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NIH Grants Policy Statement

(12/03)

Part II: Terms and Conditions of NIH Grant Awards
Subpart A: General -- File 4 of 5

ADMINISTRATIVE REQUIREMENTS

Changes in Project and Budget

In general, NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the grantee's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a grantee makes certain budget modifications or undertakes particular activities. The grantee-initiated changes that may be made under the grantee's authority and the changes that require NIH approval are outlined below and, with respect to particular types of awards, activities, or recipients, in Subpart B of this part. In addition, individual awards may restrict grantees' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained from, the awarding office GMO in advance of the change or obligation of funds as specified below under "Requests for Prior Approval."

Changes in project or budget resulting from NIH-initiated actions are discussed in other sections of this subpart.

Expanded Authorities

NIH has waived cost-related and other prior-approval requirements for many activities and expenditures, and provided authority for these activities and expenditures to the grantee. These operating authorities are termed "expanded authorities." Exhibit 3 presents a summary of expanded authorities. Certain award instruments, mechanisms, and types of recipients are excluded from the expanded authority to automatically carry over unobligated balances. This includes centers (P50, P60, P30, and others); cooperative agreements (U); Kirschstein-NRSA institutional research training grants (T); non-Fast Track Phase 1 SBIR and STTR awards (R43 and R41); clinical trials; and awards to individuals.

Certain grants or grantees also may be excluded from expanded authorities, including those that require closer project monitoring or technical assistance, and certain large multi-project grants. If excluded from some or all expanded authorities, the NGA will indicate this change from the standard terms and conditions. In addition, one or more of these authorities may be overridden by a special term or condition of the award. Therefore, grantees must review the NGA to determine whether and to what extent they are permitted to use expanded authorities.

When using expanded authorities, grantees must ensure that they exercise proper stewardship over Federal funds and that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Several expanded authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding office. Grantees should be aware that any consistent pattern of failure to adhere to those deadlines for reporting or notification will be grounds for excluding that grantee from expanded authorities.

Exhibit 3. Summary of Expanded Authorities

May exercise as expanded authority	Except
Carryover of unobligated balances from one budget period to the next	Centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NGA indicates otherwise.
Cost-related prior approvals, including research patient care costs and equipment	If the scope would change.
Extension of final budget period of a project period without additional NIH funds	If the grantee already has given itself one extension of up to 12 months.
Transfer of performance of substantive programmatic work to a third party (by consortium agreement)	If the transfer would be to a foreign component or it would result in a change in scope.

Carryover of Unobligated Balances from One Budget Period to Another Within an Approved Project Period. Awards routinely excluded from the automatic carryover of unobligated balances include centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials (regardless of mechanism), and awards to individuals. For these mechanisms, carryover of unobligated balances always requires NIH awarding office prior approval unless that requirement is waived by a term or condition of the NGA. Other awards may be excluded from use of this authority through a special term or condition in the NGA.

For awards using SNAP (see "Administrative Requirements—Monitoring—Reporting—Streamlined Non-Competing Award Process" for applicability), funds are automatically carried over to the subsequent budget period. However, the grantee will be required to indicate, as part of its grant progress report, whether its estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. If so, the grantee must provide an explanation and indicate plans for expenditure of those funds.

For those awards subject to expanded authorities but excluded from SNAP, the FSR must specify the amount to be carried over. The notification must be provided under item 12, "Remarks," on the FSR. When a grantee reports a balance of unobligated funds in excess of 25 percent of the total amount awarded, the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the grantee, including a revised budget, as part of the review.

Whether or not under SNAP, if the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the grantee's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset NIH funding for a subsequent budget period, or use a combination of these actions. The GMO also may indicate whether the balance may be carried forward to a budget period other than the succeeding one. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the NGA.

Cost-Related Prior Approvals. NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope. This also includes research patient care as described in the NIHGPS.

Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds. The grantee may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original expiration date shown in the NGA if

- no additional funds are required to be obligated by the NIH awarding office,
- the project's originally approved scope will not change, and
- any one of the following applies:

  - Additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project.
  - Continuity of NIH grant support is required while a competing continuation application is under review.
  - The extension is necessary to permit an orderly phase-out of a project that will not receive continued support.

The fact that funds remain at the expiration of the grant is not, in itself, sufficient justification for an extension without additional funds.

The grantee must notify the NIH awarding office, in writing, of the extension 10 days before the expiration date of the project period. Upon notification, the NIH awarding office will revise the project period ending date and provide an acknowledgment to the grantee. In extending the final budget period of the project period through this process, the grantee agrees to update all required certifications and assurances, including those pertaining to human subjects and animal welfare, in accordance with applicable regulations and policies. Grantees may not extend project periods previously extended by the NIH awarding office. Any additional project period extension beyond the one-time extension of up to 12 months requires NIH prior approval. (See "Prior-Approval Requirements" in this section for extensions requiring additional funds.)

Grantees are reminded that all terms and conditions of the award apply during the extended period.

Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement. Prior approval by the NIH awarding office is not required to transfer the performance of substantive programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

Prior-Approval Requirements

This subsection describes the activities and/or expenditures that require NIH prior approval. NIH prior-approval requirements are summarized in Exhibit 4, which is provided for guidance only. For the prior-approval requirements specified in the exhibit, approval is required whether or not the change has a budgetary impact and whether or not the grant also is subject to expanded authorities. The circumstances under which prior approval is required also are summarized in the exhibit.

Grantees also should consult Subpart B of this part for prior-approval requirements that apply to specific mechanisms, types of grants, and types of recipients.

Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the GMO.

Exhibit 4. Summary of Actions Requiring NIH Prior Approval

NIH prior approval is required for	Under the following circumstances
A&R	Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period. If rebudgeting would not meet this threshold but would result in a change in scope. Any single A&R project exceeding $300,000.
Capital expenditures (construction, land, or building acquisition)	All instances when purchase proposed; any proposal to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds.
Change in scope	All instances.
Changes in status of key personnel	Withdrawal from the project; absence for any continuous period of 3 months or more; reduction of time devoted to project by 25 percent or more from level in approved application.
Change of grantee organization	All instances.
Carryover of unobligated balances	If the NGA indicates that the grantee does not have the authority to automatically carry over balances.

Exhibit 4. Summary of Actions Requiring NIH Prior Approval	
NIH prior approval is required for	Under the following circumstances
Deviation from award terms and conditions	All instances. Includes undertaking any activities disapproved or restricted as a condition of the award.
Foreign component added to a grant to a domestic organization	All instances.
Need for additional NIH funding	All instances, including extension of a final budget period of a project period with additional funds.
Pre-award costs	More than 90 days before effective date of the initial budget period of a new or competing continuation award, at grantee's own risk.
Retention of research grant funds when K award made	All instances.
Second no-cost extension or extension greater than 12 months	All instances.
Transfer of funds between construction and nonconstruction work	All instances.
Transferring amounts from trainee costs	All instances.

Alterations and Renovations. NIH prior approval is required if a grantee rebudgets more than 25 percent of the total approved budget for a budget period into A&R costs. NIH prior approval also is required for lesser rebudgeting into A &R costs if the rebudgeting would result in a change in scope. If rebudgeting results in an A&R project exceeding $300,000, NIH always will consider the rebudgeting to be a change in scope. (See "Construction Grants—Administrative Requirements—Prior-Approval Requirements—Alteration and Renovation Projects under Nonconstruction Grants" in Subpart B of this part for documentation requirements for A&R projects exceeding $300,000).

Capital Expenditures. Capital expenditures for land or buildings require NIH prior approval. In addition, real property acquired with NIH grant funds may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the grantee without the written prior approval of the NIH awarding office or its successor organization.

Change in Scope. In general, the PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the grantee must obtain prior approval from the NIH awarding office for a change in the direction, type of research or training, or other areas that constitute a significant change from the aims, objectives, or purposes of the approved project

(hereafter "change in scope"). The grantee must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Actions likely to be considered a change in scope and, therefore, requiring NIH awarding office prior approval include, but are not limited to, the following:

- Change in the specific aims approved at the time of award.
- Substitution of one animal model for another.
- Any change from the approved use of animals or human subjects.
- Shift of the research emphasis from one disease area to another.
- A clinical hold by FDA under a study involving an IND or an IDE.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, this type of action always requires NIH prior approval.
- Change in key personnel (see "Change in Status, Including Absence, of Principal Investigator and Other Key Personnel" for requirements for NIH approval of alternate arrangements for or replacement of key personnel).
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. For example, if the award budget for total costs is $200,000, any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category is considered "significant rebudgeting." The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements.
- Incurrence of research patient care costs if costs in that category were not previously approved by NIH or if a grantee desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.
- Purchase of a unit of equipment exceeding $25,000.

Change in Status, Including Absence, of Principal Investigator and Other Key Personnel. The grantee is required to notify the GMO in writing if the PI or key personnel specifically named in the NGA will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award (for example, a proposed change from 40 percent effort to 30 percent or less effort). NIH must approve any alternate arrangement proposed by the grantee, including any replacement of the PI or key personnel named in the NGA.

The request for approval of a substitute PI/key person should include a justification for the change, the biographical sketch of the individual proposed, other sources of support, and any budget changes resulting from the proposed change. If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to the NIH

awarding office, the grant may be suspended or terminated. If the grantee wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

The requirement to obtain NIH prior approval for a change in status pertains only to the PI and those key personnel NIH names in the NGA regardless of whether the applicant organization designates others as key personnel for its own purposes.

Change of Grantee Organization. NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the expiration of the approved project period (competitive segment). A change of grantee organization may be accomplished under most NIH grants, including construction grants, if any of the following conditions are met:

- The grant to be transferred has been terminated in accordance with 45 CFR 74.61 or 92.43.
- A non-competing continuation award that is within an approved project period has been withheld because of the grantee's actions (see "Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support").
- The original grantee has agreed to relinquish responsibility for an active project before the expiration of the approved project period. This includes any proposed change of grantee as a result of a PI on a research project transferring from one organization to another organization. The project under the same PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.

A change of grantee that involves the transfer of a grant to or between foreign institutions or international organizations also must be approved by the IC's Advisory Council or Board.

A grant to an individual may not be transferred. However, an individual fellowship may be transferred to a new sponsoring organization. The transfer process will be the same as for a change of grantee organization. A change in an individual fellow's department or sponsor within the same organization is not considered a change of grantee organization. A successor-in-interest or a name change is not considered a change of grantee (see "Change in Grantee Organizational Status" in this section).

A change of grantee organization may involve the transfer of equipment purchased with grant funds. The transfer may be accomplished as part of the original grantee's relinquishment of the grant; otherwise, NIH reserves the right to transfer title to equipment to the new organization as indicated in "Administrative Requirements—Management Systems and Procedures—Property Management System Standards."

A change of grantee organization request must be made before the anticipated start date at the new organization and preferably several months in advance. Failure to provide timely notification may result in disapproval of the request or a delay in processing.

A change of grantee request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any

proposed changes in the scope of the project. A change may be made without peer review, provided the PI plans no significant change in research objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding office may require peer review or may disapprove the request and, if appropriate, terminate the award.

A request for a change of grantee organization must be submitted to the GMO and must include an Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement) and a Final Invention Statement and Certification from the original grantee as well as an application (PHS 398 or 416-1) from the proposed grantee or sponsoring organization. (A final FSR is due to NIH from the relinquishing organization no later than 90 days after the end of NIH support of the project.) If the original award was the result of a modular application, modular procedures apply to the request for change of grantee. For awards using the PHS 398, the application from the proposed grantee should include, at a minimum, the following:

- Face page
- Budget pages (current and future years) (Under awards resulting from modular applications, the application should include narrative budget information, including total direct and F&A costs for the current budget period and, if future budget periods remain, information about the number of modules and the basis for computing F&A costs for all future years)
- Updated biographical sketches for the PI and existing key personnel and biographical sketches for any proposed new key personnel
- Statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, providing updated information
- Updated "other support" page(s), if necessary
- Resources page
- Checklist page
- Certification of IRB/IACUC approval, if applicable
- Detailed list of any equipment purchased with grant funds being transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment).

NIH may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by NIH does not guarantee approval of a transfer application for the continued funding of a project.

NIH will accomplish a change of grantee organization by issuing a revised NGA to the original grantee reflecting the revised budget/project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. (A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement.) Concurrently, the new grantee will receive an NGA reflecting the balance reported on the relinquishing statement or, if the change of grantee organization occurs on the anniversary date of the project, the NGA to the new grantee will reflect the previously

committed direct cost level plus applicable F&A costs). This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

Change in Grantee Organizational Status. Grantees must give NIH advance notice of the following types of change in organizational status (that are not considered to be a change of grantee organization as described in this subsection):

- *Merger.* Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.

- *Successor-in-Interest.* Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant(s). An SII may result from legislative or other legal action, such as a merger or other corporate change.

- *Name Change.* Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a grantee.

Advance notification is required to ensure that the grantee still is able to meet its legal and administrative obligations to NIH and payments are not interrupted.

Grantees are encouraged to contact the GMO of the lead awarding office to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or SII. The lead awarding office ordinarily will be the IC with which the organization has the most NIH grants. If there is no advance consultation, NIH reserves the right to review the material provided, seek clarification or additional information, and make an independent determination.

A grantee's formal request for a change in organizational status should be submitted to NIH as soon as possible so that NIH can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For an SII, a letter signed by the AOOs of the current grantee (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding office, following consultation with the GMO of that awarding office. The letter must do the following:

- Stipulate that the transfer will be properly effected in accordance with applicable law.

- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.

- Request that the NIH awarding office(s) modify its (their) records to reflect the transferee as the grantee of record.

- State the effective date of the transfer.

- Provide the transferee's Entity Identification Number.

- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct).

- Include a list of all affected NIH grants (active and pending) with the following information for each:

  - Complete grant number (e.g., 5 R01 GM 12345-04).
  - Name of PI.
  - Current budget period and project period.
  - The total direct costs (as originally recommended) plus applicable F&A costs for each remaining budget period. If the SII will occur during a budget period rather than on the anniversary date, the transferor also must provide estimated levels of current-year direct and F&A costs remaining as of the SII effective date. The estimate may be reported on the PHS 3734 (Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant) or an equivalent relinquishing statement for each affected grant or may be itemized by grant number as an attachment to the letter.

- Include a complete face page (PHS 398) for each affected grant showing the transferee as the applicant organization. Each face page must be signed by both the PI and the AOO at the transferee organization.

- Include a copy of the current negotiated F&A rate agreement for the transferee.

In order to be recognized as the SII, the "new" (transferee) organization must meet each grant program's eligibility requirements. Upon review and acceptance of this information, NIH will revise the NGA(s) to show the transferee as the grantee of record.

For name changes, the grantee's written notification to the lead NIH awarding office must include the effective date of the change. Revised face pages are not required for name changes because name changes are processed with the next award action (e.g., non-competing continuation award) and the organization will submit a face page with the new information as part of that action.

Deviation from Award Terms and Conditions, including Restrictions on the NGA. NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NGA, including those in the NIHGPS. This includes undertaking any activities disapproved or restricted as a condition of the award.

Foreign Component Added to a Grant to a Domestic Organization. Adding a foreign component under a grant to a domestic organization requires NIH prior approval.

Need for Additional NIH Funding without Extension of Budget and Project Period. A request for additional funding for a current budget period to meet increased costs that are within the scope of the approved application, but that were unforeseen when the new or competing continuation application or grant progress report for non-competing continuation support was submitted, is a non-competing supplemental application. Such requests are submitted, in writing, directly to the GMO and are not required to compete with other applications for funding. Other grantee-initiated requests for supplemental funding during a current budget period are considered to change the scope of the approved project and may be required to compete for funding with other applications.

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 Copyrighting)

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/iEdison/) 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)

Exhibit 5. Extramural Invention Reporting Compliance Responsibilities			
Action required	When action must be taken	Discussion	37 CFR 401 reference
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)

Exhibit 5. Extramural Invention Reporting Compliance Responsibilities			
Action required	When action must be taken	Discussion	37 CFR 401 reference
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 301-435-1986 FREE (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.