

Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period. A request for a non-competing extension of the final budget period of a project period with a minimal amount of additional funds should be submitted to the GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests usually are for a period of up to 12 months, based on a need to provide continuity of project activities while a competing continuation application is being reviewed or to permit orderly phaseout of project activities for which there will be no further NIH support. The request must specify the proposed revised ending date and must include justification for both the extension and the additional funds requested. Special justification will be required for an extension that would exceed 12 months. NIH will not approve such requests if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. All terms and conditions of the award apply during the extended period.

Pre-Award Costs. See ["Cost Considerations—Selected Items of Cost—Pre-Award \(Pre-Agreement\) Costs."](#)

Retention of Research Grant Funds When a K Award is Made. Funds budgeted under an NIH grant for an individual's salary and fringe benefits, but available as a result of receiving a K award for that individual, may not be used for any other purpose without NIH prior approval.

Transfer of Amounts from Trainee Costs. The transfer of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other categories of expense requires NIH prior approval. This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses (see ["Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Rebudgeting of Funds"](#) in Subpart B of this part).

Transfer of Funds Between Construction and Nonconstruction Work. Under awards that provide for both construction and nonconstruction work, NIH prior approval is required to transfer funds between the two types of work.

Requests for Prior Approval

All requests for NIH awarding office prior approval must be made in writing (which includes submission by e-mail) to the GMO no later than 30 days before the proposed change. The request must be signed by both the PI and the AOO. Failure to obtain required prior approval, from the appropriate NIH awarding office may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority.

E-mail requests must be clearly identified as prior-approval requests, must reflect the complete grant number in the subject line, and should be sent by the AOO to the GMO that signed the NGA. (E-mail addresses for NIH staff can be obtained from the NIH Directory and E-Mail Forwarding Services at <http://directory.nih.gov>.) E-mail requests must include the name of the grantee, the name of the initiating PI, the PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOO. If the entire message of the request cannot be included in the body of the e-mail, the request should be submitted to NIH in hard copy.

The GMO will review the request and provide a response to the AOO indicating the final disposition of the request. The GMO will provide copies of the response to the PI and to the cognizant NIH PO. Only responses provided by the GMO are to be considered valid. Grantees that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

Whenever grantees contemplate rebudgeting or other post-award changes and are uncertain about the need for prior approval, they are strongly encouraged to consult, in advance, with the GMO.

Under a consortium agreement or contract, the prior-approval authority usually is the grantee. However, the grantee may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a consortium participant will result in a change in the overall grant project or budget requiring NIH approval, the grantee must obtain that approval from NIH before giving its approval to the consortium participant.

Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also ["Public Policy Requirements and Objectives—Availability of Information—Access to Research Data"](#) for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

As long as grantees abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the grantee to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources—"research tools"—may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

Rights in Data (Publication and Copying)

In general, grantees own the rights in data resulting from a grant-supported project. Special terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or

based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data, ^[12] or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals. Grantees also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the grantee from making copies for its own use (as provided in 45 CFR 74.36 and 92.34). The disposition of royalties and other income earned from a copyrighted work is addressed in ["Administrative Requirements—Management Systems and Procedures—Program Income."](#)

For each publication that results from NIH grant-supported research, grantees must include an acknowledgment of NIH grant support and a disclaimer stating the following:

"This publication was made possible by Grant Number _____ from _____" or "The project described was supported by Grant Number _____ from _____" and "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the [name of awarding office or NIH]."

If the grantee plans to issue a press release concerning the outcome of NIH grant-supported research, it should notify the NIH awarding office in advance to allow for coordination.

One copy of each publication resulting from work performed under an NIH grant-supported project must accompany the annual or final progress report submitted to the NIH awarding office (see ["Administrative Requirements—Monitoring—Reporting—Non-Competing Grant Progress Reports"](#) and ["Administrative Requirements—Closeout—Final Reports—Final Progress Report"](#)).

Sharing of Research Data

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. Effective with the October 1, 2003 receipt date, investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single budget period are expected to include a plan for data sharing or state why data sharing is not possible.

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the "Privacy Rule" (See ["Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Confidentiality—Standards for Privacy of Individually Identifiable Health Information"](#)). The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

Sharing of Unique Research Resources

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include synthetic compounds, organisms, cell lines, viruses, cell products, and cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized or genetically defined cells, including normal and diseased human cells; monoclonal antibodies; hybridoma cell lines; microbial cells and products; viruses and viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; certain types of animals, such as transgenic mice; and intellectual property, such as computer programs.

NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources developed with NIH funds and the associated research findings have been published or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

To provide further clarification of the NIH policy on disseminating unique research resources, NIH published *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999), which is available on the NIH website (http://www.ott.nih.gov/policy/rt_guide_final.html). This document will assist grantees in determining reasonable terms and conditions for disseminating and acquiring research tools.

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding office, the grantee also must provide a copy of documents or a sample of any material developed under an NIH grant award. The grantee may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see *Administrative Requirements—Management Systems and Procedures—Program Income*).

To facilitate the availability of unique or novel biological materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to comply with these requirements should promptly contact the GMO to discuss the circumstances, obtain information that might enable compliance, and reach an understanding in advance of an award.

Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212) and the related EO 12591 (April 10, 1987) provide incentives for the practical application of research supported through Federal funding agreements. To be able to retain rights and title to inventions made with Federal funds, so-called "subject" inventions, the grantee must comply with a series of regulations that ensure the timely transfer of the technology to the private sector, while protecting limited rights of the Federal government.

The regulations apply to any subject invention—defined as any invention either conceived or first actually reduced to practice in the performance of work under the Federal award—and to all types of recipients of Federal funding. This includes non-profit entities and small businesses or large businesses receiving funding through grants, cooperative agreements, or contracts as direct recipients of funds, or as consortium participants or subcontractors under those awards.

NIH grantees may retain intellectual property rights to subject inventions provided they do the following:

- | Report all subject inventions to NIH.
- | Make efforts to commercialize the subject invention through patent or licensing.
- | Formally acknowledge the Federal government's support in all patents that arise from the subject invention.
- | Formally grant the Federal government a limited use license to the subject invention.

Exhibit 5 summarizes recipient responsibilities for invention reporting as specified in the regulations in 37 CFR Part 401. Grantees should refer to 37 CFR Part 401 (available on the Interagency Edison site: <https://s-edison.info.nih.gov/Edison/>) for a complete discussion of the regulations.

Exhibit 5. Extramural Invention Reporting Compliance Responsibilities			
Action required	When action must be taken	Discussion	37 CFR 401 reference
Employee Agreement to Disclose All Inventions			
The PI (employee) must sign an agreement to abide by the terms of the Bayh-Dole Act and the NIHGPS as they relate to intellectual property rights.	At time of employment.	Grantee organizations and consortium participants must have policies in place regarding ownership of intellectual property.	401.14(f)(2)
Invention Report and "Disclosure"			
The grantee organization must submit to NIH a report of any subject invention. This includes a written description (the so-called "invention disclosure") of the invention.	Within 2 months of the inventor's initial report of the invention to the grantee organization.	There is no single format for disclosing the invention to the Federal government. The report must identify inventor(s), NIH grant number, and date of any public disclosure.	401.14(a)(2) 401.14(c)(1)
Rights to Consortium Participant Inventions			
Consortium participants under NIH grants retain rights to any subject inventions they make.	Within 2 months of the inventor's initial report of the invention to the consortium participant. (The consortium participant has the same invention reporting obligations as the grantee.)	The grantee cannot require ownership of a consortium participant's subject inventions as a term of the consortium agreement.	401.14(g)(1) 401.14(g)(2)
Election of Title to Invention			
The grantee must notify NIH of its decision to retain or waive title to invention and patent rights.	Within 2 years of the initial reporting of the invention to NIH.		401.14(b) 401.14(c)(2) 401.14(f)(1)
Confirmatory License			
For each invention, the grantee must provide a use license to NIH for each invention.	When the initial non-provisional patent application is filed.		401.14(f)(1)
Patent Application			
The grantee must inform NIH of the filing of any non-provisional patent application. The patent application must include a Federal government support clause.	Within 1 year after election of title, unless there is an extension.	Initial patent application is defined as a non-provisional U.S. application. The patent application number and filing date must be provided.	401.14(c)(3) 401.2(n)
Assignment of Rights to Third Party			
If the grantee is a non-profit organization, it must ask NIH approval to assign invention or U.S. patent rights to any third party, including the inventor(s).	As needed. The NIH Office of Technology Transfer serves in an advisory capacity to OER for the processing of such assignment requests.	Grantees that are for-profit entities (including small businesses) do not need to ask approval.	401.14(k)

Issued Patent			
The grantee must notify NIH that a patent has been issued.	When the patent is issued.	The patent issue date, number, and evidence of Federal government support clause must be provided.	401.5(f)(2)
Extension of Time to Elect Title or File Patent			
The grantee may request an extension of up to 2 years for election of title, or 1 year for filing a patent application.	As needed.	Request for extension of time must be made. Such requests are preapproved.	401.14(c)(4)
Change in Patent Application Status			
The grantee must notify NIH of changes in patent status.	At least 30 days before any pending patent office deadline.	This notification allows NIH to consider continuing the patent action.	401.14(f)(3)
Invention Utilization Report			
The grantee must submit information about the status of commercialization of any invention for which title has been elected.	Annually.	This report gives an indication of whether the objectives of the law are being met. Specific reporting requirements can be found in iEdison (https://s-edison.info.nih.gov/iEdison/).	401.14(h)
Annual Invention Statement			
The grantee must indicate any inventions made during the previous budget period on all grant awards.	Part of all competing applications and non-competing grant progress reports.	The information is requested as a checklist item on the PHS 398 application and on the non-competing grant progress report.	PHS 398 and PHS 2590
Final Invention Statement and Certification			
The grantee must submit to the NIH awarding office GMO a summary of all inventions made during the entire term of each grant award.	Within 90 days after the project period (competitive segment) ends.	Required information is specified on the HHS 568 form. If no inventions occurred during the project period, a negative report must be submitted.	401.14(f)(5)

Failure of the grantee to comply with any of these or other regulations cited in 37 CFR Part 401 may result in the loss of patent rights or a withholding of additional grant funds.

The Bayh-Dole Act includes provisions for the grantee to assign invention rights to third parties. Grantees that are non-profit organizations must request NIH approval for the assignment. If the assignment is approved and the rights are assigned to a third party, invention and patent reporting requirements apply to the third party. The grantee should review existing agreements with third parties and revise them, as appropriate, to ensure they are consistent with the terms and conditions of their NIH grant awards and that the objectives of the Bayh-Dole Act are adequately represented in the assignment.

Any invention made using funds awarded for educational purposes, e.g. fellowships, training grants or certain types of career development awards, is not considered a subject invention and therefore is not subject to invention reporting requirements (as provided in 45 CFR 74. and 37 CFR 401.1(b)). The grantee should seek the advice of NIH to verify whether any invention made under a career development award should be considered a subject invention.

Details regarding invention reporting and iEdison are discussed under "[Administrative Requirements—Monitoring—Reporting—Invention Reporting.](#)"

All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to the following address:

Extramural Inventions and Technology Resources Branch
 Division of Grants Policy
 Office of Policy for Extramural Research Administration
 Office of Extramural Research
 NIH
 6705 Rockledge Drive, MSC 7980
 Bethesda, MD 20892-7980
 301-435-1986 (voice)
 301-480-0272 (fax)

Management Systems and Procedures

Grantee organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Grantees may use their existing systems to manage NIH grant funds and activities as long as they are consistently applied regardless of the source of funds and meet the standards and requirements set forth in 45 CFR Part 74 or 92 and the NIHGPS. NIH may review the adequacy of those systems and may take appropriate action, as necessary, to protect the Federal government's interests, including, but not limited to, the use of special terms and conditions. NIH also will oversee the grantee's systems as part of its routine post-award monitoring. The grantee's systems also are subject to audit (see "[Administrative Requirements—Monitoring—Audit](#)").

NIH seeks to foster within grantee organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

Financial Management System Standards

Grantees are required to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR 74.21 or 92.20, as applicable. The standards and requirements for a financial management system are essential to the grant relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Grantees must have in place accounting and internal control systems that provide for appropriate monitoring of grant accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify large unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds. Grantees must notify NIH when problems are identified.

A grantee's failure to establish adequate control systems constitutes a material violation of the terms of the award. Under these circumstances, NIH may include special conditions on awards or take any of the range of actions specified in "[Administrative Requirements—Enforcement Actions.](#)" as necessary and appropriate.

[Click "Next Document" below to Continue]

[[Search Policy Statement](#)] [[Table of Contents](#)] [[Previous Document](#)] [[Next Document](#)]

