scientific and/or educational purposes, as described in Attachment 1;

(b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;

(c) are to be used only at the RECIPIENT ORGANIZATION and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and

(d) will not be transferred to anyone else within the RECIPIENT ORGANIZATION or to other Third Parties without the prior written consent of the PROVIDER and execution of an appropriate NPS agreement.

2. The RECIPIENT ORGANIZATION/SCIENTIST agree to annually notify the PROVIDER of any and all MATERIAL and MODIFICATIONS that result from the research described in Attachment 1.

3. The RECIPIENT ORGANIZATION/SCIENTIST agree to refer to the PROVIDER any thirdparty request for the PROVIDED ITEMS or MATERIAL other than requests from those persons working under the RECIPIENT SCIENTIST's direct supervision in the RECIPIENT SCIENTIST'S laboratory.

4. Under a separate agreement, the PROVIDER may allow the RECIPIENT ORGANIZATION to distribute MODIFICATIONS to third parties for non-commercial scientific and educational purposes only. Such agreement will be subject to Condition 7 below.

5. The RECIPIENT ORGANIZATION/SCIENTIST agree to notify the PROVIDER of every discovery or invention that relates in any respect to RESEARCH RESULTS, including MODIFICATIONS, derived from study of PROVIDED ITEMS prior to any public disclosure, within thirty (30) days of making an invention disclosure to the person(s) responsible for patent matters in the inventing organization, and within thirty (30) days of filing any type of application for a patent or other intellectual property claim in the United States or other country. Parties that elect not to file patent applications on such subject inventions must so advise PROVIDER no less than thirty (30) days prior to any disclosure to the public and within (90) days from the date of notifying PROVIDER of the subject inventions.

6.Except as provided in this Agreement, no express or implied licenses or other rights are provided to the RECIPIENT ORGANIZATION/SCIENTIST under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER or PROVIDER SCIENTIST, including any altered forms of the COLLECTED SPECIMEN or MATERIAL made by the PROVIDER or PROVIDER SCIENTIST. In particular, no express or implied licenses or other rights are granted to use the PROVIDED ITEMS, MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER or PROVIDER SCIENTIST for COMMERCIAL PURPOSES.

7. If the RECIPIENT ORGANIZATION/SCIENTIST desires to use or license MATERIAL or MODIFICATIONS or RESEARCH RESULTS they create from the PROVIDED ITEMS for COMMERCIAL PURPOSES, the RECIPIENT ORGANIZATION and RECIPIENT

SCIENTIST agree, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial use agreement, benefits-sharing agreement, or license. The RECIPIENT ORGANIZATION/SCIENTIST understand that the PROVIDER shall have no obligation to grant such a license or agreement to the RECIPIENT ORGANIZATION/SCIENTIST and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the PROVIDER'S rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the federal government. If RECIPIENT ORGANIZATION/SCIENTIST are party to a current benefit-sharing or other equivalent agreement or either RECIPIENT ORGANIZATION or RECIPIENT SCIENTIST is a licensee or sub-licensee of a third party with a current benefit-sharing or other equivalent agreement, this condition applies only to commercial uses of MATERIAL, MODIFICATIONS, or other RESEARCH RESULTS other than those uses identified in the aforementioned agreement(s).

8. Any PROVIDED ITEM delivered pursuant to this Agreement is understood to be as collected or as prepared by the PROVIDER SCIENTIST, to be experimental in nature, and to potentially have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

9. Except to the extent prohibited by law, the RECIPIENT ORGANIZATION/SCIENTIST assume all liability for damages that may arise from their use of the PROVIDED ITEM or MATERIAL or RESEARCH RESULTS, or from their storage or disposal of the PROVIDED ITEM. RECIPIENT ORGANIZATION/SCIENTIST agrees to hold harmless and indemnify PROVIDER for any claim asserted by a third party related to RECIPIENT ORGANIZATION/SCIENTIST use, storage, or disposal of the PROVIDED ITEM, MATERIAL OR RESEARCH RESULTS. The PROVIDER will not be liable to the RECIPIENT ORGANIZATION/SCIENTIST for any loss, claim or demand made by the RECIPIENT ORGANIZATION/SCIENTIST, or made against the RECIPIENT ORGANIZATION/SCIENTIST by any other party, due to or arising from the use of the PROVIDED ITEM or MATERIAL or RESEARCH RESULTS by the RECIPIENT ORGANIZATION/SCIENTIST, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.

10. This agreement shall not be interpreted to prevent or delay publication of findings and RESEARCH RESULTS from the use of the PROVIDED ITEM or MATERIAL or MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the PROVIDED ITEM in all publications and other references including patent applications. The credit shall include the full name of the PROVIDER, the Permit number, the scientific name of the PROVIDED ITEM , the scientific name of any other MATERIAL, and, as applicable, NPS and other catalog number(s).

RECIPIENT ORGANIZATION/SCIENTIST agree to give PROVIDER a copy of any final reports, publications, or, in the absence of final reports and publications, other findings and RESEARCH RESULTS from use of the PROVIDED ITEMS and MATERIAL.

11. By accepting the PROVIDED ITEM, RECIPIENT ORGANIZATION/SCIENTIST agree to comply with all applicable terms and conditions of the NPS Scientific Research and Collecting Permit General Conditions available on the NPS Research Permit and Reporting System web site at <u>https://irma.nps.gov/content/RPRS/Index2.aspx</u> and with park-specific permit conditions, if any, applicable to the permit(s) cited under Section I.6 that are available from the PROVIDER.

12. The RECIPIENT ORGANIZATION/SCIENTIST agree to use the PROVIDED ITEM and any MATERIAL and RESEARCH RESULTS in compliance with all applicable statutes and regulations, including Department of Agriculture, Public Health Service and National Institutes of Health regulations and guidelines, such as those relating to research involving the use of animals or recombinant DNA. RECIPIENT ORGANIZATION/SCIENTIST are responsible for compliance with all applicable foreign and domestic federal, state and local statutes, ordinances and regulations. Any shipment of the PROVIDED ITEMS and/or MATERIAL to countries outside the United States must comply with all applicable U.S. laws, including the U.S. export control laws and related regulations.

13. This Agreement will terminate on the earliest of the following dates: (a) when the RECIPIENT ORGANIZATION/SCIENTIST return the PROVIDED ITEMS and all MATERIAL to the PROVIDER or follow the PROVIDER'S written instructions for disposition; (b) when the RECIPIENT ORGANIZATION/SCIENTIST notify and provide written evidence to the PROVIDER that the PROVIDED ITEMS and MATERIAL have been consumed in analysis or destroyed, consistent with any paragraph 17 below, and nothing remains; (c) on completion of the RECIPIENT ORGANIZATION/SCIENTIST's research described in Attachment 1; (d) on thirty (30) days' written notice by either party to the other; or (e) on the date, if any, herein specified—*[enter termination date, if any]*, provided that:

(i) if termination should occur under 13(a), (b), or (c), above, the RECIPIENT ORGANIZATION/SCIENTIST will discontinue use of the PROVIDED ITEMS and MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining PROVIDED ITEM or MATERIAL. The RECIPIENT ORGANIZATION, at its discretion, will also either destroy the MODIFICATIONS it has developed or remain bound to the PROVIDER by the terms of this agreement as they apply to MODIFICATIONS and RESEARCH RESULTS; and

(ii) in the event the PROVIDER terminates this Agreement under 13(d) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT ORGANIZATION, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT

ORGANIZATION/SCIENTIST will discontinue their use of the PROVIDED ITEMS and MATERIAL and will, upon written direction of the PROVIDER, return or destroy any remaining PROVIDED ITEMS and MATERIAL, or follow other written disposition instructions that the PROVIDER may issue. The RECIPIENT ORGANIZATION/SCIENTIST, at their discretion, will also either destroy the MODIFICATIONS or remain bound to the PROVIDER by the terms of this agreement as they apply to MODIFICATIONS and RESEARCH RESULTS.

14. Under Section II, paragraphs 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 shall survive termination.

15. The PROVIDED ITEMS are supplied at no charge by the PROVIDER.

[Include the conditions 16 and 17 only for a CSTA. Delete for an MTA.]

16. Each COLLECTED SPECIMEN (or group of specimens labeled as a group) is federal property. For COLLECTED SPECIMENS that the RECIPIENT SCIENTIST recommends for permanent retention, the RECIPIENT SCIENTIST and RECIPIENT ORGANIZATION must work with the PROVIDER to ensure that the specimen(s) a) bear NPS labels, b) are accessioned, c) are cataloged in the appropriate NPS catalog system, and d) are returned to the PROVIDER or placed on loan by the PROVIDER to an NPS-designated repository.

17. Because COLLECTED SPECIMENS are federal property, they shall not be destroyed or discarded unless NPS has authorized as follows: *[Leave boxes unchecked to prohibit destruction and/or discard.]*

- Destruction and/or discard is authorized for all COLLECTED SPECIMENS
- Destruction and/or discard is authorized for the following COLLECTED SPECIMENS only: *[List]*

BY SIGNING BELOW, THE DULY AUTHORIZED REPRESENTATIVE OF THE RECIPIENT ORGANIZATION ACKNOWLEDGES THAT HE/SHE HAS READ AND UNDERSTANDS THIS NATIONAL PARK SERVICE AGREEMENT AND UNDERSTANDS AND AGREES TO ITS TERMS AND CONDITIONS ON BEHALF OF THE ORGANIZATION AND RECIPIENT SCIENTIST AS EVIDENCED BY HIS/HER SIGNATURE BELOW, AND THE RECIPIENT SCIENTIST HAS READ AND UNDERSTANDS AND AGREES TO THE TERMS AND CONDITIONS OF THIS AGREEMENT AS EVIDENCED BY HIS/HER SIGNATURE BELOW.

RECIPIENT ORGANIZATION:

[Insert name and title of Responsible Official who can legally

bind the organization and recipient scientist]

[Insert name of Recipient Organization]

RECIPIENT SCIENTIST:

[Insert name and title] [Insert name of Recipient Organization]

PROVIDER:

[Insert name and title of Responsible Official—generally the Superintendent]

[Insert name of Provider]

August 18, 2014, Updated October 16, 2018

Date

Date

Date

Attachment 1 Proposed Research/Use Plan

Appendix D: Information and Training Resources

Information Resources

American Type Culture Collection (ATCC)—<u>http://www.atcc.org/</u>

NPS Special Collection at ATCC—<u>https://www.atcc.org/microbe-products/collections-and-projects/us-national-park-service-special-</u>collection#t=productTab&numberOfResults=24

Patent Deposits at ATCC-https://www.atcc.org/services/depositing-with-atcc/patent-deposit

Association of University Technology Managers

Technology transfer resources (includes information on the Universal Biological Material Transfer Agreement [UBMTA])—<u>http://autm.net/</u>

Bureau of Reclamation-https://www.usbr.gov/research/technology_transfer/index.html

Convention on Biological Diversity-http://www.cbd.int/

Access and benefits sharing of genetic resources—<u>http://www.cbd.int/abs/</u>

Department of the Interior-http://www.doi.gov/techtransfer/index.cfm

Departmental Manual (DM) chapters-<u>https://www.doi.gov/elips/browse</u>

Delegations of Authority relevant to Technology Transfer-207 DM 8

Technology Transfer—761 DM 1

Inventions and Patents-453 DM

Copyright-454 DM

Licensing Executives Society (USA and Canada), Inc. (LES)-http://www.lesusacanada.org/

Licensing Executives Society International, Inc. (LESI)-http://www.lesi.org/

Federal Laboratory Consortium for Technology Transfer (FLC)-http://www.federallabs.org/

The Green Book: Federal Technology Transfer Legislation and Policy, prepared by the Federal Laboratory Consortium for Technology Transfer https://www.federallabs.org/media/publication-library/federal-technology-transferlegislation-and-policy-the-green-book

U.S. Department of Agriculture, Agricultural Research Service (ARS)

Office of Technology Transfer-http://www.ars.usda.gov/business/business.htm

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Plant and Animal Genetic Resources Preservation: USDA Agricultural Research Service (includes the former National Seed Storage Laboratory, and National Center for Genetic Resources Preservation)—<u>https://www.ars.usda.gov/plains-area/fort-collins-co/center-for-agricultural-resources-research/paagrpru/</u>

National Institute of Standards and Technology (NIST)-http://www.nist.gov/index.html

Technology Partnerships Office (TPO)—<u>http://www.nist.gov/tpo/index.cfm</u>

Reports and Publications (including Department of Commerce Annual Reports to the Office of Management and Budget on Technology Transfer and Federal Laboratory (Interagency) Technology Transfer Summary Reports) http://www.nist.gov/tpo/publications/index.cfm

National Institutes of Health (NIH)-https://www.ott.nih.gov/resources

National Park Service

Archeological research and collection—Information on permits for archeological research and collecting under the Antiquities Act and Archaeological Resource Protection Act is at http://www.nps.gov/archeology/npsGuide/permits/index.htm

Management Policies, Director's Orders (DOs), and procedural guidance https://npspolicy.nps.gov/

Benefits-sharing-https://www.nps.gov/nature/benefits-sharing.htm

Templates (for NPS users)—<u>https://doimspp.sharepoint.com/sites/</u>nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

Final Environmental Impact Statement and Record of Decision—These documents are available through the NPS Electronic Technical Information Center at <u>https://pubs.nps.gov/</u> under the numbers 118039 (FEIS) and 118043 (ROD).

Museum Handbook-http://www.nps.gov/history/museum/publications/handbook.html

Research Permit and Reporting System (RPRS) --- https://irma.nps.gov/rprs/Home

State Science and Technology Institute (SSTI)-http://www.ssti.org/

U. S. Geological Survey (USGS)-https://www.usgs.gov/technology-transfer

United States Patent and Trademark Office (USPTO)-<u>http://www.uspto.gov/about/index.jsp</u>

Procedures for deposit of biological materials for patents (see this and following pages) http://www.uspto.gov/web/offices/pac/mpep/documents/2400_2401.htm

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Requirements for acceptable depositories for Biotechnology http://www.uspto.gov/web/offices/pac/mpep/documents/2400_2405.htm

General information on searching for patents http://www.uspto.gov/patents/process/search/index.jsp

Entry page to search for patents and published patent applications-<u>http://patft.uspto.gov/</u>

World Federation for Culture Collections-http://www.wfcc.info/

Training Resources

Association of University Technology Managers

Careers and Courses-<u>https://autm.net/careers-and-courses</u>

Federal Laboratory Consortium for Technology Transfer

Learning Center-https://www.federallabs.org/learning-center

Training listed on FLC regional web sites-http://www.federallabs.org/regions/

United States Patent and Trademark Office (USPTO)

USPTO Intellectual Property (IP) eLearning Modules http://www.uspto.gov/ip/training/elearn.jsp

Appendix E: Example NPS Letter of Agreement to Decline Benefits Sharing

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

NATIONAL PARK SERVICE

LETTER OF AGREEMENT

[Date]

[Enter name, title, organization, address of responsible official of organization seeking authorization.]

Dear _____,

In consideration of mutual interests, the National Park Service (NPS) has determined that it will not require benefits sharing with respect to the "Commercial Use of Research Results" described below. Upon your signature, this Letter of Agreement will meet your obligation to enter into a benefits-sharing agreement regarding the described "Commercial Use of Research Results."

This Letter of Agreement pertains to the "Commercial Use of Research Results" and related matters identified as follows:

Commercial Use of Research Results: [Describe the research results and the specific commercial use of research results covered by this agreement letter.]

Collected specimen, museum specimen, living collection item, or Material: [Identify each collected specimen, museum specimen, living collection item, or Material associated with the research results that are to be commercialized). For multiple items, reference here and attach a list as Attachment 2. For each entry of a collected specimen, museum specimen, living collection item, or Material, provide the associated Scientific Research and Collecting Permit Number, and as applicable, Collected Specimen Transfer Agreement Number, Material Transfer Agreement Number, catalog number, and loan agreement number. Enter locality, and, as applicable, collection number.]

NOTE! Identify in writing information that is confidential, such as NPS locality data that qualifies for exemption under FOIA.

NPS Scientific Research and Collecting Permit number: Locality where collected: Collection Number (field number that the collector assigns to the specimen): Collected Specimen Transfer Agreement Number:

NPS Benefits-Sharing Handbook Appendix E: Example NPS Letter of Agreement to Decline Benefits Sharing

Material Transfer Agreement Number: Catalog number: Loan agreement number:

All applicable terms and conditions in existing permits and agreements pertaining to the collected specimen, museum specimen, living collection item, Material, and research results (as defined in those permits and agreements) remain in force. If you propose commercial use of research results outside the use described in this Letter of Agreement, then you are obligated to return to NPS for potential benefits-sharing agreements. *[State any additional park-specific terms, as needed.]*

By signing this Letter of Agreement, and, to the extent allowed by law, *[XYZ]* holds the U.S. Government harmless and indemnifies the Government for all liabilities, demands, damages, expenses, and losses arising out of the research, development, sale, other disposition, or any other use of the described research results by *[XYZ]*, or any party acting on its behalf or under its authorization. The Government shall not be considered an assignee or licensee of *[XYZ]*, and this Letter of Agreement shall not be construed as constituting the foundation of a partnership, association, agency, joint venture or any other entity.

This Letter of Agreement will be in force upon signature by all parties. Please return a signed copy to *[insert name of park]*.

Sincerely,

Superintendent, [insert name of park]

Date

By signing below, I agree to the terms of this Letter of Agreement

Responsible Official, [XYZ] [Enter name and title of responsible official] Date

cc: WASO Benefits-Sharing Coordinator

Appendix F: Template for a Cooperative Research and Development Agreement for Benefits Sharing

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

[Remove all notes and instructions before sending a draft to the Partner for review.]

[Place the following confidentiality statement on the cover of the agreement. Modify it to specifically address the contents of the agreement.]

Confidentiality Notice

The following items in this Agreement [provide the title of the Agreement and Agreement number] are marked confidential as protected by law: [list the protected clauses]

This information must be withheld from unauthorized individuals.

[Insert a page break.]

Agreement # [PARK]-2014-1.0

[Enter identification number consisting of PARK acronym - year - sequential number. revision number (0 for the first version).]

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA) FOR BENEFITS SHARING

between

THE UNITED STATES DEPARTMENT OF THE INTERIOR NATIONAL PARK SERVICE

[insert NPS unit name]

and

[insert Partner's full name]

ARTICLE I. Background and Objectives

WHEREAS, the National Park Service (NPS) mission in managing units of the National Park System is "to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations" (54 USC 100101); and

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WHEREAS, NPS coordinates research activities, facilitates the exchange of research-related information pertaining to the natural resources found in units of the National Park System, and otherwise manages the use of national park resources in part for purposes of scientific study by federal agencies and non-federal public and private agencies, organizations, individuals, or other entities (54 USC 100705); and

WHEREAS, the *[Insert park name and acronym, use acronym (PARK) for the rest of the CRADA]* fosters scientific research and NPS has determined that *[PARK]* is a "federal laboratory" within the meaning of 15 USC 3710a(d)(2); and

WHEREAS, [Insert Partner's name and acronym (XYZ)—use the acronym for the rest of the CRADA] is dedicated to [XYZ inserts brief statement], [if applicable, XYZ inserts "is a small business as defined by the Small Business Administration"], and agrees to cooperate with NPS to undertake beneficial scientific research relating to certain scientific specimens collected from [PARK], and to share information and data resulting from such research that [PARK] may use to protect and monitor [PARK] resources; and

WHEREAS, *[XYZ]* agrees and recognizes that efforts by *[PARK]* to "conserve the scenery and the natural and historic objects and the wild life therein" contribute significantly to *[XYZ]*'s research and development of potentially useful Discoveries resulting from scientific research activities undertaken in *[PARK]*; and that the aforesaid protection of *[PARK]* resources requires sophisticated interdisciplinary scientific work by *[PARK]* staff and coordinated effort by *[PARK]* management "necessary to assure the full and proper utilization of the results of scientific study for park management decisions" (54 USC 100706); and

WHEREAS, *[PARK]* agrees and recognizes that *[XYZ]* has invested and intends to continue to invest significant time, expertise, and expense in research and development activities and infrastructure that facilitate development of useful Discoveries resulting from scientific research activities based on research specimens collected from *[PARK]*; and

WHEREAS, [XYZ] has used Research Results based on study of [PARK] Collected Specimens to develop [XYZ inserts non-confidential description of any existing Product or describes the anticipated Future Product(s), and lists any granted patents] for the purpose of [XYZ describes the Commercial Purpose(s)]; and has [XYZ describes the efforts taken so far by XYZ to advance the R&D towards Commercial Use.]

NOW THEREFORE, acting separately, not being agents of each other, and consistent with the terms and conditions of existing agreements between *[PARK]* and *[XYZ]* or other entities pertaining to the Collected Specimen, Museum Specimen, or Living Collection Item, and/or Material as follows:

[Insert a bulleted list of Scientific Research and Collecting Permits, CSTAs, MTAs, loan agreements, and any other pertinent documents. Delete reference to Museum Specimen and Living Collection Item if they do not apply.],

the parties agree as follows.

ARTICLE II. Authorities

A. NPS enters into this Agreement pursuant to the following authorities: National Park Service Organic Act, as amended, 54 USC 100101-100303; the Federal Technology Transfer Act (FTTA), as amended, 15 USC 3701–3715; and, the National Parks Omnibus Management Act of 1998 (54 USC 100702-100706).

B. XYZ enters into this Agreement pursuant to the following authorities: *[XYZ enters authorities, if applicable, otherwise delete]*

ARTICLE III. Definitions

A. Collected Specimens

The item collected by the permittee under the authority of an NPS Scientific Research and Collecting Permit, and portions thereof. Collected Specimens are natural products.

B. Commercial Purpose

See Commercial Use.

C. Commercial Use

Use of Material or Modifications or other Research Results in a product, service, or process resulting in a product or service that is sold, leased, licensed, or otherwise transferred for value received.

D. Confidential Information

Any information or material in tangible form that is marked as Confidential or Proprietary by the furnishing party at the time it is delivered to the receiving party, and information that is furnished orally if the furnishing party identifies such information as confidential or proprietary when it is disclosed and promptly confirms such designation in writing after such disclosure. Confidential Information does not include:

1) information that is publicly known or available from other sources who are not under a confidentiality obligation to the source of the information; or

2) information that has been made available by its owners to others without a confidentiality obligation; or

3) information that is already known by or available to the receiving party without a confidentiality obligation; or

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4) information that relates to potential hazards or cautionary warnings associated with the handling, use or disposal of NPS specimens; or

5) information that is required by other applicable law or by an agreement to be disclosed.

E. Discovery

New knowledge gained through search or study.

F. Future Product

Any Modification, Subject Invention or any other commercially valuable or otherwise useful material, compound or useful combination of compounds, protein, or metabolite recovered, obtained, derived, resulting, or otherwise isolated by scientific research conducted on Collected Specimens collected from *[PARK]*, Progeny, or Unmodified Derivatives, or any derivative or analog of such material, compound, protein, metabolite or other isolate, or any Discovery that is or may be patentable or otherwise protected under 35 USC (Patents), or any novel variety of plant that is or may be protectable under 7 USC 2321 *et seq.* (Plant Variety Protection) and developed from Collected Specimens collected from *[PARK]*, Progeny, or Unmodified Derivatives.

G. Intellectual Property

Creations of the mind for which a set of exclusive rights may be recognized by law. Intellectual Property includes, but is not limited to, Inventions, Discoveries, copyright, patents, trademarks, trade secrets, certain forms of traditional knowledge, and other forms of comparable knowledge.

H. Invention

Any Discovery, thing, method, material, process or idea that might be patentable or otherwise protected under 35 USC (Patents), 7 USC 2321 *et seq*. (Plant Variety Protection), and 18 USC 1905 (Trade Secrets).

I. Living Collection

Biological material that is permanently retained *ex situ* for the purpose of generating and providing living or otherwise biologically active material for research, restoration, education or other purposes. Living Collections are retained in an NPS or non-NPS repository, documented, and tracked. Items in a living collection may be the Collected Specimen, or may originate directly from a Collected Specimen, from Material, or from other biological material in the Living Collection.

J. Living Collection Item

An organism, component from an organism, or Material maintained in a living collection.

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K. Material (when capitalized)

Progeny and Unmodified Derivatives of Collected Specimens, Museum Specimens, Living Collection Items, and multiple generations thereof. The Material does not include a) Modifications or b) other substances created by a person through the use of the Material that are not Modifications, Progeny, or Unmodified Derivatives. See Modification.

L. Modification

A human-created substance that contains or incorporates Material (Progeny and/or Unmodified Derivatives).

M. Museum Specimen

A collected specimen that is permanently retained in a park museum collection. A museum specimen is non-living.

N. Net Sales

The total gross receipts that *[XYZ]*, its licensees or sublicensees receives for sales of Material, Subject Inventions, or Product(s), or copyrighted works created using the results of research under this Agreement, and from otherwise making Material, Subject Invention(s), or Product(s) available to others without sale, whether invoiced or not, less returns and allowances actually granted, packing costs, insurance costs, freight out, taxes and excise duties imposed on the transaction (if separately invoiced), and the wholesaler and cash discounts in amounts customary in the trade. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by *[XYZ]*, its licensee or sublicensees, or for the cost of collections.

O. Product

[Describe the Research Result that is the subject of the proposed commercialization. The Research Result may have been patented or otherwise prepared for market.]

P. Progeny

Unmodified descendant from a Collected Specimen or Material, such as virus from virus, cell from cell, or organism from organism.

Q. Proprietary Information

Information that embodies trade secrets or that is confidential technical, business, or financial information provided that such information:

(i) Is not generally known or available from other sources without obligations concerning its confidentiality;

(ii) Has not been made available by the owners to others without obligations concerning its confidentiality; and

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(iii) Is not already available to the Government without obligations concerning its confidentiality.

R. Research Results

Material (including Material retained in a living collection), modifications, Intellectual Property, Inventions, data, Discoveries, and/or other knowledge, processes, products, or applications resulting from research activities of researchers or their institutions or companies.

S. Subject Data

All recorded information first produced in the performance of work under the Permits, Collected Specimen Transfer Agreements (CSTA), Material Transfer Agreements (MTAs), loan agreements, or this Agreement.

T. Subject Invention

Any Invention conceived or first actually reduced to practice in the performance of work under the Permits, CSTAs, MTAs, and/or loan agreements listed in Article I, or under this Agreement.

U. Unmodified Derivative

A human-created substance that is not a portion of the Collected Specimen and, instead, constitutes an unaltered copy of a functional subunit or of a product expressed by the Collected Specimen or Material. Some examples include: copies of cells of the Collected Specimen, purified or fractionated subsets of the Material, proteins expressed by DNA/RNA extracted from the Collected Specimen or Material.

ARTICLE IV. Statement of Work

A. [XYZ] [This section must be written specifically for the technology covered by the CRADA].

1. *[XYZ]* or its licensees or sublicensees under its authority will prepare the Product for market. Work will include but not be limited to *[Include this clause only if a Product has been identified and defined above under "Definitions." Provide a non-confidential description of the work.]*

2. *[XYZ]* or its licensees or sublicensees under its authority may perform additional work to discover further Commercial Uses for the Product or Future Product. *[Delete reference to Product in this clause if it has not been defined under "Definitions."]*

B. NPS

1. NPS will conserve and protect the resources and values of *[PARK]*, including protecting from adverse impacts the site where the research specimens were collected.

2. NPS may facilitate *[XYZ]* research of Product and Future Product, as needed, by contributing labor, expertise, equipment, facilities, information, computer software, and other forms of laboratory support, subject to available funding and compliance with applicable laws and regulations. *[Delete the word "Product" if Product has not yet been identified.]*

ARTICLE V. Terms and Conditions

A. Pre-Existing NPS Permits and Agreements

The terms and conditions of all applicable Permits, CSTAs, MTAs, and/or loan agreements as listed above in Article I, Background and Objectives, shall remain in force throughout the Agreement and shall survive termination.

B. Commercialization of Future Product

Use of Future Product for a Commercial Purpose that may be identified during the course of research and development requires an amendment to this Agreement pursuant to Article XII.A, Amendments. Should future research lead to development of Future Product that appears to have a Commercial Purpose, *[XYZ]* or its licensees or sublicensees must obtain all applicable federal, tribal, state or other permits.

C. Practical Application of Product

[XYZ] shall expend reasonable efforts and resources to bring the Product to the point of practical application meaning to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the Invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms. *[XYZ]* shall offer the Product for distribution and/or sale within

[Ask XYZ to provide the number of years] year(s) of the Effective Date of this Agreement unless this period is extended by mutual agreement of the parties. NPS shall not unreasonably withhold approval of any request by [XYZ] to extend this period if such request is supported by evidence of reasonable efforts by [XYZ] to bring the Product to practical application, meaning distribution and/or sale, including any reasonable and diligent application for regulatory approvals required by any federal, tribal, state or other government agency in the United States.

[If no Product has emerged yet, substitute the following paragraph C and recognize that many years may pass before a Product can be sold.]

[XYZ] shall expend reasonable efforts and resources to identify a Product. [XYZ] shall offer the Product for sale within _____ [Ask XYZ to provide the number of years] year(s) of the Effective Date of this Agreement unless this period is extended by mutual agreement of the parties. NPS shall not unreasonably withhold approval of any request by [XYZ] to extend this period if such request is supported by evidence of reasonable efforts by [XYZ] to bring the Product to practical application, including any reasonable

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and diligent application for regulatory approvals required by any federal, tribal, state or other government agency in the United States.

D. Availability of Product

After bringing the Product to the point of practical application in the United States, *[XYZ]* shall keep the Product reasonably available to the United States public during the term of this Agreement.

E. [XYZ] Licensing

[XYZ], at any time, may license or sublicense in whole or in part, any rights and interests that NPS grants to [XYZ] under the terms and conditions of this CRADA. [XYZ] may exercise such right without obtaining additional authorization from NPS, but [XYZ] expressly agrees that in so licensing or sublicensing, it will specifically reserve to NPS all rights and privileges provided in this Agreement for NPS, including the provisions of the appendices. In the event of a license or sublicense, [XYZ] will notify NPS of each license and sublicense.

F. Required Permits

[XYZ] and its licensees or sublicensees must obtain all additional permits required by federal, tribal, state or other government agency in the United States to carry out research and development and ultimately, as appropriate, commercialization of the Product and Future Product, including, but not limited to, public health and environmental compliance. [XYZ] shall provide and shall require its licensees or sublicensees to provide scientific and other information as required by the permitting agency for any associated environmental analyses and shall also appropriately apply the permitting agency's findings from any associated environmental analyses in accordance with the National Environmental Policy Act, the Endangered Species Act or other legal requirements, as applicable.

G. Intellectual Property and Data

1. [XYZ] Inventions

[XYZ] may retain title to any Subject Invention made solely by its employees or assigned to [XYZ]. [XYZ] may choose to file patent applications on such Subject Inventions at its own expense and in a timely fashion. [XYZ] may elect not to file patent applications on such Subject Inventions provided that it so advises NPS within ninety (90) days from the date it reports the Subject Inventions to NPS as required in Article IX.B.1. Thereafter, NPS may elect to file patent applications on the Subject Inventions and [XYZ] agrees to assign its right, title and interest in such Subject Inventions to NPS and cooperate with NPS in the preparation and filing of patent applications thereon. The assignment of the entire right, title and interest shall be subject to [XYZ]'s retention of a nonexclusive, irrevocable, paid-up license to practice, or have practiced, the Subject Inventions throughout the world.

2. Grant of License to U.S. Government

[XYZ] agrees to grant to the U.S. Government a nonexclusive, nontransferable, irrevocable, paid-up license in the patents that cover Subject Inventions and are assigned to [XYZ] to practice the Invention or have the Invention practiced, throughout the world by or on behalf of the U.S. Government. Such nonexclusive license shall be evidenced by a confirmatory license agreement prepared by [XYZ] in a form satisfactory to NPS.

3. U.S. Government Rights

The parties understand that the Government shall have unlimited rights in all information provided to the parties under this CRADA providing that such information is not marked as being copyrighted or as Proprietary Information pursuant to Article IX.B.2. *[XYZ]*, unless otherwise agreed to in writing by both parties, hereby grants to NPS the right to use, reproduce, create derivative works, distribute and display such research reports (as described in Article IX.B.3) in any media now known or utilized in the future and allow others to do so on its behalf or as otherwise required for any research, educational or government purpose.

ARTICLE VI. Term of Agreement

A. Effective Date [Use only one of the following two paragraphs.]

[Select this paragraph if the Product has been successfully patented] This Agreement shall enter into force as of the date of the last signature of the parties as shown on the signature page and, unless the Agreement is terminated subject to Article XII.B, will remain effective until the last patent for the Product and any Future Products has expired or been abandoned.

[Select this paragraph if patents have not been issued] This Agreement shall enter into force as of the date of the last signature of the parties as shown on the signature page and, unless the Agreement is terminated subject to Article XII.B, will remain effective for an initial term of five (5) years from the Effective Date. [XYZ] shall have the right to renew this Agreement for successive periods up to five (5) years upon written notice mailed to [PARK] at least sixty (60) days prior to the expiration of the initial term and each subsequent renewal term, provided, however, that [XYZ] shall have no right to renew this Agreement in the event that either party hereto has exercised a right of termination under Article XII.B or in the event that [XYZ] is not making good faith efforts to bring the Product or any Future Product(s) to the point of practical application as defined in Article V.C. [Delete the word "Product" if a product has not been identified in Article III.]

ARTICLE VII. Key Officials

A. Key Official Contacts

Key officials are essential to ensure maximum coordination and communications between the parties regarding the work being performed.

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 For [PARK]: Key Official Name Title
 Park Name
 Park Street/P.O. Box
 Park City, State, Zip Code
 Phone
 Fax
 Email
 For [XYZ]:
 Key Official Name
 Title
 Organization Name
 Organization Street/P.O. Box
 Organization City, State, Zip Code

Fax Email

Phone

B. Communications between Key Officials

[XYZ] will address any communication regarding this Agreement to the [PARK] Key Official with a copy to the [PARK] superintendent.

[PARK] will address any communication regarding this Agreement to the [XYZ] Key Official.

ARTICLE VIII. Prior Approval

[Include any prior approvals other than the prior approval for Attributions in XIII.B.2.]

ARTICLE IX. Deliverables and Reports

A. Benefits-Sharing Obligation

1. [Use only one of the following two paragraphs.]

[If a Product has been identified in Article III, use this paragraph.] [XYZ] will share benefits with NPS as described and scheduled in Appendices A (monetary benefits) and B (non-monetary benefits).

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[If a Product has not been identified yet and if NPS has decided to negotiate benefits at a later date use this paragraph and reference the future negotiations in Appendices A and B.] Should [XYZ] develop Subject Inventions and Research Results related to specimens collected under the NPS Scientific Research and Collecting Permit(s) cited in Article I for potential future commercial or other revenue-generating purposes, this Agreement must be amended pursuant to Article XII.A prior to use of Future Product for Commercial Purpose pursuant to Articles V.B.

2. Payment Method

[XYZ] will make on-time payments in U.S. Dollars as set forth in Appendix A, net of all non-U.S. taxes (if any) to [Enter PARK and assigned Pay.Gov Form Number] in Pay.Gov. These payments include a one-time upfront payment, annual maintenance payments, and performance-based payments [delete any payment types that do not apply]. Except for the up-front payment, all payments are to be made annually on October 1. NPS reserves the right to change the method of payment with 30 days' notice.

3. Late Payments

[XYZ] will pay interest on overdue amounts for each 30-day period, or portion thereof, that payment is delayed beyond the periods described in Appendix A. The percent of interest charged will be based on the Treasury Current Value of Funds Rate (CVFR) for overdue federal government receivables as published annually in the Federal Register by October 31, and recalculated quarterly with revisions, if any, posted in a Treasury Financial Manual (TFM) Bulletin (see https://tfm.fiscal.treasury.gov/v1/bull.html).

4. Non-monetary Benefits

[XYZ] will provide non-monetary benefits to NPS as shown in Appendix B. In cases where [XYZ] is a federal entity, it may grant to NPS right, title, or interest in its federally owned Invention (a non-monetary benefit), which grant entitles NPS to seek monetary benefits from third parties receiving separately negotiated licenses (35 USC 207).

5. Use of Benefits by NPS

NPS will use monetary and non-monetary benefits received to conserve resources protected and managed by the NPS, and as otherwise consistent with the FTTA.

6. Overpayments

NPS will offset any [XYZ] overpayments against payments due the following year.

B. Reports

1. Disclosure of Inventions and Patents

[XYZ] agrees to disclose to NPS every Subject Invention that may be patentable or otherwise protectable prior to any disclosure to the public, within thirty (30) days of making an Invention disclosure to the person(s) responsible for patent matters in the inventing organization, and within thirty (30) days of filing in the United States or other country any type of application for a patent or other Intellectual Property claim for the Subject Invention. These disclosures should be in sufficient enough detail to enable a reviewer to make and use the Invention under 35 USC 112. The disclosure shall also identify any statutory bars, such as printed publications describing the Subject Invention or public use or sale of the Subject Invention in the United States. [XYZ] further agrees to disclose to NPS any subsequent statutory bar that occurs for a Subject Invention disclosures shall also and use for which a patent application has not been filed. All such disclosures shall be marked as Confidential under 35 USC 205.

2. Proprietary Information

[XYZ] shall place a Proprietary notice on all information it delivers to NPS under this Agreement that [XYZ] asserts is Proprietary Information, as defined in Article III. NPS agrees that it will use any information that [XYZ] designates as Proprietary and furnishes to NPS under this Agreement, only for the purpose of carrying out this Agreement. NPS agrees not to disclose, copy, reproduce, or otherwise make available in any form whatsoever information designated as Proprietary to any other person, firm, corporation, partnership, association, or other entity without the consent of [XYZ], except as such information must be disclosed under the Freedom of Information Act, as amended (5 USC 552, et seq.) provided, however, that such data shall not be released to the public if a patent application is to be filed (35 USC 205) until the party having the right to file the patent application has had a reasonable time to file. NPS agrees to use its best efforts to protect information designated as Proprietary from unauthorized disclosure. [XYZ] agrees that NPS is not liable for the disclosure of information designated as Proprietary for which, after notice to and consultation with [XYZ], a court of competent jurisdiction requires disclosure.

3. Research Report

[XYZ] will prepare and provide to NPS an annual written report concerning the research and development and Commercial Uses addressed in this Agreement, which report shall identify and summarize all patents, Inventions, Research Results, research plans, and status of compliance with all applicable permits, laws, and regulations for the year of the report. Upon receipt of the report, NPS has the right to require additional details and copies of documents summarized in the report. In the event [XYZ] asserts that particular information delivered to NPS is Proprietary, [XYZ] agrees additionally to provide to NPS a non-confidential, non-proprietary summary of such information for public disclosure.

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4. Payment Report

[Select this paragraph about license income for CRADAs if Partner licenses the technology.] Concurrently with each payment, [XYZ] shall submit a written report to NPS setting forth (a) the period to which the payment applies, and for the applicable period, (b) the amount and type of license income received pursuant to the Statement of Work, and (c) the calculation of payments due to NPS. If no payments are due NPS for any report period, the report shall so state.

[Select this paragraph about Net Sales if a Partner sells the Product(s).] Concurrently with each payment, or at such other time as payments are due, [XYZ] shall submit a written report to NPS setting forth (a) the period to which the payment applies, and for the applicable period (b) the amount and description of Net Sales upon which a payment is payable, (c) the total gross income realized by [XYZ] from the sale, licensing, or other provision of Material, Modifications, Subject Invention(s), or Product(s) to itself and others without sale, during such applicable period, and (d) the calculation of payments due to NPS. If no payments are due NPS for any report period, the report shall so state.

5. Records

[XYZ] agrees to keep records, as applicable, showing [XYZ]'s gross license income and the sales or other dispositions of all works upon which payments are due under the provisions of this Agreement. These records shall be in sufficient detail to enable NPS to determine the payments payable by [XYZ]. [XYZ] agrees to retain the records for a minimum period of five (5) years from the date a subject payment is due. [XYZ] further agrees to permit an auditor that NPS selects to examine [XYZ]'s books and records from time to time during its ordinary business hours and not more often than once a year to the extent necessary to verify the reports that Article IX.B requires. NPS will bear the initial expense of the audit. If the audit indicates that NPS was underpaid by at least ten percent (10%) for any calendar year, or five thousand dollars (\$5,000.00), whichever is greater, [XYZ] will reimburse NPS for the expense of the audit, together with an amount equal to the additional payments to which NPS is entitled and applicable interest calculated as described in Article IX.A.3.

ARTICLE X. Publications of Research Results

No party will unilaterally publish a joint publication without consulting the other party. This restriction does not apply to an individually published popular publication of previously jointly published technical matter. Publications pursuant to this Agreement may be produced independently or in collaboration with others; however, in all cases proper credit will be given to the efforts of those parties contributing to the information being published. In the event no agreement is reached concerning the manner of publication or interpretation of results, either party may separately publish its information after due notice and submission of proposed manuscripts to the other. In such instances, the party publishing the information will give due

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credit to the cooperation but assume full responsibility for any statements on which there is a difference of opinion.

NPS and *[XYZ]* agree to confer and consult at least thirty (30) days prior to either party's submission for publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. The party receiving the document for review has thirty (30) days from receipt to object in writing detailing the objections to the proposed submission. If the receiving party does not provide any objections within 30 days, the proposing party may proceed with publishing the document.

ARTICLE XI. Property Utilization

Unless otherwise agreed to in writing by the parties,

1. Any property furnished by *[XYZ]* to *[PARK]* will become the property of *[PARK]* and will be used and disposed of as set forth in this Agreement and in NPS Property Management Regulations; and

2. Any property furnished by [PARK] to [XYZ] will remain U.S. Government property.

ARTICLE XII. Modification, Termination and Disputes

A. Amendments

The Agreement may be modified by written consent of all of the parties to cover the need for any alterations that may arise subsequent to the Effective Date of this Agreement.

B. Termination

1. Either party has the right to terminate this Agreement if either party fails to observe any of the material terms and conditions of the Agreement, and, after sixty (60) days from receipt of written notice, fails to cure the default.

2. NPS shall have the right to immediately terminate this Agreement without written notice to [XYZ] in the event [XYZ] or its licensees does(do) any of the following: i. Files a petition in bankruptcy, or is adjudicated bankrupt or insolvent, or dissolves or discontinues its business, or makes an assignment for the benefit of creditors. [XYZ] must give NPS immediate notice (within five (5) days) of the filing of any petition in bankruptcy, filing of any petition seeking relief of the same or different kind under any provision of the Bankruptcy Act, or making any assignment for the benefit of creditors. For purposes of the bankruptcy statutes, NPS considers this Agreement an executory contract exempt from inclusion in the assets of [XYZ] pursuant to 11 USC 365.

ii. Upon the commencement of distribution and/or sale of Product, fails to distribute and/or sell any Product within one year.

iii. In case of the dissolution or cessation of operations by [XYZ].

3. Notwithstanding the foregoing, the NPS may terminate this Agreement for the convenience of the Government, at any time, when it is determined to be in the best interest of the public to do so. NPS shall notify *[XYZ]* within five (5) working days following the termination.

4. Termination Report

In the event of termination, *[XYZ]* will prepare a report on results to date of termination and the cost of the report will be deducted from any amounts due to NPS. This provision shall survive termination of the Agreement.

5. Rights and Obligations Surviving Termination

Termination of this Agreement shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. No termination or expiration of this Agreement, however effectuated, shall release the parties hereto from their rights, duties, and obligations under Article V.A and G, Article IX, Article XIII. G.2, Article XIII.H, and payments and other benefits due under Appendices A and B.

6. Non-monetary and Monetary Benefits Retained Non-monetary and monetary benefits received by NPS will be retained by NPS upon termination.

C. Disputes

1. Performance during Disputes

Pending the resolution of any dispute or claim pursuant to this Article, the parties agree that they will diligently pursue performance of all obligations in accordance with the direction of the NPS signatory.

2. Joint Signatories' Resolution of Disputes

NPS and *[XYZ]* agree to use their best efforts to settle all disputes between them. Any dispute arising under this Agreement that is not disposed of by agreement of the parties shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall resolve the dispute.

3. Institution Directors' Resolution of Disputes

If the signatories are unable to jointly resolve the dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted to the

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Director of the NPS and the [Insert title such as President or CEO] of [XYZ], or their designees, for resolution.

4. Arbitration

If disputes are not resolved under Articles XII.C.1 and 2, NPS and *[XYZ]* agree to consider arbitrating any dispute in accordance with the rules of the American Arbitration Association as an alternative to litigation, which both NPS and *[XYZ]* pledge their best efforts to avoid, with any arbitration proceeding being nonbinding unless otherwise agreed to in advance by NPS and *[XYZ]*. NPS and *[XYZ]* acknowledge and agree that arbitration is frequently expensive and time consuming, and thus, NPS and *[XYZ]* agree that in advance of any arbitration hereunder each shall use its mutual best efforts to negotiate a comprehensive set of procedures designed to ensure that such arbitration is conducted expeditiously and at the lowest reasonable cost.

5. Legal Recourse

In the event of failed nonbinding arbitration, *[XYZ]* and NPS specifically acknowledge the right to pursue all legal and equitable remedies necessary to cure any breach of their obligations under this Agreement that are not satisfactorily resolved under this Agreement.

ARTICLE XIII. Required and Standard Clauses

A. Non-Discrimination

All activities pursuant to this Agreement shall be in compliance with the requirements of Executive Order 11246, as amended; Title 6 of the Civil Rights Act of 1964, as amended, (78 Stat. 252; 42 USC 2000d *et seq.*); Title V, Section 504 of the Rehabilitation Act of 1973, as amended, (87 Stat. 394; 29 USC 794); the Age Discrimination Act of 1975 (89 Stat. 728; 42 USC 6101 *et seq.*); and with all other federal laws, regulations, and Executive Orders prohibiting discrimination on grounds of race, color, sexual orientation, national origin, disabilities, religion, age, or sex.

B. Endorsements and Attributions

- 1. Endorsements.
- (a) Promotional Material

[XYZ] shall not publicize or otherwise circulate promotional material (such as advertisements, sales brochures, press releases, speeches, still and motion pictures, articles, manuscripts, or other publications) that states or implies governmental, departmental, bureau, or government employee endorsement of a business, product, service, or position that [XYZ] represents. No release of information relating to this award may state or imply that the Government approves of [XYZ's] work products, or considers [XYZ's] work product to be superior to other products or services.

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(b) No Endorsement

By entering into this Agreement, NPS does not directly or indirectly endorse any product or service provided or to be provided by *[XYZ]*, its successors, assignees, or licensees.

2. Attributions

(a) Use of Name and Marks

[XYZ] shall not use the name of [Spell out full PARK name.], NPS, National Park Service, or the NPS arrowhead logo or the name or logo of the Department of the Interior on any public information releases relating to any Invention, product or service that is directly or indirectly related to either this Agreement or any patent license or assignment agreement that implements this Agreement without the prior approval of [PARK].

(b) NPS Credit Line

Upon request by NPS, *[XYZ]* agrees to include an NPS-provided credit line in information that *[XYZ]* publicly releases relating to any Invention, product or service that is directly or indirectly related to this Agreement and to require its licensees and sublicensees to include an NPS-provided credit line in such information they publicly release.

(c) Disclaimer

[XYZ] will ensure that all information submitted for publication or other public releases of information regarding this project will carry the following disclaimer:

"The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the opinions or policies of the U.S. Government. Mention of trade names or commercial products does not constitute their endorsement by the U.S. Government."

(d) Prior NPS Approval

[XYZ] will obtain prior NPS approval for any public information release that refers to the Department of the Interior, any bureau, any employee (by name or title), or this Agreement. The proposed release, including specific text, layout, and photographs, must be submitted to *[PARK]* along with the request for approval.

(e) Application to Assignees and Licensees

[XYZ] agrees to incorporate the provisions of this Article XIII.B into any [XYZ] license, sublicense or other contract or agreement.

C. Anti-Deficiency Act

Pursuant to 31 USC 1341, nothing contained in this Agreement shall be construed as binding the NPS to expend any sum in excess of appropriations made by Congress for the purposes of this Agreement.

D. Compliance with Applicable Law

The parties shall comply with all applicable laws and regulations, and with ratified treaties, international agreements and conventions whether now in force or hereafter enacted or promulgated. Nothing in this Agreement shall be construed as in any way impairing the general powers of the NPS for supervision, regulation, and control of its employees and property under such applicable laws, regulations, and rules.

E. Member of Congress

No member of, or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, nor to any benefit that may arise from this Agreement (41 USC 22).

F. Additional Clauses

1. Entire Agreement

This Agreement and Appendices constitute and contain the entire agreement of the parties respecting its subject matter and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether written or oral, between the parties respecting its subject matter.

2. Severability

If any term or provision of this Agreement is held to be invalid or illegal, such term or provision shall not affect the validity or enforceability of the remaining terms and provisions.

3. No Waiver of Terms

No term or provision of this Agreement shall be waived and no breach excused unless such waiver or consent shall be in writing and signed by the party claimed to have waived or consented. No waiver of a breach shall be deemed to be a waiver of a different or subsequent breach. Failure by either party to enforce, or delay in exercising, or partially exercising, any covenants or rights or remedies under this Agreement shall not be deemed or construed as a waiver of such rights, nor shall waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other or subsequent instances.

4. No Default in Event of Legal Changes

In the event that further lawful performance of this Agreement or any part hereof by either party shall be rendered impossible by or as a consequence of any law, regulation,

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order, rule, direction, priority, seizure, allocation, requisition, or any other official action by any department, bureau, board, administration, or other instrumentality or agency of any government or political subdivision thereof having jurisdiction over such party, such party shall not be considered in default hereunder by reason of any failure to perform occasioned thereby.

5. Agency

[XYZ] is not an agent or representative of the United States, the Department of the Interior, or NPS, nor will [XYZ] represent itself as such to third parties. NPS employees are not agents of [XYZ] and will not represent themselves as such to third parties. No joint venture, joint enterprise or other entity is created by this Agreement.

6. Governing Law

The construction validity, performance and effect of this Agreement for all purposes shall be governed by applicable federal laws.

7. Notices

All notices pertaining to or required by this Agreement shall be in writing and shall be directed to Key Officials with copies to the signatory(ies).

8. Captions and Headings

The captions, headings, article numbers and paragraph numbers appearing in this Agreement are inserted only as a matter of convenience and in no way shall be construed as defining or limiting the scope or intent of the provision of this Agreement nor in any way affecting this Agreement.

9. Survival

Any and all provisions which, by themselves or their nature, are reasonably expected to be performed after the expiration or termination of this Agreement shall survive and be enforceable after the expiration or termination of this Agreement. Any and all liabilities, actual or contingent, that have arisen during the term of and in connection with this Agreement, shall survive expiration or termination of this Agreement.

G. Assignment and Successors

1. Assignment

No transfer or assignment of this Agreement, or any part thereof or interest therein, directly or indirectly, voluntarily or involuntarily, shall be made unless such transfer or assignment is first approved in writing by all the parties to this Agreement.

2. Successors

This Agreement shall be a binding obligation to the successors and permitted assignees of all the right, title and interest of each party hereto. Any such successor or assignee of

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a party's interest shall, upon receiving that interest, expressly assume in writing to the other party the performance of all the terms and conditions of this Agreement to be performed by said party. *[XYZ]* agrees to require any such successor or assignee to expressly assume in writing the performance of all the terms and conditions of this Agreement to be performed by said party. Any such assignment shall not relieve the assignor of any of its obligations under this Agreement.

H. Warranty, Liability and Indemnification

1. No Liability of or Warranty by United States

Except as provided in 28 USC 1498, the United States shall not be liable for the use or manufacture of any Invention made under this Agreement or for the infringement of any patent or copyright during the performance of this Agreement. NPS makes no express or implied warranty as to any matter whatsoever, including the conditions of the research or any Invention or Product, whether tangible or intangible, made or developed under this Agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any Invention or Product. These provisions shall survive termination of the Agreement.

2. Technical Developments and Products

[XYZ] holds the U.S. Government harmless and indemnifies the Government for all liabilities, demands, damages, expenses, and losses arising out of the research, development, sale, other disposition, or any other use of the Subject Invention, Future Product, or Product *[include "or Product" only if a product has been identified above]* by *[XYZ]*, or any party acting on its behalf or under its authorization. In respect to this Article, the Government shall not be considered an assignee or licensee of *[XYZ]*. This provision shall survive termination of this Agreement.

3. Force Majeure

Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this Agreement (and which it has been unable to overcome by the exercise of due diligence), including but not limited to flood, drought, earthquake, storm, fire, pestilence, lightening, and other natural catastrophes, epidemic, war, riot, civil disturbance or disobedience, strikes, labor dispute, or failure, threat of failure or sabotage of *[PARK]* facilities, or any order or injunction made by a court or public agency. In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

4. Tort Liability

The NPS shall be liable for the acts or omissions of its employees, acting within the course and scope of their employment, to the extent provided under the Federal Tort Claims Act, 28 USC 1346 and 2671-80. To the extent permitted by applicable law, *[XYZ]* shall be liable for the negligent or wrongful acts or omissions of its employees, acting within the course and scope of their employment.

5. Insurance

[XYZ] agrees to purchase public and employee liability insurance from a responsible company or companies with a minimum limitation of One Million Dollars (\$1,000,000) for any one claim, and an aggregate limitation of Three Million Dollars (\$3,000,000) from any number of claims arising from one incident. The policies shall name the United States as an additional insured, shall specify that the insured shall have no right of subrogation against the United States for payments of any premiums or deductibles due hereunder, and shall specify that the insurance shall be assumed by, be for the account of, and be at the insured's sole risk. Prior to beginning the work authorized herein, [XYZ] shall provide the NPS with confirmation of such insurance coverage.

-- Signatures begin on next page -- *[insert hard page break here]*

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SIGNATURES

In Witness Whereof, the parties have executed this Agreement on the dates set forth below. This Agreement may be signed in counterparts, each of which will be deemed to be an original. All such counterparts shall together constitute a single, executed instrument when all parties have so signed.

FOR NPS

Print Name Superintendent, [full PARK name]

Date

FOR [XYZ]

Print Name Title

Date

NPS Concurrences

Regional Director

Date

Associate Director, Natural Resource Stewardship and Science

Date

[Insert other concurrence signatures, if needed]

-- APPENDICES begin on next page -- *[insert hard page break here]*

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August 18, 2014, Updated October 16, 2018

Appendix A: Monetary Benefits

After negotiations regarding the monetary payments have been completed, list all of the payments and state the due dates. All of the elements in the example below would have resulted from negotiations. Expect your park's benefits package to be different from this example.

Example of up-front payment: Upon execution of this CRADA, *[XYZ]* shall pay to *[PARK]* an up-front payment of \$X.

Example of performance-based payment based on license income: For each federal fiscal year during the term of this CRADA, *[XYZ]* shall pay to *[PARK]* a performance-based payment of X% of *[XYZ]* gross license fees.

Example of performance-based payment based on Net Sales income: For each federal fiscal year during the term of this CRADA, *[XYZ]* shall pay to *[PARK]* a performance-based payment of X% of *[XYZ]* Net Sales income.

Example of annual maintenance payment: For each federal fiscal year during the term of this CRADA, *[XYZ]* shall pay to *[PARK]* an annual maintenance payment of \$X, creditable to performance-based payments. The annual maintenance payment will not be due in any year for which performance-based payments exceed \$X.

Example of payment due date statement: Payments to *[PARK]* will be due annually on October 1 each year.

Example of statement for Appendix A if the benefits-sharing agreement does not require monetary benefits: [PARK] does not require any payments from *[XYZ]* for use of the Product for Commercial Purposes. In the event that a Future Product is identified, this Agreement must be amended pursuant to Article XII.A and Article V.B prior to use of Future Product for Commercial Purposes.

Appendix B: Non-Monetary Benefits

After negotiations have been completed, list the non-monetary benefits. See Section 6.0 Step 5d in the Benefits-Sharing Handbook for examples of non-monetary benefits.

Appendix G: Template for a General Agreement for Benefits Sharing

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

[Remove all notes and instructions before sending a draft to the Partner for review.]

[Place the following confidentiality statement on the cover of the agreement. Modify it to specifically address the contents of the agreement.]

Confidentiality Notice

The following items in this Agreement [provide the title of the Agreement and Agreement number] are marked confidential as protected by law: [list the protected clauses]

This information must be withheld from unauthorized individuals.

[Insert a page break.]

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[Enter agreement number following instructions in the Handbook for DO#20: Agreements.]

GENERAL AGREEMENT FOR BENEFITS SHARING

between

THE UNITED STATES DEPARTMENT OF THE INTERIOR NATIONAL PARK SERVICE [insert NPS unit name] and [insert Partner's full name]

ARTICLE I. Background and Objectives

WHEREAS, the National Park Service (NPS) mission in managing units of the National Park System is "to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations" (54 USC 100101); and

WHEREAS, NPS coordinates research activities, facilitates the exchange of research-related information pertaining to the natural resources found in units of the National Park System, and otherwise manages the use of national park resources in part for purposes of scientific study by

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federal agencies and non-federal public and private agencies, organizations, individuals, or other entities (54 USC 100705); and

WHEREAS, [Insert Partner's name and acronym (XYZ)—use the acronym for the rest of the General Agreement] is dedicated to [XYZ inserts brief statement.], and agrees to cooperate with NPS to undertake beneficial scientific research relating to certain scientific specimens collected from [PARK], and to share information and data resulting from such research that [PARK] may use to protect and monitor [PARK] resources; and

WHEREAS, [XYZ] agrees and recognizes that efforts by [PARK] to "conserve the scenery and the natural and historic objects and the wild life therein" contribute significantly to [XYZ]'s research and development of potentially useful Discoveries resulting from scientific research activities undertaken in [PARK]; and that the aforesaid protection of [PARK] resources requires sophisticated interdisciplinary scientific work by [PARK] staff and coordinated effort by [PARK] management "necessary to assure the full and proper utilization of the results of scientific study for park management decisions" (54 USC 100706); and

WHEREAS, *[PARK]* agrees and recognizes that *[XYZ]* has invested and intends to continue to invest significant time, expertise, and expense in research and development activities and infrastructure that facilitate development of useful Discoveries resulting from scientific research activities based on research specimens collected from *[PARK]*; and

WHEREAS, [XYZ] has used Research Results based on study of [PARK] Collected Specimens to develop [XYZ inserts non-confidential description of any existing Product or describes the anticipated Future Product(s), and lists any granted patents] for the purpose of [XYZ describes the Commercial Purpose(s)]; and has [XYZ describes the efforts taken so far by XYZ to advance the R&D towards Commercial Use.]

NOW THEREFORE, acting separately, not being agents of each other, and consistent with the terms and conditions of existing agreements between *[PARK]* and *[XYZ]* or other entities pertaining to the Collected Specimen, Museum Specimen, or Living Collection Item, and/or Material as follows:

[Insert a bulleted list of Scientific Research and Collecting Permits, CSTAs, MTAs, loan agreements, and any other pertinent documents. Delete reference to Museum Specimen and Living Collection Item if they do not apply.],

the parties agree as follows.

ARTICLE II. Authorities

A. NPS enters into this Agreement pursuant to the following authorities: National Park Service Organic Act, as amended, 54 USC 100101-100303; the National Parks Omnibus Management Act of 1998 (54 USC 100702-100706); and 35 USC 207.

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B. XYZ enters into this Agreement pursuant to the following authorities: *[XYZ enters authorities, if applicable, otherwise delete]*

ARTICLE III. Definitions

A. Collected Specimens

The item collected by the permittee under the authority of an NPS Scientific Research and Collecting Permit, and portions thereof. Collected Specimens are natural products.

B. Commercial Purpose

See Commercial Use.

C. Commercial Use

Use of Material or Modifications or other Research Results in a product, service, or process resulting in a product or service that is sold, leased, licensed, or otherwise transferred for value received.

D. Confidential Information

Any information or material in tangible form that is marked as Confidential or Proprietary by the furnishing party at the time it is delivered to the receiving party, and information that is furnished orally if the furnishing party identifies such information as confidential or proprietary when it is disclosed and promptly confirms such designation in writing after such disclosure. Confidential Information does not include:

1) information that is publicly known or available from other sources who are not under a confidentiality obligation to the source of the information; or

2) information that has been made available by its owners to others without a confidentiality obligation; or

3) information that is already known by or available to the receiving party without a confidentiality obligation; or

4) information that relates to potential hazards or cautionary warnings associated with the handling, use or disposal of NPS specimens; or

5) information that is required by other applicable law or by an agreement to be disclosed.

E. Discovery

New knowledge gained through search or study.

F. Future Product

Any Modification, Subject Invention or any other commercially valuable or otherwise useful material, compound or useful combination of compounds, protein, or metabolite recovered,

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obtained, derived, resulting, or otherwise isolated by scientific research conducted on Collected Specimens collected from *[PARK]*, Progeny, or Unmodified Derivatives, or any derivative or analog of such material, compound, protein, metabolite or other isolate, or any Discovery that is or may be patentable or otherwise protected under 35 USC (Patents), or any novel variety of plant that is or may be protectable under 7 USC 2321 *et seq.* (Plant Variety Protection) and developed from Collected Specimens collected from *[PARK]*, Progeny, or Unmodified Derivatives.

G. Intellectual Property

Creations of the mind for which a set of exclusive rights may be recognized by law. Intellectual Property includes, but is not limited to, Inventions, Discoveries, copyright, patents, trademarks, trade secrets, certain forms of traditional knowledge, and other forms of comparable knowledge.

H. Invention

Any Discovery, thing, method, material, process or idea that might be patentable or otherwise protected under 35 USC (Patents), 7 USC 2321 *et seq*. (Plant Variety Protection), and 18 USC 1905 (Trade Secrets).

I. Living Collection

Biological material that is permanently retained *ex situ* for the purpose of generating and providing living or otherwise biologically active material for research, restoration, education or other purposes. Living Collections are retained in an NPS or non-NPS repository, documented, and tracked. Items in a living collection may be the Collected Specimen, or may originate directly from a collected specimen, from Material, or from other biological material in the Living Collection.

J. Living Collection Item

An organism, component from an organism, or Material maintained in a living collection.

K. Material (when capitalized)

Progeny and Unmodified Derivatives of Collected Specimens, Museum Specimens, Living Collection Items, and multiple generations thereof. The Material does not include a) Modifications or b) other substances created by a person through the use of the Material that are not Modifications, Progeny, or Unmodified Derivatives. See Modification.

L. Modification

A human-created substance that contains or incorporates Material (Progeny and/or Unmodified Derivatives).

M. Museum Specimen

A collected specimen that is permanently retained in a park museum collection. A museum specimen is non-living.

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N. Net Sales

The total gross receipts that *[XYZ]*, its licensees or sublicensees receives for sales of Material, Subject Inventions, or Product(s), or copyrighted works created using the results of research under this Agreement, and from otherwise making Material, Subject Invention(s), or Product(s) available to others without sale, whether invoiced or not, less returns and allowances actually granted, packing costs, insurance costs, freight out, taxes and excise duties imposed on the transaction (if separately invoiced), and the wholesaler and cash discounts in amounts customary in the trade. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by *[XYZ]*, its licensee or sublicensees, or for the cost of collections.

O. Product

[Describe the Research Result that is the subject of the proposed commercialization. The Research Result may have been patented or otherwise prepared for market.]

P. Progeny

Unmodified descendant from a Collected Specimen or Material, such as virus from virus, cell from cell, or organism from organism.

Q. Proprietary Information

Information that embodies trade secrets or that is confidential technical, business, or financial information provided that such information:

(i) Is not generally known or available from other sources without obligations concerning its confidentiality;

(ii) Has not been made available by the owners to others without obligations concerning its confidentiality; and

(iii) Is not already available to the Government without obligations concerning its confidentiality.

R. Research Results

Material (including Material retained in a living collection), modifications, Intellectual Property, Inventions, data, Discoveries, and/or other knowledge, processes, products, or applications resulting from research activities of researchers or their institutions or companies.

S. Subject Data

All recorded information first produced in the performance of work under the Permits, Collected Specimen Transfer Agreements (CSTA), Material Transfer Agreements (MTAs), loan agreements, or this Agreement.

T. Subject Invention

Any Invention conceived or first actually reduced to practice in the performance of work under the Permits, CSTAs, MTAs, and/or loan agreements listed in Article I, or under this Agreement.

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U. Unmodified Derivative

A human-created substance that is not a portion of the Collected Specimen and, instead, constitutes an unaltered copy of a functional subunit or of a product expressed by the Collected Specimen or Material. Some examples include: copies of cells of the Collected Specimen, purified or fractionated subsets of the Material, proteins expressed by DNA/RNA extracted from the Collected Specimen or Material.

ARTICLE IV. Statement of Work

A. [XYZ] [This section must be written specifically for the technology covered by the General *Agreement*].

1. *[XYZ]* or its licensees or sublicensees under its authority will prepare the Product for market. Work will include but not be limited to *[Include this clause only if a Product has been identified and defined above under "Definitions." Provide a non-confidential description of the work.]*

2. *[XYZ]* or its licensees or sublicensees under its authority may perform additional work to discover further Commercial Uses for the Product or Future Product. *[Delete reference to Product in this clause if it has not been defined under "Definitions."*]

B. NPS

1. NPS will conserve and protect the resources and values of *[PARK]*, including protecting from adverse impacts the site where the research specimens were collected.

2. NPS may facilitate [XYZ] research of Product and Future Product, as needed, by contributing labor, expertise, equipment, facilities, information, computer software, and other forms of laboratory support, subject to available funding and compliance with applicable laws and regulations. [Delete the word "Product" if Product has not yet been identified. Note: NPS may request reimbursement for supplies and rental equipment.]

ARTICLE V. Terms and Conditions

A. Pre-Existing NPS Permits and Agreements

The terms and conditions of all applicable Permits, CSTAs, MTAs, and/or loan agreements as listed above in Article I, Background and Objectives, shall remain in force throughout the Agreement and shall survive termination.

B. Commercialization of Future Product

Use of Future Product for a Commercial Purpose that may be identified during the course of research and development requires an amendment to this Agreement pursuant to Article XII.A, Amendments. Should future research lead to development of Future Product that appears to

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have a Commercial Purpose, *[XYZ]* or its licensees or sublicensees must obtain all applicable federal, tribal, state or other permits.

C. Practical Application of Product

[XYZ] shall expend reasonable efforts and resources to bring the Product to the point of practical application meaning to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the Invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms. *[XYZ]* shall offer the Product for distribution and/or sale within

[Ask XYZ to provide the number of years] year(s) of the Effective Date of this Agreement unless this period is extended by mutual agreement of the parties. NPS shall not unreasonably withhold approval of any request by [XYZ] to extend this period if such request is supported by evidence of reasonable efforts by [XYZ] to bring the Product to practical application, meaning distribution and/or sale, including any reasonable and diligent application for regulatory approvals required by any federal, tribal, state or other government agency in the United States.

[If no Product has emerged yet, substitute the following paragraph C and recognize that many years may pass before a Product can be sold.]

[XYZ] shall expend reasonable efforts and resources to identify a Product. [XYZ] shall offer the Product for sale within _____ [Ask XYZ to provide the number of years] year(s) of the Effective Date of this Agreement unless this period is extended by mutual agreement of the parties. NPS shall not unreasonably withhold approval of any request by [XYZ] to extend this period if such request is supported by evidence of reasonable efforts by [XYZ] to bring the Product to practical application, including any reasonable and diligent application for regulatory approvals required by any federal, tribal, state or other government agency in the United States.

D. Availability of Product

After bringing the Product to the point of practical application in the United States, *[XYZ]* shall keep the Product reasonably available to the United States public during the term of this Agreement.

E. [XYZ] Licensing

[XYZ], at any time, may license or sublicense in whole or in part, any rights and interests that NPS grants to [XYZ] under the terms and conditions of this Agreement. [XYZ] may exercise such right without obtaining additional authorization from NPS, but [XYZ] expressly agrees that in so licensing or sublicensing, it will specifically reserve to NPS all rights and privileges provided in this Agreement for NPS, including the provisions of the appendices. In the event of a license or sublicense, [XYZ] will notify NPS of each license and sublicense.

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F. Required Permits

[XYZ] and its licensees or sublicensees must obtain all additional permits required by federal, tribal, state or other government agency in the United States to carry out research and development and ultimately, as appropriate, commercialization of the Product and Future Product, including, but not limited to, public health and environmental compliance. [XYZ] shall provide and shall require its licensees or sublicensees to provide scientific and other information as required by the permitting agency for any associated environmental analyses and shall also appropriately apply the permitting agency's findings from any associated environmental analyses in accordance with the National Environmental Policy Act, the Endangered Species Act or other legal requirements, as applicable.

G. Intellectual Property and Data

1. [XYZ] Inventions

[XYZ] may retain title to any Subject Invention made solely by its employees or assigned to [XYZ]. [XYZ] may choose to file patent applications on such Subject Inventions at its own expense and in a timely fashion. [XYZ] may elect not to file patent applications on such Subject Inventions provided that it so advises NPS within ninety (90) days from the date it reports the Subject Inventions to NPS as required in Article IX.B.1. Thereafter, NPS may elect to file patent applications on the Subject Inventions and [XYZ] agrees to assign its right, title and interest in such Subject Inventions to NPS and cooperate with NPS in the preparation and filing of patent applications thereon. The assignment of the entire right, title and interest shall be subject to [XYZ]'s retention of a nonexclusive, irrevocable, paid-up license to practice, or have practiced, the Subject Inventions throughout the world.

2. Grant of License to U.S. Government

[XYZ] agrees to grant to the U.S. Government a nonexclusive, nontransferable, irrevocable, paid-up license in the patents that cover Subject Inventions and are assigned to [XYZ] to practice the Invention or have the Invention practiced, throughout the world by or on behalf of the U.S. Government. Such nonexclusive license shall be evidenced by a confirmatory license agreement prepared by [XYZ] in a form satisfactory to NPS.

3. U.S. Government Rights

The parties understand that the Government shall have unlimited rights in all information provided to the parties under this Agreement providing that such information is not marked as being copyrighted or as Proprietary Information pursuant to Article IX.B.2. *[XYZ]*, unless otherwise agreed to in writing by both parties, hereby grants to NPS the right to use, reproduce, create derivative works, distribute and display such research reports (as described in Article IX.B.3) in any media now known or utilized in the future and allow others to do so on its behalf or as otherwise required for any research, educational or government purpose.

ARTICLE VI. Term of Agreement

A. Effective Date [Use only one of the following two paragraphs.]

[Select this paragraph if the Product has been successfully patented] This Agreement shall enter into force as of the date of the last signature of the parties as shown on the signature page and, unless the Agreement is terminated subject to Article XII.B, will remain effective until the last patent for the Product and any Future Products has expired or been abandoned.

[Select this paragraph if patents have not been issued] This Agreement shall enter into force as of the date of the last signature of the parties as shown on the signature page and, unless the Agreement is terminated subject to Article XII.B, will remain effective for an initial term of five (5) years from the Effective Date. [XYZ] shall have the right to renew this Agreement for successive periods up to five (5) years upon written notice mailed to [PARK] at least sixty (60) days prior to the expiration of the initial term and each subsequent renewal term, provided, however, that [XYZ] shall have no right to renew this Agreement in the event that either party hereto has exercised a right of termination under Article XII.B or in the event that [XYZ] is not making good faith efforts to bring the Product or any Future Product(s) to the point of practical application as defined in Article V.C. [Delete the word "Product" if a product has not been identified in Article III.]

ARTICLE VII. Key Officials

A. Key Official Contacts

Key officials are essential to ensure maximum coordination and communications between the parties regarding the work being performed.

1. For *[PARK]*: Key Official Name Title Park Name Park Street/P.O. Box Park City, State, Zip Code Phone Fax Email

2. For *[XYZ]*: Key Official Name Title Organization Name

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Organization Street/P.O. Box Organization City, State, Zip Code Phone Fax Email

B. Communications between Key Officials

[XYZ] will address any communication regarding this Agreement to the [PARK] Key Official with a copy to the [PARK] superintendent.

[PARK] will address any communication regarding this Agreement to the [XYZ] Key Official.

ARTICLE VIII. Prior Approval

[Include any prior approvals other than the prior approval for Attributions in XIII.B.2.]

ARTICLE IX. Deliverables and Reports

A. Benefits-Sharing Obligation

1. [Use only one of the following two paragraphs.]

[If a Product has been identified in Article III, use this paragraph.] [XYZ] will share benefits with NPS as described and scheduled in Appendices A (monetary benefits) and B (non-monetary benefits). [Note: When NPS receives monetary payments under a General Agreement, NPS must deposit the funds in the U.S. Treasury. NPS does not have authority to retain monetary payments under a General Agreement.]

[If a Product has not been identified yet and if NPS has decided to negotiate benefits at a later date use this paragraph and reference the future negotiations in Appendices A and B.] Should [XYZ] develop Subject Inventions and Research Results related to specimens collected under the NPS Scientific Research and Collecting Permit(s) cited in Article I for potential future commercial or other revenue-generating purposes, this Agreement must be amended pursuant to Article XII.A prior to use of Future Product for Commercial Purpose pursuant to Articles V.B.

2. Payment Method

[XYZ] will make on-time payments in U.S. Dollars as set forth in Appendix A, net of all non-U.S. taxes (if any) to *[Enter PARK and assigned Pay.Gov Form Number]* in Pay.Gov. These payments include a one-time upfront payment, annual maintenance payments, and performance-based payments *[delete any payment types that do not apply]*. Except for the up-front payment, all payments are to be made annually on

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October 1. NPS reserves the right to change the method of payment with 30 days' notice.

3. Late Payments

[XYZ] will pay interest on overdue amounts for each 30-day period, or portion thereof, that payment is delayed beyond the periods described in Appendix A. The percent of interest charged will be based on the Treasury Current Value of Funds Rate (CVFR) for overdue federal government receivables as published annually in the Federal Register by October 31, and recalculated quarterly with revisions, if any, posted in a Treasury Financial Manual (TFM) Bulletin (see https://tfm.fiscal.treasury.gov/v1/bull.html).

4. Non-monetary Benefits

[XYZ] will provide non-monetary benefits to NPS as shown in Appendix B. [PARK] will acknowledge receipt of each non-monetary benefit. In cases where [XYZ] is a federal entity, it may grant to NPS right, title, or interest in its federally owned Invention (a non-monetary benefit), which grant entitles NPS to seek monetary benefits from third parties receiving separately negotiated licenses (35 USC 207).

5. Use of Benefits by NPS

NPS will use non-monetary benefits received to conserve resources protected and managed by the NPS. NPS will receive and deposit monetary benefits in the U.S. Treasury.

6. Overpayments

NPS will offset any [XYZ] overpayments against payments due the following year.

B. Reports

1. Disclosure of Inventions and Patents

[XYZ] agrees to disclose to NPS every Subject Invention that may be patentable or otherwise protectable prior to any disclosure to the public, within thirty (30) days of making an Invention disclosure to the person(s) responsible for patent matters in the inventing organization, and within thirty (30) days of filing in the United States or other country any type of application for a patent or other Intellectual Property claim for the Subject Invention. These disclosures should be in sufficient enough detail to enable a reviewer to make and use the Invention under 35 USC 112. The disclosure shall also identify any statutory bars, such as printed publications describing the Subject Invention or public use or sale of the Subject Invention in the United States. [XYZ] further agrees to disclose to NPS any subsequent statutory bar that occurs for a Subject Invention disclosed but for which a patent application has not been filed. All such disclosures shall be marked as Confidential under 35 USC 205.

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2. Proprietary Information

[XYZ] shall place a Proprietary notice on all information it delivers to NPS under this Agreement that [XYZ] asserts is Proprietary Information, as defined in Article III. NPS agrees that it will use any information that [XYZ] designates as Proprietary and furnishes to NPS under this Agreement, only for the purpose of carrying out this Agreement. NPS agrees not to disclose, copy, reproduce, or otherwise make available in any form whatsoever information designated as Proprietary to any other person, firm, corporation, partnership, association, or other entity without the consent of [XYZ], except as such information must be disclosed under the Freedom of Information Act, as amended (5 USC 552, et seq.) provided, however, that such data shall not be released to the public if a patent application is to be filed (35 USC 205) until the party having the right to file the patent application has had a reasonable time to file. NPS agrees to use its best efforts to protect information designated as Proprietary from unauthorized disclosure. [XYZ] agrees that NPS is not liable for the disclosure of information designated as Proprietary for which, after notice to and consultation with [XYZ], a court of competent jurisdiction requires disclosure.

3. Research Report

[XYZ] will prepare and provide to NPS an annual written report concerning the research and development and Commercial Uses addressed in this Agreement, which report shall identify and summarize all patents, Inventions, Research Results, research plans, and status of compliance with all applicable permits, laws, and regulations for the year of the report. Upon receipt of the report, NPS has the right to require additional details and copies of documents summarized in the report. In the event [XYZ] asserts that particular information delivered to NPS is Proprietary, [XYZ] agrees additionally to provide to NPS a non-confidential non-proprietary summary of such information for public disclosure.

4. Payment Report

[Select this paragraph about license income if Partner licenses the technology.] Concurrently with each payment, [XYZ] shall submit a written report to NPS setting forth (a) the period to which the payment applies, and for the applicable period, (b) the amount and type of license income received pursuant to the Statement of Work, and (c) the calculation of payments due NPS for deposit in the U.S. Treasury. If no payments are due for any report period, the report shall so state.

[Select this paragraph about Net Sales if a Partner sells the Product(s).] Concurrently with each payment, or at such other time as payments are due, [XYZ] shall submit a written report to NPS setting forth (a) the period to which the payment applies, and for the applicable period (b) the amount and description of Net Sales upon which a payment is payable, (c) the total gross income realized by [XYZ] from the sale, licensing, or other provision of Material, Modifications, Subject Invention(s), or Product(s) to itself and others without sale, during such applicable period, and (d) the calculation of payments

due to NPS for deposit in the U.S. Treasury. If no payments are due for any report period, the report shall so state.

5. Records

[XYZ] agrees to keep records, as applicable, showing [XYZ]'s gross license income and the sales or other dispositions of all works upon which payments are due under the provisions of this Agreement. These records shall be in sufficient detail to enable NPS to determine the payments payable by [XYZ]. [XYZ] agrees to retain the records for a minimum period of five (5) years from the date a subject payment is due. [XYZ] further agrees to permit an auditor that NPS selects to examine [XYZ]'s books and records from time to time during its ordinary business hours and not more often than once a year to the extent necessary to verify the reports that Article IX.B requires. NPS will bear the initial expense of the audit. If the audit indicates that NPS was underpaid by at least ten percent (10%) for any calendar year, or five thousand dollars (\$5,000.00), whichever is greater, [XYZ] will reimburse NPS for the expense of the audit and will pay NPS an amount equal to the additional payments to which NPS is entitled and applicable interest calculated as described in Article IX.A.3. Except for reimbursement of audit expenses, NPS will deposit the additional amounts (payments due and applicable interest) in the U.S. Treasury.

ARTICLE X. Publications of Research Results

No party will unilaterally publish a joint publication without consulting the other party. This restriction does not apply to an individually published popular publication of previously jointly published technical matter. Publications pursuant to this Agreement may be produced independently or in collaboration with others; however, in all cases proper credit will be given to the efforts of those parties contributing to the information being published. In the event no agreement is reached concerning the manner of publication or interpretation of results, either party may separately publish its information after due notice and submission of proposed manuscripts to the other. In such instances, the party publishing the information will give due credit to the cooperation but assume full responsibility for any statements on which there is a difference of opinion.

NPS and *[XYZ]* agree to confer and consult at least thirty (30) days prior to either party's submission for publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. The party receiving the document for review has thirty (30) days from receipt to object in writing detailing the objections to the proposed submission. If the receiving party does not provide any objections within 30 days, the proposing party may proceed with publishing the document.

ARTICLE XI. Property Utilization

Unless otherwise agreed to in writing by the parties,

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1. Any property furnished by [XYZ] to [PARK] will become the property of [PARK] and will be used and disposed of as set forth in this Agreement and in NPS Property Management Regulations; and

2. Any property furnished by [PARK] to [XYZ] will remain U.S. Government property.

ARTICLE XII. Modification, Termination and Disputes

A. Amendments

The Agreement may be modified by written consent of all of the parties to cover the need for any alterations that may arise subsequent to the Effective Date of this Agreement.

B. Termination

1. Either party has the right to terminate this Agreement if either party fails to observe any of the material terms and conditions of the Agreement, and, after sixty (60) days from receipt of written notice, fails to cure the default.

2. NPS shall have the right to immediately terminate this Agreement without written notice to *[XYZ]* in the event *[XYZ]* or its licensees does(do) any of the following:

i. Files a petition in bankruptcy, or is adjudicated bankrupt or insolvent, or dissolves or discontinues its business, or makes an assignment for the benefit of creditors. *[XYZ]* must give NPS immediate notice (within five (5) days) of the filing of any petition in bankruptcy, filing of any petition seeking relief of the same or different kind under any provision of the Bankruptcy Act, or making any assignment for the benefit of creditors. For purposes of the bankruptcy statutes, NPS considers this Agreement an executory contract exempt from inclusion in the assets of *[XYZ]* pursuant to 11 USC 365.

ii. Upon the commencement of distribution and/or sale of Product, fails to distribute and/or sell any Product within one year.

iii. In case of the dissolution or cessation of operations by [XYZ].

3. Notwithstanding the foregoing, the NPS may terminate this Agreement for the convenience of the Government, at any time, when it is determined to be in the best interest of the public to do so. NPS shall notify *[XYZ]* within five (5) working days following the termination.

4. Termination Report

In the event of termination, *[XYZ]* will prepare a report on results to date of termination and the cost of the report will be deducted from any amounts due to NPS for deposit in the U.S. Treasury. This provision shall survive termination of the Agreement.

5. Rights and Obligations Surviving Termination

Termination of this Agreement shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. No termination or expiration of this Agreement, however effectuated, shall release the parties hereto from their rights, duties, and obligations under Article V.A and G, Article IX, Article XIII.G.2, Article XIII.H, and payments and other benefits due under Appendices A and B.

6. Non-monetary and Monetary Benefits Retained

Non-monetary benefits received by NPS will be retained by NPS upon termination. Monetary benefits received by NPS and deposited in the U.S. Treasury will be retained by the U.S. Government upon termination.

C. Disputes

1. Performance during Disputes

Pending the resolution of any dispute or claim pursuant to this Article, the parties agree that they will diligently pursue performance of all obligations in accordance with the direction of the NPS signatory.

2. Joint Signatories' Resolution of Disputes

NPS and *[XYZ]* agree to use their best efforts to settle all disputes between them. Any dispute arising under this Agreement that is not disposed of by agreement of the parties shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall resolve the dispute.

3. Institution Directors' Resolution of Disputes

If the signatories are unable to jointly resolve the dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted to the Director of the NPS and the *[Insert title such as President or CEO]* of *[XYZ]*, or their designees, for resolution.

4. Arbitration

If disputes are not resolved under Articles XII.C.1 and 2, NPS and *[XYZ]* agree to consider arbitrating any dispute in accordance with the rules of the American Arbitration Association as an alternative to litigation, which both NPS and *[XYZ]* pledge their best efforts to avoid, with any arbitration proceeding being nonbinding unless otherwise agreed to in advance by NPS and *[XYZ]*. NPS and *[XYZ]* acknowledge and agree that arbitration is frequently expensive and time consuming, and thus, NPS and

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[XYZ] agree that in advance of any arbitration hereunder each shall use its mutual best efforts to negotiate a comprehensive set of procedures designed to ensure that such arbitration is conducted expeditiously and at the lowest reasonable cost.

5. Legal Recourse

In the event of failed nonbinding arbitration, *[XYZ]* and NPS specifically acknowledge the right to pursue all legal and equitable remedies necessary to cure any breach of their obligations under this Agreement that are not satisfactorily resolved under this Agreement.

ARTICLE XIII. Required and Standard Clauses

A. Non-Discrimination

All activities pursuant to this Agreement shall be in compliance with the requirements of Executive Order 11246, as amended; Title 6 of the Civil Rights Act of 1964, as amended, (78 Stat. 252; 42 USC 2000d *et seq.*); Title V, Section 504 of the Rehabilitation Act of 1973, as amended, (87 Stat. 394; 29 USC 794); the Age Discrimination Act of 1975 (89 Stat. 728; 42 USC 6101 *et seq.*); and with all other federal laws, regulations, and Executive Orders prohibiting discrimination on grounds of race, color, sexual orientation, national origin, disabilities, religion, age, or sex.

B. Endorsements and Attributions

- 1. Endorsements.
- (a) Promotional Material

[XYZ] shall not publicize or otherwise circulate promotional material (such as advertisements, sales brochures, press releases, speeches, still and motion pictures, articles, manuscripts, or other publications) that states or implies governmental, departmental, bureau, or government employee endorsement of a business, product, service, or position that [XYZ] represents. No release of information relating to this award may state or imply that the Government approves of [XYZ's] work products, or considers [XYZ's] work product to be superior to other products or services.

(b) No Endorsement

By entering into this Agreement, NPS does not directly or indirectly endorse any product or service provided or to be provided by *[XYZ]*, its successors, assignees, or licensees.

2. Attributions

(a) Use of Name and Marks

[XYZ] shall not use the name of [Spell out full PARK name.], NPS, National Park Service, or the NPS arrowhead logo or the name or logo of the Department of the Interior on any public information releases relating to any Invention, product or service that is directly or indirectly related to either this Agreement or any patent license or assignment agreement that implements this Agreement without the prior approval of [PARK].

(b) NPS Credit Line

Upon request by NPS, *[XYZ]* agrees to include an NPS-provided credit line in information that *[XYZ]* publicly releases relating to any Invention, product or service that is directly or indirectly related to this Agreement and to require its licensees and sublicensees to include an NPS-provided credit line in such information they publicly release.

(c) Disclaimer

[XYZ] will ensure that all information submitted for publication or other public releases of information regarding this project will carry the following disclaimer:

"The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the opinions or policies of the U.S. Government. Mention of trade names or commercial products does not constitute their endorsement by the U.S. Government."

(d) Prior NPS Approval

[XYZ] will obtain prior NPS approval for any public information release that refers to the Department of the Interior, any bureau, any employee (by name or title), or this Agreement. The proposed release, including specific text, layout, and photographs, must be submitted to *[PARK]* along with the request for approval.

(e) Application to Assignees and Licensees

[XYZ] agrees to incorporate the provisions of this Article XIII.B into any [XYZ] license, sublicense or other contract or agreement.

C. Anti-Deficiency Act

Pursuant to 31 USC 1341, nothing contained in this Agreement shall be construed as binding the NPS to expend any sum in excess of appropriations made by Congress for the purposes of this Agreement.

D. Compliance with Applicable Law

The parties shall comply with all applicable laws and regulations, and with ratified treaties, international agreements and conventions whether now in force or hereafter enacted or

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promulgated. Nothing in this Agreement shall be construed as in any way impairing the general powers of the NPS for supervision, regulation, and control of its employees and property under such applicable laws, regulations, and rules.

E. Member of Congress

No member of, or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, nor to any benefit that may arise from this Agreement (41 USC 22).

F. Additional Clauses

1. Entire Agreement

This Agreement and Appendices constitute and contain the entire agreement of the parties respecting its subject matter and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether written or oral, between the parties respecting its subject matter.

2. Severability

If any term or provision of this Agreement is held to be invalid or illegal, such term or provision shall not affect the validity or enforceability of the remaining terms and provisions.

3. No Waiver of Terms

No term or provision of this Agreement shall be waived and no breach excused unless such waiver or consent shall be in writing and signed by the party claimed to have waived or consented. No waiver of a breach shall be deemed to be a waiver of a different or subsequent breach. Failure by either party to enforce, or delay in exercising, or partially exercising, any covenants or rights or remedies under this Agreement shall not be deemed or construed as a waiver of such rights, nor shall waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other or subsequent instances.

4. No Default in Event of Legal Changes

In the event that further lawful performance of this Agreement or any part hereof by either party shall be rendered impossible by or as a consequence of any law, regulation, order, rule, direction, priority, seizure, allocation, requisition, or any other official action by any department, bureau, board, administration, or other instrumentality or agency of any government or political subdivision thereof having jurisdiction over such party, such party shall not be considered in default hereunder by reason of any failure to perform occasioned thereby.

5. Agency

[XYZ] is not an agent or representative of the United States, the Department of the Interior, or NPS, nor will [XYZ] represent itself as such to third parties. NPS employees

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are not agents of *[XYZ]* and will not represent themselves as such to third parties. No joint venture, joint enterprise or other entity is created by this Agreement.

6. Governing Law

The construction validity, performance and effect of this Agreement for all purposes shall be governed by applicable federal laws.

7. Notices

All notices pertaining to or required by this Agreement shall be in writing and shall be directed to Key Officials with copies to the signatory(ies).

8. Captions and Headings

The captions, headings, article numbers and paragraph numbers appearing in this Agreement are inserted only as a matter of convenience and in no way shall be construed as defining or limiting the scope or intent of the provision of this Agreement nor in any way affecting this Agreement.

9. Survival

Any and all provisions which, by themselves or their nature, are reasonably expected to be performed after the expiration or termination of this Agreement shall survive and be enforceable after the expiration or termination of this Agreement. Any and all liabilities, actual or contingent, that have arisen during the term of and in connection with this Agreement, shall survive expiration or termination of this Agreement.

G. Assignment and Successors

1. Assignment

No transfer or assignment of this Agreement, or any part thereof or interest therein, directly or indirectly, voluntarily or involuntarily, shall be made unless such transfer or assignment is first approved in writing by all the parties to this Agreement.

2. Successors

This Agreement shall be a binding obligation to the successors and permitted assignees of all the right, title and interest of each party hereto. Any such successor or assignee of a party's interest shall, upon receiving that interest, expressly assume in writing to the other party the performance of all the terms and conditions of this Agreement to be performed by said party. *[XYZ]* agrees to require any such successor or assignee to expressly assume in writing the performance of all the terms and conditions of this Agreement to be performed by said party. *[XYZ]* agrees to require any such successor or assignee to expressly assume in writing the performance of all the terms and conditions of this Agreement to be performed by said party. Any such assignment shall not relieve the assignor of any of its obligations under this Agreement.

H. Warranty, Liability and Indemnification

1. No Liability of or Warranty by United States

Except as provided in 28 USC 1498, the United States shall not be liable for the use or manufacture of any Invention made under this Agreement or for the infringement of any patent or copyright during the performance of this Agreement. NPS makes no express or implied warranty as to any matter whatsoever, including the conditions of the research or any Invention or Product, whether tangible or intangible, made or developed under this Agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any Invention or Product. These provisions shall survive termination of the Agreement.

2. Technical Developments and Products

[XYZ] holds the U.S. Government harmless and indemnifies the Government for all liabilities, demands, damages, expenses, and losses arising out of the research, development, sale, other disposition, or any other use of the Subject Invention, Future Product, or Product *[include "or Product" only if a product has been identified above]* by [XYZ], or any party acting on its behalf or under its authorization. In respect to this Article, the Government shall not be considered an assignee or licensee of [XYZ]. This provision shall survive termination of this Agreement.

3. Force Majeure

Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this Agreement (and which it has been unable to overcome by the exercise of due diligence), including but not limited to flood, drought, earthquake, storm, fire, pestilence, lightening, and other natural catastrophes, epidemic, war, riot, civil disturbance or disobedience, strikes, labor dispute, or failure, threat of failure or sabotage of *[PARK]* facilities, or any order or injunction made by a court or public agency. In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

4. Tort Liability

The NPS shall be liable for the acts or omissions of its employees, acting within the course and scope of their employment, to the extent provided under the Federal Tort Claims Act, 28 USC 1346 and 2671-80. To the extent permitted by applicable law, *[XYZ]* shall be liable for the negligent or wrongful acts or omissions of its employees, acting within the course and scope of their employment.

5. Insurance

[XYZ] agrees to purchase public and employee liability insurance from a responsible company or companies with a minimum limitation of One Million Dollars (\$1,000,000)

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for any one claim, and an aggregate limitation of Three Million Dollars (\$3,000,000) from any number of claims arising from one incident. The policies shall name the United States as an additional insured, shall specify that the insured shall have no right of subrogation against the United States for payments of any premiums or deductibles due hereunder, and shall specify that the insurance shall be assumed by, be for the account of, and be at the insured's sole risk. Prior to beginning the work authorized herein, *[XYZ]* shall provide the NPS with confirmation of such insurance coverage.

-- Signatures begin on next page -- *[insert hard page break here]*

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SIGNATURES

In Witness Whereof, the parties have executed this Agreement on the dates set forth below. This Agreement may be signed in counterparts, each of which will be deemed to be an original. All such counterparts shall together constitute a single, executed instrument when all parties have so signed.

FOR NPS

Print Name Superintendent, [full PARK name]

Date

FOR [XYZ]

Print Name Title

Date

NPS Concurrences

Regional Director

Date

Associate Director, Natural Resource Stewardship and Science

Date

[Insert other concurrence signatures, if needed]

-- APPENDICES begin on next page -- [insert hard page break here]

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August 18, 2014, Updated October 16, 2018

Appendix A: Monetary Benefits

Note: Monetary payments that NPS receives under a General Agreement must be deposited in the U.S. Treasury. NPS does not have authority to retain monetary payments under a General Agreement. After negotiations regarding the monetary payments have been completed, list all of the payments and state the due dates. All of the elements in the example below would have resulted from negotiations. Expect your park's benefits package to be different from this example.

Example of up-front payment: Upon execution of this Agreement, *[XYZ]* shall pay to NPS for deposit in the U.S. Treasury an up-front payment of \$X.

Example of performance-based payment based on Net Sales income: For each federal fiscal year during the term of this Agreement, *[XYZ]* shall pay to NPS for deposit in the U.S. Treasury a performance-based payment of X% of *[XYZ]* Net Sales income.

Example of annual maintenance payment: For each federal fiscal year during the term of this Agreement, *[XYZ]* shall pay to NPS for deposit in the U.S. Treasury an annual maintenance payment of \$X, creditable to performance-based payments. The annual maintenance payment will not be due in any year for which performance-based payments exceed \$X.

Example of payment due date statement: Payments to NPS for deposit in the U.S. Treasury will be due annually on October 1 each year.

Example of statement for Appendix A if the benefits-sharing agreement does not require monetary benefits: [PARK] does not require any payments from *[XYZ]* for use of the Product for Commercial Purposes. In the event that a Future Product is identified, this Agreement must be amended pursuant to Article XII.A and Article V.B prior to use of Future Product for Commercial Purposes.

Appendix B: Non-Monetary Benefits

After negotiations have been completed, list the non-monetary benefits. See Section 6.0 Step 5d in the Benefits-Sharing Handbook for examples of non-monetary benefits.

Appendix H: Example of a Park Request for Designation as a Federal Laboratory

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

Memorandum

Date:

То:	Director
Through:	Regional Director
From:	Superintendent, PARK National Park
Subject:	Request for Designation of PARK National Park as a "Federal Laboratory"

I request your designation of PARK National Park (PARK) as a "federal laboratory" under the Federal Technology Transfer Act (FTTA). Such designation would enable PARK to enter into Cooperative Research and Development Agreements (CRADAs) to facilitate science and innovation and share in benefits arising from the commercial application of research results originating from PARK specimens.

A "federal laboratory" is "a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government" (15 U.S.C. § 3710a(d)(2)(A)). As one court has noted, the term "federal laboratory" was intended to include the widest possible range of research institutions operated by the federal government (see *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000), agreeing that Yellowstone National Park is a "federal laboratory").

JUSTIFICATION [Preparer's Note: The following bullets are only examples for your reference. Substitute or add information pertinent to your park, as applicable.]

PARK qualifies as a "federal laboratory," because a substantial purpose of the park is the performance and application of scientific research as evidenced by the following:

• Example—PARK permits reputable agencies, organizations, individuals, or other entities to use PARK for purposes of scientific study. (54 USC 100705. Availability for scientific study)

NOTE! *Preparer's Note: Cite the park's mission statement and the document where this mission is stated; the statement should include reference to scientific research.*

• Example—Mission Statement: The National Park Service at PARK National Park contributes to knowledge about natural and cultural resources and associated values;

NPS Benefits-Sharing Handbook Appendix H: Example of a Park Request for Designation as a Federal Laboratory

management decisions about resources and visitors are based on adequate scholarly and scientific information. (PARK General Management Plan or Foundation Statement, YEAR).

NOTE! *Preparer's Note: Describe physical and virtual facilities and systems. (For example, a GIS facility is a virtual facility.) Not all park federal laboratories will need to demonstrate all of the items in the example below.*

• Example—Research facilities: PARK National Park maintains or authorizes permitted researchers to maintain research facilities and equipment including but not limited to weather data collection stations; seismic monitoring stations; field sampling equipment ; wet and dry laboratories for preparation and study of physical and biological specimens and samples; a museum collection containing specimens collected from PARK for use in studies; GPS equipment; physical and electronic libraries with scientific and historical references; archives of resource management and scientific research records; and GIS and other databases containing regularly updated scientific information about park biological, physical, and cultural resources, and socio-economic characteristics.

NOTE! *Preparer's Note: The following bullets summarize the scientific research occurring at the park by park employees and others. Include the number of research studies by park employees and others over prior three years.*

- Example—Scientific research by park employees: Over the last three years, the park resource managers conducted an average of X studies each year in the course of their regular duties as authorized by the Superintendent.
- Example—Scientific research by others: Over the last three years, PARK National Park permitted an average of X independent studies each year. These permits authorized X principal investigators and co-investigators (including technicians) to perform research activities in the park covering physical, biological, cultural, and socio-economic studies.

NOTE! *Preparer's Note: Include Cooperative Ecosystem Studies Unit (CESU) research in the park.*

• Example—PARK National Park participates in a CESU network collaborating with, for example, other federal agencies, universities, state agencies, non-governmental organizations, and other non-federal institutional partners. In the past three years, X employees have contributed to CESU studies undertaken within PARK National Park, serving as principle or co-investigators. Additional PARK employees provided support and assistance to these studies. Many of these studies are in direct service to resource management goals and/or investigations related to various compliance processes under NEPA. The PARK National Park CESU Project List is appended to this memorandum.

NOTE! Preparer's Note: Include Inventory and Monitoring activities.

NPS Benefits-Sharing Handbook Appendix H: Example of a Park Request for Designation as a Federal Laboratory

• Example—PARK National Park is part of the NETWORK I&M Network. The I&M program in the park monitors the following Vital Signs [*list Vital Signs*].

NOTE! *Preparer's Note: State how many NPS employees are doing inventory, monitoring, and scientific research in the park. Include all assistance that made the science possible such as providing flaggers for a road survey or rangers who spend time assisting researchers or park resource management employees.*

• Example—Approximately, X PARK employees (or X% of all PARK employees) are directly involved in performing and administering the scientific work described above. Approximately X additional employees each year assist this scientific work as needed.

NOTE! *Preparer's Note: Cite any other relevant information. If the park has the capacity to support independent researchers, include those details—the park does not have to be a Learning Center to support research.*

• Example—PARK National Park hosts the Science Learning Center consisting of many partnerships focused on ultimately increasing the effectiveness and communication of research and science results in the national parks. The Center attracts non-NPS scientists to conduct research in the park. Facilities dedicated primarily to the Center consist of [*list facilities*]. The Natural History Institute is the park's primary nonprofit Learning Center partner providing operational support with two full-time staff positions (Program Director and Program Coordinator) and several seasonal interns. This partner generates, markets, and executes Center programs (fee and non-fee) under NPS oversight. The Natural History Institute dedicates portions of its funding toward Center operations and programmatic elements. Other instrumental partners include the Research Company, and the School District.

To designate PARK National Park as a federal laboratory, please sign the statement below. Otherwise, return the document unsigned along with any comments that you might have regarding this request.

DESIGNATION OF PARK NATIONAL PARK AS A FEDERAL LABORATORY

I have reviewed the above justification and find that PARK National Park fulfills the requirements for designation as a federal laboratory under the Federal Technology Transfer Act (15 U.S.C. § 3710a(d)(2)(A)) and hereby designate PARK National Park as a federal laboratory.

Director, National Park Service

Date

Appendix I: Template for a Request for Approval of Negotiations and Terms

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

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[Date]

Memorandum

To:	Associate Director, Natural Resource Stewardship and Science
Through:	Regional Director
Through:	Superintendent, PARK NP
From:	Negotiating Team Lead
Subject:	Request for Approval of Proposed Term Sheet Elements and Negotiation Ranges for a Benefits-Sharing Agreement between PARTNER and PARK National Park

[Enter full PARTNER and PARK names once in document with abbreviation in parentheses and then use abbreviated name in following text.]

This document describes and requests your approval of certain principal negotiation terms and ranges for monetary benefits for a proposed National Park Service (NPS) Benefits-Sharing Agreement. The Agreement will be negotiated and administered through PARK National Park (PARK) with assistance from the WASO Benefits-Sharing Coordinator.

Confidentiality

The Terms are confidential information and shall not be disclosed to any third party without the consent of the parties to the proposed Agreement, except that the parties may disclose the Terms described and the existence of the Term Sheet to their respective officers, directors, employees, attorneys and other advisers, provided that such persons agree to the confidentiality restrictions contained herein.

Approval Requested

The proposed Agreement will include [Select one option: 1) solely non-monetary benefits, 2) solely monetary benefits, 3) a combination of the following non-monetary and monetary benefits] as stated below. The negotiations team seeks your approval 1) of the proposed terms and benefits, and 2) to negotiate within the proposed ranges of potential benefits. To initiate negotiation of the Agreement, NPS will present PARTNER with a proposed Term Sheet showing the identified terms and only the high end of the negotiation ranges.

NPS Benefits-Sharing Handbook Appendix I: Template for a Request for Approval of Negotiations and Terms

NPS negotiates and structures each Agreement on a case-by-case basis, taking into account the importance of study of the NPS collected specimen to the development of the technology. All parties are encouraged to approach the negotiations process as a collaborative and interactive process that results in a fair agreement for both PARTNER and PARK.

Term Sheet Elements

Term Sheet Element	Description
Purpose of Proposed Agreement	This proposed Agreement will establish the rights and responsibilities of the parties relative to benefits sharing for commercialization of the technology described below, subject to the PARTNER obtaining all necessary permits required by state, federal or other authorities.
Current Permits, Agreements and Licenses	[List and provide titles and associated numbers for all current and applicable Scientific Research and Collecting Permits, Collected Specimen Transfer Agreements, Material Transfer Agreements, loan agreements, licenses, or other pertinent documents].
Technologies and Applications	The new technologies will be used for <u>[Specify all existing</u> <u>technologies, including the PARTNER's intended products or</u> <u>services subject to this benefits-sharing agreement. State</u> <u>whether the end product or service will or will not incorporate</u> <u>Material]</u> .
NPS Compensable Interest in Material and Research Results	U.S. Government has a compensable interest in Material and Research Results related to the Current Permits, Agreements and Licenses.
Parties to Benefits-Sharing	NPS will require benefits-sharing with PARTNER for commercial uses of the Technologies and Applications by PARTNER, its licensees and sublicensees. NPS [will/will not] require separate benefits-sharing agreements with PARTNER's_licensees and sublicensees. [PARK must choose whether to have separate benefits-sharing agreements with licensees.]
Research in PARK	If any researcher wants to perform field research or collect specimens in PARK, that person must hold a valid NPS Scientific Research and Collecting Permit for the study described in the permit objectives. NPS issues or denies such permits without regard to whether the applicant is a party to this proposed Agreement.
Time Frame of this Agreement	The Agreement will be in effect as long as PARTNER receives income related to the Technologies and Applications.
Other Terms	Any other terms to be included in the Term Sheet.

NPS Benefits-Sharing Handbook Appendix I: Template for a Request for Approval of Negotiations and Terms

Benefits and Negotiation Ranges

Proposed Benefits to PARK	Negotiation Ranges
<u>Up-front Payment</u> (a one-time payment)	\$ to \$
<u>Annual Maintenance Payment</u> Annual maintenance payments are non-refundable in the event of termination.	<pre>\$to \$</pre>
Performance-based Payments A percent of the gross revenue stream received by PARTNER from its licensee(s) (including but not limited to license issue fees, annual payments, royalties, or additional payments received from licensees in consideration for any license granted for the technology). The proposed performance-based payment is based on the provision by PARK of the collected research specimen and/or Material, as applicable, and is in accordance with "economic rent" models. The performance-based payment will be reduced by the amount of the annual maintenance payment.	% to % of the gross revenue stream received by PARTNER from its licensee(s)
<u>Non-monetary Benefits</u> List and describe non-monetary benefits, such as training, consulting services, research-related equipment provided by PARTNER.	[Describe all desired non- monetary benefits and the minimum acceptable non- monetary benefits]

Initiation of negotiation using the proposed terms and negotiation ranges is approved.

Recommended:

Superintendent, PARK National Park

Concurred:

Regional Director, X Regional Office

Approved:

Associate Director, Natural Resource Stewardship and Science Date

Date

Date

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

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Term Sheet for a Benefits-Sharing Agreement between PARTNER and PARK National Park

[Enter full PARTNER and PARK names once with abbreviation in parentheses and then use abbreviated names in following text.]

This document describes certain principal terms for negotiation purposes for a proposed National Park Service (NPS) Benefits-Sharing Agreement. The Agreement will be negotiated and administered through PARK National Park (PARK) with assistance from the NPS Benefits-Sharing Coordinator.

Text Box: Unless instructions are provided in Italics, the wording in this Term Sheet should be used as provided, along with insertion of park and partner names.].

Confidentiality

The Terms are confidential information and shall not be disclosed to any third party without the consent of the parties to the proposed Agreement, except that the parties may disclose the Terms described and the existence of the Term Sheet to their respective officers, directors, employees, attorneys and other advisers, provided that such persons agree to the confidentiality restrictions contained herein.

Definitions

Collected specimen: The item collected by the permittee under the authority of an NPS Scientific Research and Collecting Permit, and portions thereof. Collected specimens are natural products.

Material (when capitalized): Progeny, and unmodified derivatives of collected specimens, museum specimens, living collection items, and multiple generations thereof. The Material does not include a) modifications or b) other substances created by a person through use of the Material that are not modifications, progeny, or unmodified derivatives.

Modification: A human-created substance that contains or incorporates Material (progeny and/or unmodified derivatives).

Progeny: Unmodified descendant from a collected specimen or Material, such as virus from virus, cell from cell, or organism from organism.

Research Results: Material (including Material retained in a living collection), modifications, intellectual property, inventions, data, discoveries, and/or other knowledge, processes, products, or applications resulting from research activities of researchers or their institutions or companies. Note: "Research results" excludes collected specimens and museum specimens.

NPS Benefits-Sharing Handbook Appendix J: Template for a Term Sheet

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Unmodified Derivative: A human-created substance that is not a portion of the collected specimen and, instead, constitutes an unaltered copy of a functional subunit or of a product expressed by the collected specimen or Material. Some examples include: copies of cells of the collected specimen, purified or fractionated subsets of the Material, proteins expressed by DNA/RNA extracted from the collected specimen or Material.

PROPOSED GENERAL TERMS		
Purpose of Proposed Agreement	This proposed Agreement will establish the rights and responsibilities of the parties relative to benefits sharing for commercialization of the technology described below, subject to the PARTNER obtaining all necessary permits required by state, federal or other authorities.	
Current Permits, Agreements and Licenses	[List and provide titles and associated numbers for all current and applicable Scientific Research and Collecting Permits, Collected Specimen Transfer Agreements, Material Transfer Agreements, loan agreements, licenses, or other pertinent documents].	
Technologies and Applications	The new technologies will be used for <u>[Specify all</u> <u>existing technologies, including the PARTNER's</u> <u>intended products or services subject to this benefits-</u> <u>sharing Agreement. State whether the end product or</u> <u>service will or will not incorporate Material</u>].	
NPS Compensable Interest in Material and Research Results	U.S. Government has a compensable interest in Material and Research Results related to the Current Permits, Agreements and Licenses.	
Parties to Benefits Sharing	NPS will require benefits sharing with PARTNER for commercial uses of the Technologies and Applications by_PARTNER, its licensees and sublicensees. NPS [will/will not] require separate benefits-sharing agreements with PARTNER's licensees and sublicensees. [PARK must choose whether to have separate benefits-sharing agreements with licensees.]	
Research in PARK	If any researcher wants to perform field research or collect specimens in PARK, that person must hold a valid NPS Scientific Research and Collecting Permit for the study described in the permit objectives. NPS issues or denies such permits without regard to whether the applicant is a party to this proposed Agreement.	

NPS Benefits-Sharing Handbook Appendix J: Template for a Term Sheet

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PROPOSED GENERAL TERMS		
Time Frame of this Agreement	The Agreement will be in effect as long as PARTNER receives income related to the Technologies and Applications.	
Other Terms	Any other terms.	

The proposed Agreement will include [Select one option: 1) solely non-monetary benefits, 2) solely monetary benefits, 3) a combination of the following non-monetary and monetary benefits] as stated in the Proposed Benefits Terms chart below.

NPS negotiates and structures each agreement on a case-by-case basis, taking into account the importance of the NPS Material to the development of the Technologies and Applications. The parties will negotiate collaboratively and in good faith to achieve a fair agreement for both PARTNER and PARK.

PROPOSED BENEFITS TERMS		
Proposed Benefits to PARK	Amount/Description	
<u>Up-front Payment</u> (a one-time payment)	\$	
Annual Maintenance Payment Annual maintenance payments are non-refundable in the event of termination.	\$ per year	
Performance-based Payments PARTNER agrees to pay PARK X percent of the PARTNER'S gross revenue stream from commercial use of the Technologies and Applications (including but not limited to sales income, license issue fees, annual payments, royalties, or additional payments received from licensees or other sources.) The performance-based payment will be reduced by the amount of any annual maintenance payment.	X% of the PARTNER'S gross revenue stream	
Non-monetary Benefits [Examples include training, consulting services, research- related equipment that the PARTNER provides.]	[Describe]	

Appendix K: Example of a Record of Benefits Received

Record of Benefits Received			
INSTRUCTIONS: Create this spreadsheet in Excel and modify to meet your needs. Use page 1 as a cover sheet to record the details of each agreement. Use page 2			
to track benefits received for each agreement. NOTE! 7	<i>This template is available to NPS users in Excel at</i>		
https://doimspp.sharepoint.com/sites/nps-nrss-ioad	<u>/SitePages/Benefits-Sharing-Program.aspx</u>		
CONFIDENTIALITYPayment breakdown by type ma by the non-NPS party. Total income to NPS by fiscal ye	ay be considered confidential by the non-NPS party. Do not disclose unless specific permission is granted ear for each agreement may be disclosed.		
B	enefits-sharing Agreement Description and Terms		
Full formal name of agreement	Cooperative Research and Development Agreement for Benefits Sharing Between PARK National Park, National Park Service, and PARTNER State University		
ID (benefits-sharing agreement number)	PARK-2014-1.0		
Start date	9/30/2014		
Initial end date	9/30/2019		
Renewable?	yes		
Current end date	9/30/2019		
Informal reference name	Example		
Type of benefits-sharing agreement	CRADA		
Payments due	Annually 10/1		
Upfront payment	\$ 5.00		
Date upfront payment due	10/1/2014		
Annual payment	\$ 1.00		
Performance-based payment	yes		
Other payment (describe)	none		
Reminder to payee (due date)	Annually 9/1		
Reimbursable account no.			
One-time non-monetary benefits? (If yes, summarize)	yes, collecting kits		
Recurring non-monetary benefits (If yes, summarize)	yes, kit training, lake monitoring event		

Copy this spreadsheet and rd of Actions and Benefit FY2016 Date Amount 10/1/15 \$ 1.00 10/1/15 \$ 2.00 \$ 3.00 \$ 3.00	ts Received FY201 FY2017	15-2019 mount D 1.00 10.	FY20	18 Amount 5 1.00 5 5.00	FY Date 10/1/18 10/1/18	2019 Am \$	nount
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ın-Sep 2	Jun-Sep	2 Jun-	Sep	2	Aug- Sep		2
9/1	5/16 1	5/16 1 5/15/17	5/16 1 5/15/17 1 5/	5/16 1 5/15/17 1 5/15/18	5/16 1 5/15/17 1 5/15/18 1	5/16 1 5/15/17 1 5/15/18 1 5/15/19 Aug-	5/16 1 5/15/17 1 5/15/18 1 5/15/19 Aug-

August 18, 2014, Updated October 16, 2018

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

Park Benefits-Sharing Annual Report

Instructions: All parks that participate in benefits sharing must complete an annual report. The Annual Report is based on the fiscal year and includes the following sections:

- 1. Administrative Information
- 2. Benefits-Sharing Program Summary Report
- 3. Detailed Report for Each Benefits-Sharing Agreement
- 4. Parks designated as a federal laboratory only: Federal Laboratory Report

Parks should use the tables in this template to compile the information for the Annual Report. Longer descriptions may be referenced in the table and attached as a separate sheet. Label the text on the attached sheet with corresponding report name and requested information block. Provide only non-confidential information.

SECTION 1: ADMINISTRATIVE INFORMATION

Information Requested (Administrative)	Reported Information
Fiscal Year	FY
Park Name	
Park point of contact (POC) name for report	
POC telephone	
POC email	
Date of report	

SECTION 2: BENEFITS-SHARING PROGRAM SUMMARY REPORT

Instructions: Provide summary information for all of the park's agreements to share or decline benefits that were active anytime during the fiscal year. When listing new permits or agreements, include only those permits and agreements that were fully executed during the fiscal year.

Requested Information (Summary for All	Reported Information
Agreements)	
Number of active benefits-sharing agreements (Total)	
CRADAs	
Other	
Number of new benefits-sharing agreements executed	
during FY (Total)	
CRADAs	

Requested Information (Summary for All Agreements)	Reported Information
Other	
Total monetary benefits received during FY from all	\$
benefits-sharing agreements, including General	
Agreements	
Total monetary benefits received and deposited in the	\$
U.S. Treasury.	
Examples of key non-monetary benefits received in	
FY	
Identification of permitted research activities (not	
previously reported) that are likely to lead to	
commercial application in future years. Enter study	
number, most recent permit number, or other	
identifier.	
Number of new agreements to decline benefits sharing	
Other relevant information	

SECTION 3: DETAILED REPORT FOR EACH BENEFITS-SHARING AGREEMENT

Instructions: Provide identifying information that is recurring and constant from year to year. (Do not include information for agreements to decline benefits sharing.)

Requested Information (Recurring)	Reported Information
Agreement ID number	
Name of Agreement	
Agreement Type [select one: CRADA, Cooperative	
Agreement, General Agreement, Other]	
Brief summary of the agreement [Include major	
milestones]	

Instructions: Provide variable information that is specific to each fiscal year. For research permits, CSTAs, MTAs, and loan agreements, list only those permits and agreements that are specific to the benefits-sharing agreement. Lapsed monetary benefits are funds not obligated during the period of availability. For example, monetary benefits that NPS receives under a CRADA must be obligated within two fiscal years of the fiscal year of receipt.

Requested Information (Variable)	Reported Information
Description of research and development (R & D) activities	
[Include major milestones achieved]	
Summary of any invention disclosures and/or patent	
application disclosures this fiscal year [Include patent	
application Serial Number and state if patent application	
has been published by the United States Patent and	
Trademark Office (USPTO). Use a separate line in the next	
column to describe each disclosure.]	

Requested Information (Variable)	Reported Information
Patent number, title, assignee and inventors for any patents	
granted this fiscal year [Use a separate line in the next	
column to describe each patent.]	
Non-monetary benefits received [Use a separate line in the	
next column to describe each benefit.]	
Non-monetary benefits used [Use a separate line in the	
next column to describe each benefit.]	
Total income from monetary benefits	\$
Income from Upfront Payments	
Income from Annual Payment	
Income from Performance-based Payments	
Income from Other Payments	
Total expenditures of monetary benefits [Enter "Not	\$
applicable" for General Agreement]	
Describe how monetary benefits were used [Use a separate	
line in the next column to briefly describe each use and	
associated dollar amount. Reference PMIS project number,	
as applicable. Enter "Not applicable" for General	
Agreement]	
For a General Agreement, monetary benefits that NPS	\$
received and deposited in the U.S. Treasury	
Total lapsed monetary benefits (unobligated)	\$
New research permits [List by permit number]	
New CSTAs [List by number, or by date if number not	
available]	
New MTAs [List by number, or by date if number not	
available]	
New loan agreements [List by number, or by date if	
number not available]	
Comments, if any:	

SECTION 4: FEDERAL LABORATORY REPORT

Instructions: For the fiscal year, each park designated as a federal laboratory must provide information on all Licenses that NPS issues and Employee Inventions as follows.

Licenses

Instructions: For each IP that NPS owns and for which NPS has active licenses, report the following information for each license:

Requested Information (Licenses)	Reported Information
License title	
Year of execution	
Exclusive, partially exclusive, non-exclusive [select one]	
"Invention" or "Other IP"? [select one]	
Does the license provide for income to NPS? —yes/no	
Total income	\$
Earned royalty income	\$
License issuance fee (if any)	\$
Milestone payments (if any)	\$
Other payments	\$
Time elapsed from the date on which the licensee requested	
the license in writing to the date NPS executed the license	
[List days, weeks, months, or years]	
Earned royalty income obligated [Reference information	\$
on uses of the income by listing PMIS numbers]	
Income, other than earned royalty income, obligated	\$
[Reference information on uses of the income by listing	
PMIS numbers]	
License terminated for cause—yes/no [State reason]	
Licenses terminated for reasons other than cause [State	
reason]	

Employee Inventions

Instructions: For each NPS employee inventor, report on each invention disclosed this fiscal year, and on all active patent applications through the fiscal year in which the patent is granted or denied.

Requested Information (Employee Inventions)	Reported Information
Name of employee	
Date invention disclosed	
Invention summary [Non-confidential]	
Date patent application filed, if applicable	
Patent application serial number	
Date patent granted, if applicable	
Patent number, if applicable	
Date patent denied, if applicable	

Appendix M: Example of a Confidentiality Agreement

NOTE! This template is available to NPS users as a Word document at https://doimspp.sharepoint.com/sites/nps-nrss-ioad/SitePages/Benefits-Sharing-Program.aspx

CONFIDENTIALITY AGREEMENT WITH [Insert NPS unit name] / National Park Service

This CONFIDENTIALITY AGREEMENT is entered into as of this _____ day of _____, ____ by [*insert NPS unit name*] / National Park Service, and [*insert institution name*] in order to protect the confidential information that is disclosed to Recipient by Discloser.

The party disclosing confidential information ("Discloser") is

The party receiving confidential information ("Recipient"), is ______

NOW THEREFORE, in consideration of the mutual covenants contained herein, the parties agree as follows:

1. The Recipient's representatives for receiving confidential information are:______; Recipient(s) shall not disclose the confidential information to any of its employees other than those who have a need to review it and which employees are legally obligated to honor the confidentiality provisions herein.

2. The confidential information disclosed under this Agreement is described as:

3. The confidential information is disclosed under this Agreement for the following purposes:

4. The Recipient shall keep the information confidential and shall use the confidential information only for the purposes described above. The Recipient shall not make any copies of the confidential information except as necessary for its employees who are entitled to review it under Section 1 above. Any copies that are made shall be identified as belonging to the Discloser and marked "confidential", "proprietary", or with a similar legend.

5. To the extent permitted by law, the Recipient shall protect the disclosed confidential information by using the same degree of care, but no less than a reasonable degree of care, to prevent the unauthorized use, dissemination or publication of the confidential information as the Recipient uses to protect its own confidential information of a like nature.

NPS Benefits-Sharing Handbook Appendix M: Example of a Confidentiality Agreement

6. The Recipient shall have a duty to protect all confidential information which is disclosed to it, whether disclosed in writing, orally or in any other manner and which is identified as confidential at the time of disclosure. If the disclosure is in writing, it shall be marked "confidential." If the disclosure is not in writing, Discloser shall provide Recipient with a written memorandum summarizing and designating such information as confidential within thirty (30) days of the disclosure.

7. This Agreement imposes no obligation upon the Recipient with respect to confidential information which (a) was in the Recipient's possession before receipt from the Discloser; (b) is or becomes a matter of public knowledge through no fault of the Recipient; (c) is rightfully received by the Recipient from a third party without a duty of confidentiality; (d) is disclosed by Discloser to a third party without a duty of confidentiality on the third party; (e) is independently disclosed by the Recipient with Discloser's prior written approval.

8. The Discloser warrants that it has the right to make the disclosures under the Agreement.

9. The Recipient acquires no intellectual property rights under this Agreement.

10. Neither party has an obligation under this Agreement to purchase, sell or license any service or item from the other party.

11. The Recipient shall adhere to the U.S. Export Administration Laws and Regulations and shall not export or re-export technical data or products from the Discloser or the direct product of such technical data to any proscribed country listed in the U.S. Export Administration Regulations, unless properly authorized by the U.S. Government. (See 15 CFR 730.)

12. The parties do not intend that any agency or partnership relationship be created between them by this Agreement.

13. All additions or modifications to this Agreement must be in writing and signed by both parties.

14. This Agreement is made under and shall be governed by the laws of the United States.

-- Signatures begin next page --

FOR RECIPIENT:
Institution Name:
By:
Print Name:
Title:
Address:
FOR DISCLOSER:
Institution Name:
By:
Print Name:
Title:
Address:

Appendix N: Summary of Laws on Benefits Sharing and Technology Transfer

NPS Authority for Benefits Sharing

54 USC 100705 codified from the National Parks Omnibus Management Act authorizes the Secretary of the Interior to "enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements." Because the Act does not provide detail on implementation, such as the type of arrangements that NPS should use or the authority to directly retain monetary benefits (rather than conveying them to the U.S. Treasury), NPS relies on additional authorities to implement benefits sharing, including the FTTA described below under Technology Transfer.

NPS Authorities to Enter Into Agreements

Congress has provided the NPS with authority to enter into various types of agreements with other federal bureaus; with state, county, municipal, and tribal governments; and with private companies, corporations, groups, and individuals. Some examples of legislative authority for entering into these agreements include, but are not limited to, those listed in the following paragraphs. In addition, the enabling legislation for various National Park System units provides additional site-specific authorities.

54 USC 100703 authorizes and directs the Secretary to enter into Cooperative Agreements with colleges and universities, including but not limited to land grant schools, in partnership with other federal and state agencies, to establish cooperative study units to conduct multi-disciplinary research and develop integrated information products on the resources of the National Park System, or the larger region of which parks are a part.

54 USC 100101-101702 authorizes the NPS to enter into Cooperative Agreements with public or private educational institutions, states, and their political subdivisions, for the purpose of developing adequate, coordinated, cooperative research and training programs concerning the resources of the National Park System. Pursuant to such agreements, the cooperator may accept from or make available to the NPS technical and support staff, financial assistance for mutually agreed upon research projects, supplies and equipment, facilities, and administrative services relating to cooperative research units as the Secretary deems appropriate (research projects subject to Federal Acquisition Regulation excluded).

54 USC 101702 authorizes the NPS to enter into Cooperative Agreements for the public purpose of carrying out National Park Service programs. Pursuant to such agreements, the NPS may provide funds to state, local and tribal governments, other public entities, educational institutions, and private nonprofit organizations.

Consolidated Natural Resources Act of 2008 (PL 110-229; 122 Stat. 754-876) Cooperative Agreements for National Park Natural Resource Protection, authorizes the NPS to enter into Cooperative Agreements with state, local, or tribal governments, other federal agencies, other public entities, educational institutions, private nonprofit organizations, or participating private

NPS Benefits-Sharing Handbook Appendix N: Summary of Laws on Benefits Sharing and Technology Transfer

landowners for the purpose of protecting natural resources of units of the National Park System through collaborative efforts on land inside and outside of National Park System units.

Authorities for Federal Technology Transfer

Since 1980, Congress has enacted a series of laws to promote technology transfer and to provide technology transfer mechanisms and incentives. The intent of these laws and related Executive Orders is to encourage the pooling of resources when developing commercial technologies. The bidirectional sharing between federal laboratories and private industry includes not only technologies, but personnel, facilities, methods, expertise, and technical information in general. (Federal Laboratory Consortium, *Federal Technology Transfer Legislation and Policy*)

15 USC 3710, Utilization of Federal Technology, establishes the continuing responsibility of the federal government to ensure the full use of the results of the Nation's federal investment in research and development. Federal laboratories and scientists are instructed to strive where appropriate to transfer federally owned or federally originated technology to others including to the private sector.

15 USC 3710a provides a broad definition of "federal laboratory" and authorizes federal laboratory directors to enter into Cooperative Research and Development Agreements (CRADAs).

15 USC 3710c provides criteria for the expenditure of any income an agency receives from a CRADA.

Technology transfer laws are often referred to by the Acts that established each part of the law. Some of the commonly referenced Acts are listed below. A full inventory of federal legislation that has influenced technology transfer may be found in the Federal Laboratory Consortium for Technology Transfer's publication, *Federal Technology Transfer Legislation and Policy*, known as "The Green Book." (See <u>https://www.federallabs.org/media/publication-library/federaltechnology-transfer-legislation-and-policy-the-green-book</u>.)

The **Stevenson-Wydler** Technology Innovation Act of 1980 was the first of a continuing series of laws to define and promote technology transfer. The primary focus of the Act concerned the dissemination of information from the federal government and getting federal laboratories more involved in the technology transfer process.

The **Bayh-Dole** Act of 1980 allowed small businesses, universities, and not-for-profit organizations to obtain titles to inventions developed with federal funds.

The **Federal Technology Transfer Act** of 1986 (FTTA) provided authorization for the exchange of personnel, services, and equipment among the laboratories and non-federal partners. Other specific requirements, incentives and authorities were added, including permission for current and former federal employees to participate in commercial development, to the extent that there is no conflict of interest, and requiring that government-employed inventors share in

NPS Benefits-Sharing Handbook Appendix N: Summary of Laws on Benefits Sharing and Technology Transfer

royalties from patent licenses. The law required all federal laboratory scientists to consider technology transfer an individual responsibility.

Intellectual Property

35 USC, Patents, provides the legal basis for protecting intellectual property through patenting. Of relevance to NPS benefits sharing and technology transfer, **35 USC 122** establishes the confidentiality of a patent application until the United States Patent and Trademark Office (USPTO) publishes it; and **35 USC 209** authorizes federal agencies to license federally owned patented inventions and requires the agency to keep the licensee's financial and marketing information confidential, exempting such information from disclosure under FOIA. PL 112-29, Leahy-Smith America Invents Act (September 16, 2011), amends 35 USC to change key aspects of the U.S. patent system, including changing from "first-to-invent" to "first-to-file."

18 USC 1831 *et seq.* defines trade secrets and establishes their confidentiality. Trade secrets can include many types of information that derive independent economic value from not being generally known to the public.

International Benefit Sharing

The **Convention on Biological Diversity** (CBD) is a multilateral treaty with 193 Parties not including the United States of America. The CBD and the voluntary **Bonn Guidelines** under it suggest procedures to ensure fair and equitable sharing of the benefits arising from the use of certain genetic resources. The **Nagoya Protocol** on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) is an international agreement under the CBD adopted in 2010. It will enter into force 90 days after the fiftieth instrument of ratification. The United States is not a signatory to the Nagoya Protocol. (See http://www.cbd.int/.)