



NPS BENEFITS SHARING

National Park Service
George Wright Society Conference
April 2, 2015

Introductions



■ NPS

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■ DOI Office of the Solicitor

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Photo: Thermal algae, Monument Geyser Basin, Yellowstone NP. Photo by NPS/Dunmire.

Overview

- What is benefits sharing?
- What are the fundamental principles of benefits sharing?
- What basic points do I need to know about permits and other authorizations to access and use NPS resources?
- What are the basic features of benefits-sharing agreements?
- Does NPS always seek to share benefits?
- How do parks manage benefits?
- What policy and guidance is available?
- What is the global perspective on benefits sharing?

What is NPS benefits sharing?

- 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.
- Key factors:
 - Permitted research
 - Research results in a commercial application
 - NPS enters into a benefits sharing agreement
 - NPS receives monetary or non-monetary benefits
 - NPS applies benefits to enhance resource protection
 - Commercial sale of collected specimens is prohibited

Fundamental principles

- Commercial use or sale of collected specimens is prohibited
- Existing NPS law and policy do not prohibit or authorize commercial use of research results derived from collected specimens. Management Policies 4.2.4 requirement for a “supplemental written authorization” means an agreement to share or decline benefits.

NPS has compensable interest in research results from collected specimens, Material (progeny and unmodified derivatives), modifications (which incorporate Material)

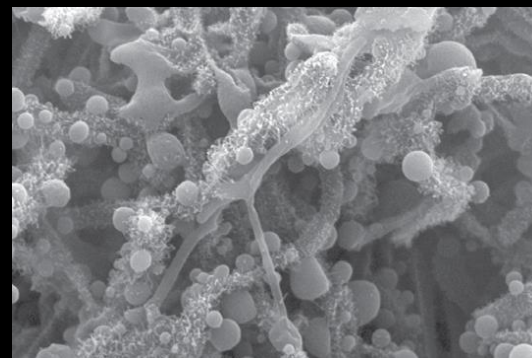


Permit basics



- NPS issues permits for scientific and educational purposes only
- NPS maintains a firewall between issuing permits and negotiating benefits sharing
- Permits have benefits-sharing condition related to commercial application of research results

Agreement basics



- Negotiated on case-by-case basis
- Are between parks and entities other than individuals
- May share or decline to share benefits
- Benefits may be monetary and/or non-monetary
- Are made public, except for confidential information protected by law
- Do not authorize any research activities in parks or any activities that require an NPS permit, CSTA, MTA, or loan agreement
- Generally qualify for NEPA categorical exclusion
- Are all reviewed by DOI Office of the Solicitor

Does NPS always seek to share benefits?

- No
- Evaluate on case-by-case basis
- Share when potential benefits would have value to NPS and general public
- Do not require a benefits-sharing agreement when superintendent determines commercial use of research results is primarily educational and would benefit general public (e.g., scholarly journals, textbooks, field guides, museum exhibits)
- Decline to share when potential benefits would not create value for NPS and general public



Parks manage benefits

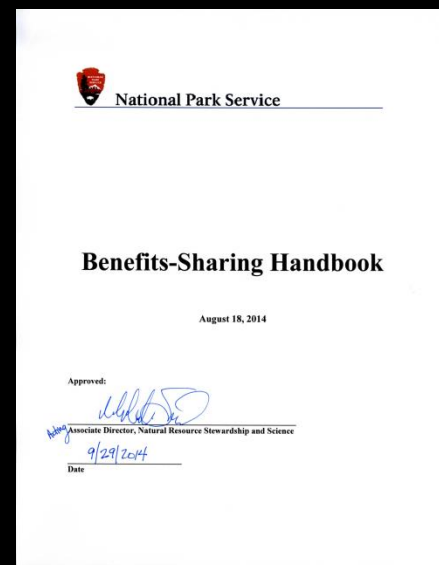


- Use benefits to
 - improve conservation and protection of park resources
 - strengthen the scientific capacity of NPS scientists through collaboration with other governmental and non-governmental researchers
- Document and report use of monetary and non-monetary benefits

Photo: After years of planning, a biologist releases endangered humpback chubs into Shinumo Creek in Grand Canyon NP. Photo by NPS/Melissa Trammell.

Policy and Guidance

- Director's Order #77-10
- NPS Benefits-Sharing Handbook
 - Responsibilities (park, region, WASO)
 - Research permits and benefits sharing
 - NPS specimen and Material management—permits, cataloging, loan agreements, transfer agreements
 - Developments that trigger benefits-sharing actions
 - Commercial use of research results
 - Agreements to share or decline benefits
 - Receiving and using monetary and non-monetary benefits, annual reporting
 - Technology transfer, employee inventions, patents
 - International perspective on benefits sharing





Global Perspective

- *Bonn Guidelines (2002) and Nagoya Protocol (2010)* on access to genetic resources and fair and equitable sharing of benefits arising from their use adopted by parties to the Convention on Biological Diversity (CBD)
- Protocols offer voluntary guidance for access and benefits sharing (ABS), including
 - Providing access to genetic (non-human) resources
 - Requiring prior informed consent of providers of traditional knowledge (TK)
 - Determining the basis for benefits sharing
- U.S. not a party, but participates in discussions

Legal Authorities & Early History

- What is the history of NPS benefits sharing?
- What are the legal authorities for benefits sharing?
- What is compensable interest and why is that important?
- What is the relationship between benefits sharing and federal technology transfer?
- What would prompt a park to be designated a federal laboratory under the FTTA?
- When might patents and licenses come into play in relation to benefits sharing?
- How are employee inventions addressed under FTTA?

The story of *Thermus aquaticus*



- 1960s—Brock collects/isolates *T. aquaticus* from thermal pool in Yellowstone NP
- Brock deposits *T. aquaticus* at ATCC
- 1965—Brock isolates Taq polymerase (Taq), an enzyme extracted from *T. aquaticus* that is stable at near boiling temperatures
- 1980s—Invention of Polymerase Chain Reaction (PCR) uses Taq
- PCR used to amplify short segments of DNA
- PCR now basis of multi-million dollar business
- *T. aquaticus* remains available in NPS Special Collection at ATCC

History



- 1997—YELL CRADA with biotech firm Diversa Corporation (under FTTA).
- 1998—Lawsuit *Edmonds Inst v. Babbitt*, 93 F. Supp. 2d 63 (D.D.C. 2000)
- 1998—Congress enacted NPOMA with authority for “benefits-sharing”
- 2000—Federal court upheld NPS-Diversa CRADA but required NEPA analysis
- 2009—NPS issued servicewide Benefits-Sharing FEIS
- 2010—NPS issued ROD
- 2013—Policy (Director’s Order # 77-10) issued
- 2014—Benefits-Sharing Handbook issued

Authorities

- NPOMA (1998) authorizes the Secretary to “enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements” (54 USC 100705(d))
- FTTA authorizes parks designated as federal labs to enter into CRADAs, manage federal lab inventions and IP, and retain revenue/other benefits (15 USC 3710)
- Other agreement authorities enable NPS to share benefits with other public entities, educational institutions, and nonprofits

What is compensable interest and why is that important?

- Definition of Compensable interest—A legal share in physical or intellectual property that is entitled to compensation when others use that share of the property
- U.S. Government has a compensable interest in Material and research results related to current permits, agreements and licenses pertinent to a benefits-sharing agreement
- Compensable interest appears as a term in benefits-sharing agreements

More about Federal Tech Transfer

- Federal tech transfer and benefits sharing
- Federal Laboratory Designation
 - a "facility owned . . . or otherwise used by a Federal agency," a "substantial purpose of which is the performance of research."
- Patents and Licenses
- Employee Inventions
 - Interior (DOI) Manual Chapter 453 DM 1

US006565644B2

(12) **United States Patent**
Kepler et al.

(10) **Patent No.:** US 6,565,644 B2
(45) **Date of Patent:** May 20, 2003

(54) **MICRO-ENCAPSULATED CRACK RESISTANT CEMENT**

(75) **Inventors:** William F. Kepler, Golden, CO (US); Kurt E. von Fay, Morrison, CO (US)

(73) **Assignee:** The United States of America as represented by the Secretary of the Interior, Washington, D.C.

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 3 days.

(21) **Appl. No.:** 09/891,452

(22) **Filed:** Jun. 27, 2001

(65) **Prior Publication Data**
US 2003/0000425 A1 Jan. 2, 2003

(51) **Int. Cl.7** C04B 24/24

(52) **U.S. CL** 106/713; 106/724

(58) **Field of Search** 206/219; 106/713, 106/724, 696

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Primary Examiner—Paul Macantonio
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(57) **ABSTRACT**
A cement mixture is provided for preventing or reducing the formation of micro-cracks during hydration. The cement mixture includes both a conventional cement and a cement micro-encapsulated in a time-release polymer coating. The micro-encapsulated cement does not hydrate until a few hours to a few days after the bulk of the conventional cement has hydrated, thereby allowing for autogenous healing of small cracks.

12 Claims, No Drawings

Key Points for Permittees and Park Staff

- What conditions in NPS Scientific Research and Collecting Permits address use of research results?
- How can research with a non-commercial purpose result in a commercial application?
- What requirements and tracking procedures link a researcher to benefits sharing?
- What about NEPA compliance for benefits sharing?
- What roles do NPS employees play in managing benefits sharing?
- How do employees avoid conflicts of interest when managing benefits sharing?
- Why is a firewall important?
- When is confidentiality important?

What conditions in NPS Scientific Research and Collecting Permits address use of research results?

- Research authorized for scientific or educational purposes only
- Research results must be for public benefit
- Results must be accessible to the public
- Results must not be used for commercial purposes without a benefits-sharing agreement (General Condition #6)



What other authorizations have similar terms?



- Collected Specimen Transfer Agreement (CSTA)
- Material Transfer Agreement (MTA)
- Loan Agreement
- Archeological permit (benefits-sharing term to be added)

What is the basis for such conditions in NPS permits and other authorizations?

- The commercial use or sale of collected specimens themselves is prohibited by
 - 36 CFR 2.1(c)(3)(v)
 - NPS *Management Policies* 2006 4.2.4
- A supplemental written agreement is required for commercial use of research results by
 - Management Policies 4.2.4
 - Director's Order #77-10: NPS Benefits Sharing

How can research with a non-commercial purpose result in a commercial application?

- Examples:
 - Researcher authorized to collect a microbe to conduct basic research on its biology, discovers an enzyme that has medicinal properties, develops a mechanism to synthesize the enzyme at industrial scale
 - Researcher authorized to study frog chemical defenses discovers a toxin that may have medicinal value, and develops and patents a way to synthesize the toxin
 - Researcher authorized to study growth regulators in rare plant having unusual growth characteristics, discovers a new growth regulator, develops mechanism to synthesize it at industrial scale

What requirements and tracking procedures link a researcher to benefits sharing?

- General Condition 6 and similar terms in other authorizations require a researcher to enter into a benefits-sharing agreement with NPS
- NPS learns about a benefits-sharing potential from the permittee or other authorized user, by tracking a researcher's publications, by scanning notices of inventions and submissions of patent applications
- Benefits-sharing requirement is enforceable—signatures on permits and agreements show acceptance of the requirement

What about NEPA compliance for benefits sharing agreements?

- Agreements must comply with law, including NEPA
- Federal actions not having potential to impact the human environment usually qualify for categorical exclusion:
 - Agreement to share or decline benefits (NPS categorical exclusion 3.3C)
 - CSTA, MTA, loan agreement (NPS categorical exclusion 3.3Y)
 - Federal actions that may have an impact on the human environment require additional analysis
- Related activities require separate, site-specific environmental review

What roles do NPS employees play in managing benefits sharing?

- Director
- Associate Director, NRSS
 - WASO benefits-sharing coordinator
 - Office of Research & Technology Assessment (ORTA)
- Other WASO Associate Directors
- Regional Director
- Superintendent
 - Park permit coordinator
 - Park museum curator
 - Park benefits-sharing coordinator
 - Benefits-sharing negotiating team lead
 - Park living collections curator

How do NPS employees avoid conflicts of interest when managing benefits sharing?

- Ensure no conflicts when developing agreements
- Uphold confidentiality provisions
- Maintain a “firewall” between issuing permits and similar authorizations and negotiating benefits-sharing agreements
- Ensure employees have no related financial interests
- Address actual and apparent conflicts of interest
- Consult ethics officer whenever receipt of personal benefits is involved
- Consult ethics officer when proposing to privately participate in commercial development in job-related subject area

Why is a firewall important?

- A firewall prevents conflict of interest when managing permits and other authorizations and negotiating and managing benefits sharing
- Research permits and other authorizations are the foundation for benefits sharing
 - Considerations to issue research permits and other authorizations must be kept separate from decisions regarding preparing and negotiating benefits sharing
 - The superintendent must not consider past or potential benefits while making a decision to issue a permit
- Individuals with responsibility for benefits-sharing agreements must not coordinate research permits, CSTAs, MTAs, or loan agreements

When is confidentiality important?

- Government employees by law are not to disclose to unauthorized parties confidential and proprietary information disclosed to them
- Information that another party provides and marks CONFIDENTIAL must be kept confidential by recipients
 - indefinitely
 - for an agreed time period
 - until owner releases it
 - until released to the public by non-federal action
- 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
- NPS may receive confidential information at any time

Benefits and Agreements

- What are some examples of non-monetary benefits?
- What are some examples of monetary benefits?
- Why are there different agreement types?
- How does a park decide the agreement type to use?
- How does a park set negotiating parameters?
- How does a park go about negotiating an agreement—what are the steps?
- When might a park decline to share benefits?
- How does a park collect, use, and account for benefits?
- Do monetary benefits have to be spent by a deadline?

Non-Monetary and Monetary Benefits



- Non-monetary: Knowledge, Training, Supplies and Equipment and Special Services



- Monetary: Upfront Payment, Annual Maintenance Payment, Milestone Payment, Other

Agreement Types

- CRADA
 - Park must be designated a federal laboratory
 - Non-federal parties may provide monetary benefits to NPS
 - Federal/non-federal parties may provide non-monetary benefits
- General Agreement
 - Federal/non-federal parties may provide non-monetary benefits to NPS
 - Non-federal parties may provide monetary benefits to U.S. Treasury
 - Federal entities may grant interest in invention to NPS from separate licensing but only parks designated as fed labs can retain monetary benefit
- Cooperative Agreement
 - Educational institutions, state/local governments may provide monetary or non-monetary benefits
 - NPS must have substantial involvement and project must have a public purpose
- Agreement to Decline Benefits
 - NPS declines based on technical and/or economic reasons

Setting Negotiation Parameters

- Case-by-case basis, taking into account importance of study of collected specimen to the new technology
- A collaborative negotiation based on following terms and elements
 - Purpose of Proposed Agreement
 - Current Permits, Agreements and License
 - Technologies and Applications
 - NPS Compensable Interest in Material and Research Results
 - Parties to Benefit Sharing
 - Research in PARK
 - Time Frame of the Agreement
 - Other Terms



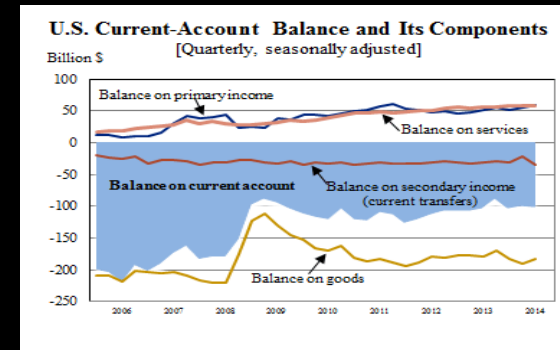
Steps to Negotiating an Agreement

- Step 1: Obtain the Director's designation of the park as a federal laboratory (CRADA only)
- Step 2: Notify management of park's intent to develop an agreement to share or decline benefits
- Step 3: Form a negotiating team
- Step 4: Collect background information



Photo: Yosemite NP lichenologist Martin Hutten, right, and an American Alpine Club mountaineer document the colorful lichen-rich cliff near Vernal Falls, Yosemite NP. Photo by Crista-Lee Mitchell, 2008, AP.

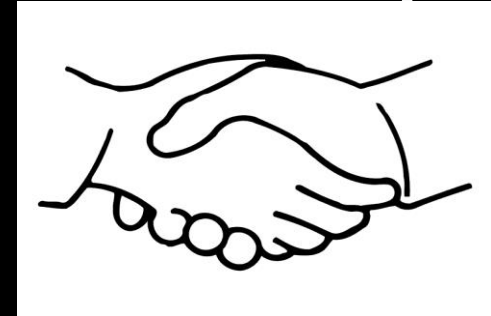
Steps to Negotiation (continued)



- Step 5 Begin the benefits-sharing negotiation process
 - Step 5a: Initiate a dialog with the other party
 - Step 5b: Complete market research
 - Step 5c: Identify desired monetary benefits (if only non-monetary go to Step 5d)
 - Step 5d: Identify desired non-monetary benefits
 - Step 5e: Develop the term sheet

Steps to Negotiation (continued)

- Step 6: Share the Term Sheet with the other party and start negotiating
- Step 7: Develop the draft agreement and continue negotiating
- Step 8: Comply with NEPA and all other legal mandates
- Step 9: Seek final review and approval of NPS officials
- Step 10: File original agreement in park and distribute copies

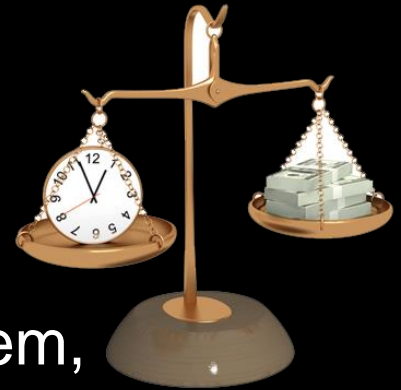


Declining Benefits

- Parks may decide to decline benefits
- The park must draft a letter of agreement or other agreement signed by parties to decline benefits
- Parks may decline based on technical and/or economic reasons and NOT ON AN OPINION AS TO WHETHER COMMERCIAL ACTIVITY SHOULD OCCUR

Collecting, Using and Accounting for Benefits

- Partner must use the Pay.Gov system to make electronic payments using the Automated Clearing House (ACH) system, a credit card, or Pay pal
- All standard NPS accounting and procurement procedures apply to receipt and expenditure of the funds
- FTTA requires all funds be obligated within 2 fiscal years from the end of the year when funds received
- Funds must be spent to enhance resource protection or to offset costs of administering benefits sharing



Tools for Benefits Sharing

<http://www.nature.nps.gov/benefitssharing/policy.cfm>

- Director's Order #77-10: NPS Benefits Sharing
- NPS Benefits-Sharing Handbook
 - Procedural Instructions
 - Glossary
 - Templates and Examples
 - Designation as a federal lab
 - Agreements (CRADA, General Agreement, CSTA, MTA)
 - Letter to Decline Benefits Sharing
 - Request for Approval of Negotiations and Terms
 - Record of Benefits Received and Annual Report
 - Confidentiality Agreement



Questions?



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