

EXHIBIT 2



NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH



MARCH 2026

INTRODUCTION

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. These terms and conditions apply not only to the recipients of NIH Grant Awards, but also flow down to any subawards as well as to subrecipients unless specified otherwise in the regulation or the terms and conditions of the specific NIH award (see "Consortium Agreements" on page IIB-109).

This document also is designed to be useful to those interested in NIH grants by providing information about NIH, its organization, its staff and its grants process. The NIHGPS is available [online](#). This version includes many links within the document as well as links to some web resources outside of this document. Users are strongly encouraged to use the on-line version of this document to benefit from these links.

NIHGPS ORGANIZATION

The NIHGPS has three parts, which allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- **Part I: NIH Grants General Information.** Part I (chapters 1 and 2) contains a glossary defining commonly used terms and abbreviations used throughout the document; describes NIH and its relationship to other organizations within the Department of Health and Human Services (HHS); specifies recipient, NIH, and other HHS staff responsibilities and outlines the grant application and review processes.
- **Part II: Terms and Conditions of NIH Grant Awards.** Part II (chapters 3-19) includes generally applicable terms and conditions (Part IIA). This part also specifies the terms and conditions that apply to particular types of grants, recipients, and activities that differ from, supplement, or elaborate on the standard terms and conditions (Part IIB). These requirements, in separate chapters, pertain to multiple PD/PI applications and awards; construction, modernization and major alteration and renovation grants; research training grants and fellowships; career development awards; modular applications and awards; conference grants, consortium agreements; grants to foreign and international organizations (and grants with substantial foreign components awarded to domestic organizations), grants to Federal institutions and payments to Federal employees; grants to for-profit organizations; and research patient care activities.
- **Part III: Points of Contact.** Part III (chapter 20) lists pertinent offices with their contact information.

CONVENTIONS

Certain conventions are followed throughout this document. The term "grant" is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term "recipient" generally is used to refer to recipients of grants and cooperative agreements. "NIH" may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by NIH, including actions by its ICs, with an action by a recipient or other organization. A reference to "Part II (IIA or IIB)" or "Part III" without further elaboration means the corresponding part of the NIHGPS.

SUPERSESION

This version of the Grants Policy Statement includes policies and requirements that have been published via Guide Notices in effect as of March 17, 2026. The updates published in this version of the GPS consolidate all such Guide Notices and supersede the April 2024 version of the NIHGPS.

ADDITIONAL INFORMATION

The Office of Policy for Extramural Research Administration (OPERA) develops and maintains this document. Changes in statutes, regulations, or policies that take effect before the next revision of the NIHGPS will be published separately in the *NIH Guide for Grants and Contracts*. Recipients are responsible for reviewing the [*NIH Guide for Grants and Contracts*](#) for changes and for implementing them, as appropriate. Subscribe to the *NIH Guide for Grants and Contracts* Listserv at <https://grants.nih.gov/funding/nih-guide-for-grants-and-contracts/subscribe>.

As required by 2 CFR Part 200.315, recipients that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, NIH directs the requester to the public source. Otherwise, the IC FOI coordinator handles the request, consulting with the affected recipient and the PD/PI. This requirement also provides for assessment of a reasonable fee to cover recipient costs and (separately) the NIH costs of responding.

This requirement to release research data does not apply to for-profit organizations or to research data produced by State or local governments. However, if a State or local governmental recipient contracts with an IHE, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Additional information is available on the [Data Management & Sharing Policy Overview](#) web page. (Also see [Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources](#).)

2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds have a vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate cybersecurity and other actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, tablets, mobile devices, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also [Public Policy Requirements and Objectives—Federal Information Security Management Act](#).

2.4 THE PEER REVIEW PROCESS

NIH policy is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, timely, and conducted in a manner that strives to eliminate bias. Competing applications for NIH grants and cooperative agreements, including renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006 and 21st Century Cures Act. The peer review system used by NIH, often referred to as the “dual review system,” is based on two sequential levels of review for each application—initial review for scientific and technical merit by NIH's Center for Scientific Review (CSR), and a second level of review for mission relevance by the IC National Advisory Council / Board.

The NIH peer review process has evolved over the years to accommodate increasingly collaborative and multi-disciplinary research, changes in workload, resource constraints, and recommendations of various scientific and professional groups. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at NIH's web site or Peer Review Policies and Practices on the NIH [Grants & Funding web site](#).

2.4.1 Initial Review

2.4.1.1 Responsibilities

The Division of Receipt and Referral (DRR) within the CSR receives all competing grant applications submitted to NIH.

CSR centrally reviews the application for completeness and responsiveness to the NOFO, as applicable, conducts the initial technical review for scientific merit and prepares the summary statements.

CSR Referral Officers, who are senior health scientist administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to a specific study section for initial review of the scientific merit of the application. These assignments are made on the basis of the application's contents and referral guidelines.

CSR's study sections are organized into Review Branches by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc Special Emphasis Panels (SEPs) are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that their application has been received and that they can find information about the application's SRO, SRG, and IC assignments in eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO, not the PO, is the primary contact for communication with the applicant until the summary statement is released. An applicant organization may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR, and submitted to the SRO.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least three reviewers to write a critique of the application, provide initial scores, and to be prepared to discuss the application in detail.

Following the initial review, the SRO prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of the discussion, and an overall impact score. Summary statements are then provided to the IC's Advisory Councils, the PD(s)/PI(s), and applicant institution's Authorized Organization Representative.

2.4.1.2 Overall Impact

Reviewers assess overall impact in the determination of scientific and technical merit; overall impact is defined based on the different types of applications. When considering applications for research grants and cooperative agreements, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the

project proposed). These criteria are evaluated and scored in accordance with the applicable peer review framework (standard or Simplified Review Framework (SRF).)

NIH utilizes SRF for the peer review of the majority of competing research project grants (applications under the following activity codes: R01, R03, R15, R16, R21, R33, R34, R36, R61, RC1, RC2, RC4, RF1, RL1, RL2, U01, U34, U3R, UA5, UC1, UC2, UC4, UF1, UG3, UH2, UH3, UH5, (including the following phased awards: R21/R33, UH2/UH3, UG3/UH3, R61/R33).

All other research project grant applications utilize the standard peer review criteria.

2.4.1.3 Standard Scored Review Criteria (Non SRF-applicable activity codes)

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, enhance health, and reduce illness and disability. For research grant applications, and most other types of applications, reviewers evaluate the overall impact of the proposed project based on five regulatory criteria: Significance, Investigator(s), Innovation, Approach, and Environment.

For non SRF-applicable activity codes, reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and determine a separate score for each. An application does not need to be strong in all categories to be evaluated likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

The NOFO should be consulted for additional information describing each of the scored review criteria.

2.4.1.4 Standard Additional Review Criteria (Non SRF-applicable activity codes)

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Human Subjects, Policies
- Vertebrate Animals
- Biohazards
- Resubmission /Renewal / Revision Applications

The NOFO should be consulted for additional information describing each of the relevant additional review criteria.

2.4.1.5 Standard Additional Review Considerations (Non SRF-applicable activity codes)

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Provision of Family Care Facilities (for Conference Grant Applications)
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

The NOFO should be consulted for additional information describing each of the relevant additional review considerations.

Although these review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R24 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and research related activities. However, for some activities (e.g., construction grants and research project grants subject to the Simplified Review Framework), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in NOFOs.

2.4.1.6 Simplified Review Framework (SRF)

Due to the inherent complexity of the peer review process, NIH utilizes the Simplified Review Framework (SRF) for the peer review of the majority of competing research project grants (applications under the following activity codes: R01, R03, R15, R16, R21, R33, R34, R36, R61, RC1, RC2, RC4, RF1, RL1, RL2, U01, U34, U3R, UA5, UC1, UC2, UC4, UF1, UG3, UH2, UH3, UH5, (including the following phased awards: R21/R33, UH2/UH3, UG3/UH3, R61/R33). The SRF enables peer reviewers to better focus on the central questions necessary to assess the scientific and technical merit of a proposed research project: the importance of the proposed research, whether the proposed research methods are rigorous and feasible, and whether the investigators and institution have the expertise and resources necessary to carry out the project as proposed. Additionally, the use of the SRF aids NIH in mitigating the effect of reputational bias by refocusing the evaluation of the investigator/environment to within the context of the proposed and research and also reduces burden on the reviewer by shifting policy compliance activities to NIH staff.

SRF Review Criteria

The SRF reorganizes the five regulatory criteria into three factors as listed below. Each factor is evaluated by the Reviewer in the determination of scientific merit, and in providing an overall impact score. Factors 1 and 2 will each receive a separate criterion score; Factor 3 will be evaluated for sufficiency. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Factor 1. Importance of the Research (scored 1-9):

- *Significance*
- *Innovation*

Factor 2. Rigor and Feasibility (Scored 1-9)

- *Approach (also includes Inclusion and Clinical Trial Study Timeline)*

Factor 3. Expertise and Resources (considered in overall impact: no individual score provided)

- *Investigator(s), Environment*
 - *Evaluated as 'appropriate' or 'gaps identified'*
 - *Reviewer is required to provide further explanation, if gaps are defined.*

SRF Additional Review Criteria (can affect overall impact score)

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items:

- Protections for Human Subjects
- Vertebrate Animals
- Biohazards
- Resubmission / Renewal / Revision Applications

The NOFO should be consulted for additional information describing each of the relevant additional review criteria.

SRF Additional Review Considerations (No effect on overall impact score)

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. The NIH policy for appeals of initial peer review does not apply to appeals of the technical evaluation of Research and Development contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT awards. In addition, NIH will not review a resubmission application when an appeal of initial peer review is pending on the original application. As stated in the Notice of Funding Opportunity, appeals of initial peer review outcome will not be accepted for applications in response to an RFA.

An appeal is a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence from the Authorized Organization Representative (AOR).

An applicant who is concerned about procedural aspects related to the completed initial peer review of their application first should consider the comments in the summary statement, and then should contact the appropriate NIH Program Official (PO). Following discussion of concerns with the PO, if the PD/PI and/or an official of the applicant organization wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than

the AOR) only or with a “cc” to the AOR will not be accepted. The PO will send the PD/PI and/or institutional official, and AOR, an acknowledgement letter within 10 days of receipt of the appeal letter.

An appeal letter will be accepted only if the letter 1) describes the flaws in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest, as specified in regulation at [42 CFR Part 52h.5 “Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects”](#), on the part of one or more non-Federal peer reviewers.
- Lack of appropriate expertise within the SRG.
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

If review staff and program staff do not support the appeal, or do not agree on its merit, the PD/PI and/or an institutional official (not necessarily the AOR) may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the request directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and their concurrence to the PO. A communication from the PD/PI or institutional official (other than the AOR) only or with a “cc” to the AOR will not be accepted.

If review staff and program staff do not support the appeal, or do not agree on its merit, and the appeal letter is not withdrawn, the appeal letter will be made available to Council. The IC may not deny the PD/PI or applicant organization the opportunity to have an appeal letter made available to Council. Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal, and recommend that the application be re-reviewed.
- The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. No action by the Council is equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know. If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting. If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation of the IC's plan for making the appeal available to Council.

If the Council recommended that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same

or a different SRG, depending on the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions will be announced in NIH Guide Notices and/or the relevant Notice of Funding Opportunity.

2.4.3 National Advisory Council or Board Review

The IC National Advisory Council or Board (hereafter “Council”) provides the second level peer review of applications for grants and cooperative agreements. The Council members review the summary statement and are asked to concur with the initial peer review for scientific and technical merit, as judged by the SRG, and to consider relevance to the IC’s programs and priorities. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC’s mission. The Council may concur with the SRG’s recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review.

In addition, Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the threshold for Special Council Review. These are investigators who currently receive \$2 million or more in total costs (inclusive of direct and indirect) per year of NIH funding to support Research Project Grants. Council members will be asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This does not represent a cap to NIH funding.

With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

2.4.4 Disposition of Applications

Consistent with 2 CFR 200.204 and 200.205, all incomplete applications, non-compliant applications, and applications determined to be nonresponsive to NOFO requirements will not be reviewed. If the NOFO remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle. An application may resubmit one application may be submitted for an appropriate due date up to 37 months after the application due date of the initial application, provided the NOFO allows resubmission applications. Any application on the same topic proposed as a resubmission more than 37 months from the initial receipt date will not be accepted; it must be formatted and submitted as a new application.

For complete, compliant and responsive applications, following the initial scientific peer review, the summary statement will be available to the PD/PI and AORs of the applicant organization with the Signing Official (SO) user role in the eRA Commons. Applicants just receiving their summary statements should consult the NIH Next Steps page for detailed guidance. If an application does not result in funding, there may be an opportunity to respond to the reviewers’ comments and resubmit the application, provided the NOFO allows resubmission applications. Applicants seeking advice beyond that available online may want to contact the NIH Program Officer listed at the top of the summary statement.

The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an

application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application (referred to as a resubmission) for review in a future cycle.

Some of the ICs publish paylines as part of their [funding strategies](#) to guide applicants on their likelihood of receiving funding. Application scores can only be compared against the payline for the fiscal year when the application will be considered for funding, which is not necessarily the year when it was submitted. At the beginning of fiscal years when the agency awaits an actual budget, there may be a delay of several months to determine paylines. If the application is assigned to an IC that does not announce a payline, the Program Officer listed at the top of the summary statement may be able to provide guidance on the likelihood of funding.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in [Completing the Pre-Award Process](#) below.

For unsuccessful applicants, the NIH will send a centralized, automated correspondence to the applicant organizations to notify them of NIH's intent not to fund the indicated applications.

The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC approval) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if specific award conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see [Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports](#)).

2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each NOFO will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

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 AOR to the GMO that signed the NoA. Contact information is provided on each NoA and is also available in the eRA Commons. E-mail addresses for NIH staff can be also obtained from the [NIH Enterprise Directory](#). E-mail requests must include the name of the recipient, the name of the initiating PD/PI, the PD/PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOR.

The GMO will review the request and provide a response to the AOR indicating the final disposition of the request, with copies to the PD/PI and to the cognizant NIH PO. Only responses provided by the GMO are considered valid. Recipients 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 recipients 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 pass-through entity. However, the pass-through entity 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 pass-through entity must obtain that approval from NIH before giving its approval to the consortium participant.

SBIR and STTR recipients are required to seek prior approval when adding a new domestic subaward to a project post-award, where the arrangement was not originally a part of the peer reviewed and approved application. A foreign risk assessment is required for the entity selected for the subaward when the prior approval request is submitted through submission of an updated SBIR STTR Foreign Disclosure Form via the "SBIR STTR Foreign Disclosure Request for Additional Materials" (RAM) feature in eRA Commons. The recipient must receive official written approval notification from the NIH Grants Management Official prior to signing a subaward agreement.

8.2 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. PD/PIs and recipient 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 [Availability and Confidentiality of Information—Confidentiality of Information—Access to Research Data](#) in Part I 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 recipients 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 recipient 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.

8.2.1 Rights in Data (Publication and Copyrighting)

In general, recipients own the rights in data resulting from a grant-supported project. Specific 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, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. For this purpose, “data” means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.

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 recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients 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 recipient from making copies for its own use (as provided in 2 CFR Part 200.315) or prevents the recipient from being able to comply with NIH policies, including the 2024 NIH Public Access Policy. The disposition of royalties and other income earned from a copyrighted work is addressed in [Administrative Requirements—Management Systems and Procedures—Program Income](#).

All recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. In accordance with the [Stevens Amendment](#), each publication, press release, or other document about research supported by an NIH grant must include both:

- 1) An acknowledgment of NIH grant support clearly stating the percentage and dollar amount of the total costs of the program or project funded with federal money, and the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources. For example:

“Research reported in this [publication, release] was supported by [name of the Institute, Center, or other funding component] of the National Institutes of Health under grant number [specific NIH grant number in this format: R01GM012345].” A total of \$[amount], or [percentage] percent of [research/project/program] [is/was] financed with federal funds. A total of \$[amount], or [percentage] percent of [research/project/program] [is/was] financed with non-governmental funds (if applicable)", and
- 2) A disclaimer that says:

“The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

If the recipient plans to issue a press release about research supported by an NIH grant, it should notify the NIH funding component in advance to allow for coordination. See [Media Inquiries](#) for media contact information.

Publications resulting from work performed under an NIH grant-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC (see [Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports](#) and [Administrative Requirements—Closeout—Final Reports—Final Progress Report](#)). When publications are available electronically, the URL or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report. See also [NIH Public Access Policy](#) below for additional requirements for publications resulting from NIH funded research.

8.2.2 NIH Public Access Policy

The 2024 NIH Public Access Policy implements Division F, Section 217 of [PL 111-8 \(Omnibus Appropriations Act, 2009\)](#). The policy ensures that the public has access to the published results of NIH funded research at the [NIH NLM PMC](#), a free digital archive of full-text biomedical and life sciences journal literature. Under the Policy NIH-funded investigators are required to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available without embargo upon the Official Date of Publication, as defined in the Policy. The Author Accepted Manuscript is defined as the author's final version that has been accepted for journal publication, and includes all revisions resulting from the peer review process, including all associated tables, graphics and supplemental material. This policy applies to any Author Accepted Manuscript accepted for publication in a journal, on or after July 1, 2025, that is the result of funding by NIH in whole or in part, through grants and cooperative agreements (including training grants), contracts, Other Transactions, NIH intramural research, and the official work of an NIH employee.

Institutions and investigators are responsible for ensuring compliance with this Policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the Policy, were authored or co-authored by the applicant and result from NIH support must include the PMCID or NIHMS ID.

More details may be found at: <https://grants.nih.gov/faqs#/public-access-policy> and <https://grants.nih.gov/policy-and-compliance/policy-topics/public-access>.

8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. 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 are developed with NIH funds and the associated research findings have been accepted for publication, 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. At the same time NIH recognizes the rights of recipients and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the [Office of Extramural Research, Division of Extramural Inventions & Technology Resources \(DEITR\), Intellectual Property Policy page](#).

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

NIH has published a set of principles and guidelines known as the NIH Research Tools Policy for funding recipients and the biomedical community. These serve as a reference for identifying an appropriate strategy for disseminating and sharing research tools. The NIH Research Tools Policy webpage explains these principles and guidelines in more detail and provides suggestions on implementation.

For recipients working with biological materials, NIH has a policy for allowing NIH funding recipients to retain and license biological materials for which patent protection might not be pursued. To learn more, read "NIH Procedures for Handling Non-election of Title to Patentable Biological Materials".

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 IC, the recipient also must provide a copy of documents or a sample of any material developed under an NIH grant award. The recipient 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 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 and should ensure that those entities distribute them in a way that is consistent with the above referenced [NIH Research Tools Policy webpage](#). 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.

8.2.3.1 Operational and Security Standards for Controlled-Access Repositories

The Required Security and Operational Standards for NIH Controlled-Access Data Repositories apply to grants and cooperative agreements, for the purposes of the NIH GPS, and other funding mechanisms not covered by the NIH GPS (e.g. intramural contracts and Other Transactions), regardless of the activity code, that support NIH controlled-access data repositories and access management systems (hereafter NIH CADRs) that meet all the following criteria:

- Are supported by an NIH funding mechanism (e.g. grants and cooperative agreements);
- Provide long-term storage for, or provide access to, data for research purposes (hereafter, "data");
- Control access to data by prospective review of data access requests or partner with access systems that control access via prospective review of requests; and
- Use federal employees to conduct reviews and authorize access, or partner with access systems that use federal employees for those purposes.

NIH will determine which repositories are subject to these requirements and will maintain a public list of NIH CADRs, which can be found here. NIH will periodically update this list as needed.

Repositories and access management systems that control access to data, but do not meet the criteria of an NIH CADR as described above, will not be subject to these requirements. Repositories that only facilitate direct sharing between investigator teams, cloud workspaces that only temporarily store data, data

coordinating centers, and similar activities that do not manage data sharing beyond specific programs or initiatives, will not be considered an NIH CADR.

To meet the requirements, NIH CADRs must follow the NIH Controlled-Access Data Repository Guidebook to Adhere to “Required Security and Operational Standards for NIH Controlled-Access Data Repositories” (NIH CADR Guidebook), including all relevant effective dates listed in the Guidebook.

8.2.3.2 Policy for Data Management and Sharing (DMS Policy)

The NIH Policy for Data Management and Sharing (DMS Policy) applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants or other funding agreements regardless of NIH funding level or funding mechanism. The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities. A list of NIH activity codes subject to the DMS Policy is available on the NIH website, and the applicability of the DMS Policy will be specified in each NIH NOFO.

Applicants must submit a DMS Plan in each competitive grant application, and outline DMS costs in the appropriate cost categories in the budget (see NIH Application Guide for detailed instructions). DMS Plans should explain how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared. If DMS Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), DMS Plans should be updated by researchers and reviewed by the NIH ICO during regular reporting intervals or sooner. DMS Plans from NIH-funded or conducted research may be made publicly available and should not include proprietary or private information. Costs associated with data management and data sharing are subject to Federal cost principles for the reimbursement of actual costs that are allowable, allocable, reasonable, and consistently treated as described in NIHGPS Section 7.2 The Cost Principles.

Under the NIH DMS Policy, NIH expects researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may limit data sharing to some extent. Per the supplemental information “Elements of an NIH Data Management Sharing Plan,” a compelling rationale for limiting scientific data sharing should be provided and will be assessed by NIH. Shared scientific data must be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first.

[Consistent with 2 CFR 200.403 and the NIHGPS Section 7.4](#), budget requests must not include infrastructure costs that are included in institutional overhead (e.g., indirect costs) or costs associated with the routine conduct of research. Costs associated with collecting or otherwise gaining access to research data (e.g., data access fees) are considered costs of doing research and should not be included in scientific data management and sharing budgets. Costs may not be double charged or inconsistently charged as both direct and indirect costs.

Applicants may request data management and sharing costs that are allowable and reasonable when associated with (1) Curating data and developing supporting documentation, including formatting data according to accepted community standards; de-identifying data; preparing metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission to and storage at a selected repository for long-term preservation and access. (2) Local data management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository). (3) Preserving and sharing data through established repositories, such as data deposit fees necessary for making data available and accessible. For example, if a DMS Plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of

performance. If the DMS Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

Generally, DMS Plans are not considered during peer review, unless the NOFO identifies data sharing as integral to the project. DMS Plans will undergo programmatic assessment by NIH staff following peer review. ICs may request additional information at Just-in-Time in order to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research.

Once approved, the DMS Plan will become a Term and Condition of the NOA, and failure to comply may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions. In accordance with NIHGPS Section 8.1.1 NIH Standard Terms of Award, recipients must obtain prior approval to make changes to the previously approved DMS Plan (e.g. change in scientific direction, change in repository, or change in the timeline). All prior approval requests must be submitted in the eRA Prior Approval Module (see NIH Application Guide).

All allowable Data Management and Sharing costs in budget requests must be incurred (e.g., curation fees, data repository fees) during the performance period, even for scientific data and metadata preserved and shared beyond the award period.

Recipients are required to provide updates on the activities described in the DMS plan as part of the annual RPPR, and the IC will use this information to assess compliance with the previously approved DMS Plan.

For additional information and resources, [see the grants policy website on the Data Management and Sharing Policy](#).

8.2.3.3 Genomic Data Sharing (GDS) Policy

The NIH Genomic Data Sharing (GDS) Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. For the purposes of the GDS Policy, the genome is the entire set of genetic instructions found in a cell and large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data. The grants policy website on Genomic Data Sharing Policy Overview provides examples of genomic research projects that are subject to the Policy and the timeline for submission and sharing of data from such projects.

All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to describe plans for sharing genomic data in the Data Management and Sharing (DMS) Plan submitted with the application as described in 8.2.3.2 Policy for Data Management and Sharing. For guidance on developing a DMS plan that meets the requirements of the DMS and GDS policies, refer to the grants policy website on [Writing a Data Management & Sharing Plan](#). Once approved, the DMS Plan will become a Term and Condition of the NOA and compliance and enforcement will be handled as described in 8.2.3.2 Policy for Data Management and Sharing.

PD / PIs should register all studies with human genomic data that fall within the scope of the GDS Policy in the NIH database of Genotypes and Phenotypes (dbGaP) by the time that data cleaning and quality control measures begin. After registration in dbGaP, PD / PIs, through the recipient institution, should submit large-scale human genomic data as well as relevant associated data (e.g., phenotype and exposure data) to an NIH-designated data repository in a timely manner, consistent with their NIH-

approved DMS Plan. PD / PIs should also submit any information necessary to interpret the submitted genomic data, such as study protocols, data instruments, and survey tools.

For research that falls within the scope of the GDS Policy, institutions submitting data, through their Institutional Review Boards (IRBs), privacy boards, or equivalent bodies, are to review the informed consent materials to determine whether it is appropriate for data to be shared for secondary research use. For studies proposing to use genomic data from cell lines or clinical specimens that were created or collected after the effective date of the GDS Policy, NIH expects that informed consent for future research use and sharing will have been obtained even if the cell lines or clinical specimens are de-identified. The responsible Institutional Signing Official of the submitting institution must provide an Institutional Certification to the funding IC prior to award. For guidance on completing an Institutional Certification under the GDS Policy, see the NIH Scientific Data Sharing website and section 2.3.7.10.

If there are compelling scientific reasons that necessitate the use of genomic data from cell lines or clinical specimens that were created or collected after the effective date of this Policy and that lack consent for research use and data sharing, investigators should provide a justification in the funding request for their use. The funding IC will review the justification and decide whether to make an exception to the consent expectation. In some instances, the funding IC may need to determine whether to grant an exception to the data submission expectation under the GDS Policy. Studies provided exceptions to data submission under the GDS Policy will still be expected to be registered in the NIH Database of Genotypes and Phenotypes (dbGaP) for transparency.

Investigators approved to access data and their institution are responsible for maintaining the confidentiality, integrity, and security of data accessed from a NIH-designated repository in accordance with the NIH Security Best Practices for Users of Controlled-Access Data included in Data Use Certifications (DUCs), or similar data use agreements, stipulating terms of access and the requirements of the Genomic Data User Code of Conduct. Violating these terms and requirements is considered a data management incident.

If an investigator plans to use a Cloud Service Provider (CSP) and/or a third-party IT system to store and analyze controlled-access data, NIH expects the CSP and/or third party IT system to meet the same standards as outlined in the [NIH Security Best Practices for Users of Controlled-Access Data](#).

The institution, not the CSP and/or third-party IT system, will be held responsible for any failure in the oversight of controlled-access data.

NIH requires Lead Developers, and those they directly supervise, who seek access to controlled-access human genomic data under the GDS Policy for developer work (e.g., testing platforms, pipelines, analysis tools, and user interfaces that store, manage, and interact with human genomic data; providing infrastructure development and repository maintenance), to submit a request containing a Developer Use Statement (DUS) to the NIH Developer Data Access Committee (DeveloperAccessDAC@od.nih.gov) no later than at Just-in-Time (JIT) for grants and cooperative agreements. If a project has multiple Lead Developers, (e.g., for multicomponent awards), each Lead Developer must submit a DUS. All Lead Developers must be associated with an institution that is receiving or applying for NIH or other federal support for the developer work with a funding mechanism that has incorporated the developer terms of access. Once established, Lead Developers must follow the Developer Terms of Access.

Additional information about the GDS Policy can be found on NIH's "[Genomic Data Sharing Policy](#)" webpage.

8.2.3.4 Sharing Model Organisms

All applications, regardless of amount requested, where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible.

Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, Arabidopsis, fruit fly, zebrafish, and frog. Research resources to be shared include, but are not limited to, genetically modified organisms, mutant organisms, sperm, embryos, vectors, non-human embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, genetic and phenotypic data for all mutant strains.

For additional information on this policy, see the [NIH Scientific Data Sharing Model Organism Sharing Policy website](#).

8.2.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212; Executive Order 12591; 37 C.F.R. 401 et al; updated April 14, 2018.) provides NIH funding recipients incentives to promote the utilization of inventions conceived or reduced to practice (Subject Invention) in the performance of federally supported research and development. Unless waived by NIH or the funding agreement is for educational purposes, e.g. fellowships, training grants or certain types of career development awards, the Bayh-Dole Act applies to all NIH research and development funding granted to for-profit organizations regardless of size and all non-profit entities. (See 2 CFR Part 200 and 37 CFR Part 401.1(b)).

To retain rights and title to Subject Inventions, the NIH funding recipient must comply with the Bayh-Dole statute and implementing regulations that ensure the Invention will be brought to practical application while protecting certain rights of the Federal government. The compliance actions required by the Bayh-Dole Act are summarized below at Exhibit 8.

Failure of the recipient to comply with any of the Bayh-Dole regulations cited at 37 CFR Part 401 or other requirements may result in the loss of patent rights or the suspension, termination or withholding of NIH funding support. See also [Section 8.5.2](#) for additional remedies for noncompliance of the Bayh-Dole Act.

All Bayh-Dole compliance actions are required to be submitted to NIH by using the iEdison data base (See 37 CFR Part 401.16). All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to OPERA/OER at edison@nih.gov.

Exhibit 8. Extramural Invention Reporting Compliance Responsibilities

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Employee Agreement to Disclose All Subject Inventions	Recipient employees working under a federal funding award (other than clerical and nontechnical employees) must sign an agreement with the recipient organization. This agreement requires the Recipient employee to: (1) disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under NIH funding; (2) assign to the Recipient the entire right, title and interest in and to each Subject Invention made under the funding agreement; (3) execute all papers necessary to file patent applications on Subject Inventions; and, (4) establish the government's right in the Subject Inventions.	Before a Recipient or a consortium employee participates in NIH-funded research and development.	401.14(f)(2)
Consortium Participant Rights in Inventions	All consortium participants, regardless of tier, for experimental, developmental or research work retain all rights and obligations provided to the Consortium Participant in the NIH funding agreement.	At the time of issuance of a consortium agreement, recipient must include in all consortium agreements, regardless of tier, for experimental, development, or research work 37 CFR Part 401 <i>et seq</i> suitably modified to identify the parties and the rights and obligations awarded to the contractor.	401.14(g)(1) 401.14(g)(2) 401.14(g)(3)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. <i>(All Compliance Actions are to be Submitted to NIH through iEdison)</i>	37 CFR Part 401 Reference
Invention Disclosure	The term "Subject Invention" means any invention of a recipient/consortium participant conceived or first actually reduced to practice in the performance of work under a funding agreement. The recipient must submit to NIH a disclosure for all Subject Inventions. There is no single format for disclosing the invention to NIH. However, the disclosure of the Subject Invention must include: a detailed technical description of the invention conveying a clear understanding of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention; the names of all inventors; title of the Subject Invention; all federal funding agreement numbers; date of disclosure of the Subject Invention from the researcher or inventor to the Recipient; and whether a manuscript describing the invention was submitted, accepted and/or published.	Within 2 months of the inventor's disclosure to the recipient organization.	401.14(a)(2) 401.14(c)(1)
Government Assignment to Recipient of Rights in Invention of Government Employee	Disclosure to NIH that a federal employee is a co-inventor on a Subject Invention.	Within 2 months of receipt of the initial invention report.	401.14(f)(2) 401.10

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Acceptance of Manuscript following Submission of Initial Invention Disclosure	The recipient needs to promptly notify NIH of the acceptance of any manuscript describing the Subject Invention.	Promptly following the acceptance of a manuscript describing a Subject Invention.	401.14(c)(1)
Election of Title to a Subject Invention	The recipient must notify NIH of its decision to retain title to a Subject Invention and any associated patent rights. Election of title is made before the filing of an Initial Patent Application. Statutory Period is defined as the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102 (b) as amended by the Leah-Smith American Inventions Act, Public Law 112-29.	Within 2 years of the disclosure of the invention to NIH. In any case where a patent, a printed publication, public use, sale or other availability to the public has initiated the one-year Statutory Period wherein valid patent protection can still be obtained in the United States, the period for election of title is shortened by NIH to a date that is no more than 60 days prior to the end of the statutory period.	401.14(b) 401.14(c)(2) 401.2(n)
Confirmatory License	For each Subject Invention, the recipient must provide a license to NIH confirming the rights the Government has throughout the world in the Subject Invention. When a confirmatory license is filed on the Initial Patent Application the license applies to all subsequent patent applications linked in the patent family.	When the Initial Patent Application is filed.	401.14(f)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Government Support Clause	The recipient must include, within the specification of all United States patent applications and any patent issuing thereon covering a Subject Invention, the following statement, "This invention was made with government support under (grant number, including the two-letter institute code and six-digit serial number, e.g., CA012345) awarded by the National Institutes of Health. The government has certain rights in the invention."	Must be included within the specifications of any United States patent applications and any patent(s) issuing thereon covering a Subject Invention.	401.14(f)(4)
Patent Applications and Issued Patents	The recipient must inform NIH of the filing date of its Initial Patent Application , the Initial Patent Application number and title and all subsequently filed patent applications. Initial Patent Application is defined as the first provisional or nonprovisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(2) and (3), respectively, the first international application filed under the Patent Cooperation Treaty as defined in 37 CFR Part 1.9(b) that designates the United States, or the first application for a Plant Variety Protection certificate, as applicable, a non-provisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(3).	Within 1 year after election of title, or, if earlier, prior to the end of any Statutory Period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use, unless there is an extension of time granted by NIH.	401.14(c)(3) 401.14.(f)(6) 401.2(n)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Notification to NIH to Not to Continue Prosecution	Notify NIH of any decision to: not to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a part to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office including but not limited to post-grant review, review of a business method patent, <i>inter partes</i> review, and deviation proceeding; or to request, be a part to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination.	Notify NIH no less than 60 days prior to taking any action defined under "Action Required."	401.14(f)(3)
Assignment of Rights to Third Party	If the recipient is a non-profit organization, it must request NIH prior approval to assign a Subject Invention or U.S. patent rights to any third party, including the inventor(s). Recipients that are for-profit entities (including small businesses) do not need to request approval for the assignment of a Subject Invention or U.S. patent rights to any third party.	Recipient must submit a Third-Party Waiver Request or an Inventor Waiver Request and must have NIH approval before any rights of the recipient are transferred or assigned.	401.10 401.14(k)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. <i>(All Compliance Actions are to be Submitted to NIH through iEdison)</i>	37 CFR Part 401 Reference
Preference for United States Industry	Recipient cannot grant to any person, unless approved by NIH in advance, the exclusive right to use or sell any Subject Invention in the United States unless any such product embodying the Subject Invention or produced through the use of the Subject Invention is manufactured substantially in the United States.	For a waiver of this compliance requirement, a request is required to NIH providing specific details and reasons why the Subject Invention cannot be substantially manufactured in the United States.	401.14(i)
Issued Patent	Recipient must notify NIH of the date a patent is issued, patent number, and the expiration date of the issued patent.	When patent is issued.	401.5(f)(2)
Extension of Time to Disclose a Subject Invention	The recipient may request for NIH's approval for an extension of time to disclose a Subject Invention.	Not less than 30 days in advance of the 60-day disclosure reporting deadline.	401.14(c)(5)
Extension of Time to Elect Title to a Subject Invention	Recipient may request with justification, NIH's approval of a request for an extension of up to 2 years to elect title to a Subject Invention.	As needed before the expiration of the time allowed.	401.14(c)(5)
Extension of Time to File a Patent Application	The recipient may request, subject to NIH's approval, an extension time up to 1 year to file a patent application. The request must include details of why an extension is needed.	As needed before the expiration of the time allowed.	401.14(c)(5)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Extension of Time to File a Non-provisional Patent Application following the Filing of a Provisional Application as the Initial Patent Application	When a recipient requests an extension of time for filing a non-provisional application, after filing a provisional application as an Initial Patent Application , a 1-year extension will be granted unless NIH notifies the recipient within 60 days of receiving the request. Recipient must submit this request citing an extension of time pursuant to 401.14(c)(5). No additional details for the request are required.	As needed before the expiration of the time allowed.	401.14(c)(5)
Invention Utilization Report	The recipient must submit an annual utilization report with information about the status of commercialization of any Subject Invention for which title has been elected.	Annually, based on the fiscal year of the recipient.	401.14(h)
Annual Invention Statement	The recipient must indicate any inventions made during the previous budget period in Section C of the Research Performance Progress Report (RPPR).	Part of all competing applications and non-competing continuation progress reports.	SF424, (R&R) PHS 2590, RPPR
Final Invention Statement and Certification	The recipient must submit to the NIH awarding IC CGMO through the eRA Closeout Module a summary of all inventions made during the entire term of each grant award.	Within 120 days after the project period (competitive segment) ends.	401.14(f)(5)

8.2.5 Interim Research Products

Interim Research Products are complete, public research products that are not final. A common form is the preprint, which is a complete and public draft of a scientific document. Interim research products are effective ways for NIH funded scientists to speed dissemination, establish priority, obtain feedback, and reduce bias. They may also be cited in applications for NIH funding.

NIH intends to maximize impact of interim research products that are developed with NIH funds. Therefore, NIH expects recipients to ensure a high level of public access to NIH supported interim products.

To facilitate text mining and other analysis of these products as data, NIH expects standardized terms of use. NIH also expects recipients will adhere to other norms of responsible scientific communication.

Specifically, to claim an interim research product as a product of an NIH award, NIH expects that the recipient will:

- Make the product publicly available. To maximize the impact of an interim research product, NIH strongly encourages recipients to select a Creative Commons Attribution (CC-BY) license or dedicate their work to the public domain.
- In the text of the document:
 - Acknowledge NIH funding in accordance with [NIH GPS Section 8.2.1](#)
 - Clearly state that the work is not peer-reviewed
 - Declare any competing interests, as an author would do for any journal article

8.3 MANAGEMENT SYSTEMS AND PROCEDURES

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients 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 2 CFR Part 200 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 specific terms and conditions. NIH also will oversee the recipient's systems as part of its routine post-award monitoring. The recipient's systems also are subject to audit (see [Administrative Requirements—Monitoring—Audit](#)).

NIH seeks to foster within recipient 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; performance assessment; administrative simplifications; information sharing; management controls and other internal controls.

Recipient organizations must establish and maintain effective internal controls to provide reasonable assurance that they are in compliance with Federal statutes, regulations, and terms and conditions of award (2 CFR 200.303(a) and (b)). They must evaluate and monitor their compliance with statutes, regulations, and terms and conditions (2 CFR 200.303(c)), and they must take prompt action when instances of noncompliance are identified (2 CFR 200.303(d)).

Recipient organizations' internal controls should be in compliance with guidance in "Standards for Control in the Federal Government." (2 CFR 200.303(a)). Thus, recipient organizations are expected to establish codes of conduct which define expectations of integrity and ethical values and criteria of competence of personnel involved in the work supported by NIH grant funds. Codes of conduct should articulate expectations to assure compliance with terms and conditions of award, including but not limited to, providing true, complete, and accurate information on application documents (2.3.7.6); assuring work environments are free of discriminatory harassment and are safe and conducive to high-quality work (4); and meeting applicable public policy requirements (4.1).

8.3.1 Financial Management System Standards

Recipients are required to meet the standards and requirements for financial management systems set forth or referenced in 2 CFR Part 200.302 as applicable. The standards and requirements for a financial

- The procurement is expected to exceed the “simplified acquisition threshold” (currently \$250,000 per [OMB memo M-18-18](#)) (formerly the “small purchase threshold”) established by the Federal Property and Administrative Services Act, as amended, and is to be awarded without competition or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the simplified acquisition threshold specifies a “brand name” product.
- A proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When NIH prior approval is required, the recipient must make available sufficient information to enable review. This may include, at NIH discretion, presolicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the applicant or recipient or may be conditioned on the receipt of additional information. Any resulting NIH approval does not constitute a legal endorsement of the business arrangement by the Federal government nor does such approval establish NIH as a party to the contract or any of its provisions.

8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, Women's Business Enterprises, and Veteran-Owned Businesses

Recipients must make positive efforts to use small businesses, minority-owned firms, women’s business enterprises and veteran-owned businesses as sources of goods and services whenever possible. Recipients should take the steps outlined in the applicable administrative requirements (2 CFR Part 200.321) to implement this policy.

8.3.4.4 Domestic Preferences for Procurements

The recipient or subrecipient should, to the greatest extent practicable and consistent with law, provide a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United States (including but not limited to iron, aluminum, steel, cement, and other manufactured products). The requirements of this section must be included in all subawards, contracts, and purchase orders under Federal awards. See 2 CFR Part 200.322.

8.4 MONITORING

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH awarding ICs monitor their grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to NIH. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is administratively closed out and NIH is no longer providing active grant support (see [Administrative Requirements—Closeout](#)).

8.4.1 Reporting

NIH requires that recipients periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Recipients also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in [Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources](#).

The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and closeout documents (final grant progress reports and final invention statements and certifications). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to NIH (see [Financial Reports](#) below) through PMS unless otherwise indicated in the award's terms and conditions.

Recipients are allowed a specified period of time to submit required financial and final progress reports (see 2 CFR 200.328 and 2 CFR Part 200.329, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see [Administrative Requirements—Enforcement Actions](#)). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

8.4.1.1 Non-Competing Continuation Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The Research Performance Progress Report (RPPR) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information.

NIH requires the use of the RPPR for all Type 5 progress reports, including accessing the Human Subjects System link in the RPPR, if applicable, that will allow reporting of inclusion enrollment data.

Recipients may query eRA Commons Status and Research Performance Progress Report (RPPR) to view a list their organization's pending grant progress reports and respective due dates. Late submission of a grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

Recipients also have an obligation to submit a complete and accurate progress report. NIH program or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award. Incomplete or inadequate progress reports may result in a delay of continued support.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the

recipient does not submit an application for continued support, a final RPPR is required (see [Final Research Performance Progress Report](#)).

The NIH awarding IC will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, major alteration and renovation, and non-construction activities.

8.4.1.1.1 Requirement for Commons ID

For progress reports using the RPPR, the Commons ID requirement is part of the Participants Section and is required for the PD/PI(s) and those who worked on the project in a postdoctoral role. This could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

For undergraduate and graduate students supported on a particular research grant, a Commons ID is required. Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now. For graduate students, this could include project roles of graduate research assistant or graduate student.

When an individual is assigned the Undergraduate, Graduate Student, and/or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

8.4.1.1.2 Expectation for Institutions to Develop Individual Development Plans for Graduate Students and Postdoctoral Researchers

In an effort to assist graduate students and post-doctoral researchers in achieving their career goals and become contributing members of the biomedical workforce, NIH encourages recipients to develop an institutional policy requiring that an Individual Development Plan (IDP) be implemented for every graduate student and postdoctoral researcher supported by any NIH grant and reportable on the progress report, regardless of the type of NIH grant that is used for support. This is an expectation that should be broadly implemented by institutions for all graduate students and postdoctoral researchers supported by NIH. The actual reporting of the implementation of this expectation is in the RPPR; recipients must report in RPPR *Section B. Accomplishments*, Question B.4 the use of the IDP for graduate students and/or postdoctoral researchers included in RPPR *Section D*. Participants or on a Statement of Appointment Form (PHS 2271). Do not include the actual IDP; instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.

8.4.1.2 Streamlined Non-Competing Award Process

SNAP includes a number of provisions that modify annual progress reports, NoAs, and financial reports.

The NoA will specify whether an award is subject to SNAP. Awards routinely included in SNAP are “K” awards and “R” awards, except R35. Awards excluded from SNAP are those that generally do not have the authority to automatically carry over unobligated balances (centers; cooperative agreements, Kirschstein-NRSA institutional research training grants, non-Fast Track Phase I SBIR and STTR

awards), clinical trials (regardless of activity code), P01, R35, and awards to individuals. However, these grants can be included in SNAP on a grant-specific basis. In addition, specific awards may be excluded from SNAP if:

- they require close project monitoring or technical assistance, e.g., high-risk recipients, certain large individual or multi-project grants, or grants with significant unobligated balances, or
- the recipient has a consistent pattern of failure to adhere to appropriate reporting or notification deadlines.

8.4.1.2.1 Modified Annual Progress Reports

While a modified, streamlined, progress report is still a feature of grants awarded under the SNAP authorities, a streamlined version of the RPPR has replaced the eSNAP module in the eRA Commons. For all SNAP awards, the progress report is submitted using this streamlined version of the RPPR that does not include detailed budget information.

8.4.1.2.2 Modified NoAs

Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and any negotiations, and reduces the information NIH requires to review, approve, and monitor non-competing continuation awards. SNAP NoAs are issued with only total direct and indirect costs awarded for the budget period. While direct costs categorical breakdowns are not awarded, recipients are required to allocate and account for costs by category in accordance with applicable cost principles. Future year commitments on SNAP awards reflect total cost commitments (direct plus indirect costs).

8.4.1.2.3 Modified Financial Reporting Requirements

For awards under SNAP, an FFR is required only at the end of a competitive segment rather than annually. The FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see [Administrative Requirements—Closeout](#)).

8.4.1.2.4 Submitting SNAP Progress Reports

All SNAP progress reports are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). If the 15th falls on a weekend or Federal holiday, the due date is automatically extended to the next business day. Paper submissions are not acceptable, will not be used for consideration for funding, and will not become part of the official file. If a paper SNAP progress report is submitted, recipients will be required to resubmit the information electronically.

The RPPR module in the eRA Commons allows recipients to electronically prepare and submit progress reports and supporting documentation. The RPPR module provides the user with dedicated screens to collect the required progress report information, including appropriate uploads for text documents. Data submitted through RPPR for Performance Sites and Participants is retained in the system to assist the recipient in completion of future progress reports.

The RPPR may be routed to authorizing officials at the applicant institution for review and approval prior to submission to NIH. For SNAP awards, the RPPR module provides recipients with the option to delegate to the PD/PI the authority to submit the progress report directly to NIH. This optional authority is managed on a PD/PI basis in the eRA Commons; such authority can be rescinded at any time.

Guidance on RPPR submission is documented in the [RPPR Instruction Guide](#).

8.4.1.3 Progress Reports for Multiyear Funded Awards

A limited number of NIH grant awards are multi-year funded, i.e., not funded in budget years but funded in full at the start of the project period from a single fiscal year appropriation. The project period and the budget period are the same in a multi-year funded (MYF) award and are longer than one year. Progress reports for MYF awards are due annually on or before the anniversary of the budget/project period start date of the award. A progress report is not required if the award is in a no-cost extension period unless specifically required by the IC. The reporting period for a MYF progress report is the calendar year preceding the anniversary date of the award. For example, if an award is made on 04/01/2021, the MYF progress report is due on or before 04/01/2022, and should report on the activities performed under the award between 04/01/2021 and 03/31/2022. For the subsequent year the MYF progress report will be due 04/01/2023, and should report on the activities performed under the award between 04/01/2022 and 03/31/2023. Information on the content of a MYF progress report and instructions on how to submit the report through the eRA Commons are posted at [NIH Instructions for Progress Reports for Multi-year Funded \(MYF\) Awards](#) and [NIH RPPR Instruction Guide](#). The multi-year research performance progress report (MYRPPR) link to upload the report will be available two months before the anniversary date of the award, on the eRA Commons Status search page in the folder “List of Applications/Grants” in the “Action” column. Progress reports for MYF awards must be completed by the PD/PI, and then submitted by a Signing Official (SO) or a PD/PI with delegated authority from the SO to submit a progress report. Information about SO delegation of authority to a PD/PI to submit a progress report appears in the [eRA Commons User Guide under Section 10.2 Delegations](#).

8.4.1.4 Final Research Performance Progress Report (F-RPPR)

The F-RPPR has replaced the Final Progress Report for closeout. NIH is no longer accepting Final Progress Reports. Generally, the F-RPPR format is the same as the current annual RPPR. As part of the F-RPPR recipients will be required to report on Project Outcomes. This section will be made publicly available, allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).

NIH will not maintain its previous Type 2 policy which stated that “whether funded or not” the progress report contained in the Type 2 application may serve in lieu of a separate final progress report. NIH now requires that organizations submit an Interim-RPPR while their Type 2 is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution’s F-RPPR.

See the [F-RPPR Instructions](#) for more information. Recipients should also review the information found in [Final Research Performance Progress Report](#).

8.4.1.5 Financial Reports

PMS will pre-populate the cash transaction section (lines 10a through 10c) of the FFR using recipient real-time cash advance information from PMS, and adjust recipient-reported disbursements to equal cash

advance drawdowns on all non-closed sub-accounts. Recipients will be required to certify at the time of each drawdown whether the cash drawdown request is for reimbursement of actual expenditures or is an advance for immediate disbursement; recipients must assert that award funds, including those issued to subrecipients, are used in compliance with all award conditions and federal statutory requirements.

8.4.1.5.1 Financial Expenditure Reports

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the recipient organization. NIH requires all financial expenditure reports to be submitted using the Payment Management System. This includes all initial FFRs being prepared for submission and any revised FFRs being submitted or re-submitted to NIH. The eRA Commons and Payment Management systems allows participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH through PMS. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted the FFR Reconciliation and Financial Closeout Support Center (FFR-C) within the Office of Policy for Extramural Research Administration (OPERA). NIH IC grants management staff also review these expenditure reports.

Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date.

In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see [Administrative Requirements—Closeout](#)).

Before submitting FFRs to NIH, recipients must ensure that the information submitted is accurate, complete, and consistent with the recipient's accounting system. When submitting the FFR through the Payment Management System, as applicable, the AOR or the individual designated to submit this report on behalf of their institution, certifies that the information in the FFR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government. Filing a false claim may result in the imposition of civil or criminal penalties.

8.4.1.5.2 Revised Financial Reports and Expenditures

Revisions for Indirect Cost Changes. Each Federal Financial Report submitted by the recipient shall reflect the proper amount of indirect costs applicable to the grant period. If a provisional or an earlier period's permanent rate is used in the report, a subsequent adjustment to the FFR is necessary if a lower permanent rate(s) applicable to the grant is established, except for Institutions of Higher Education (IHEs) subject to 2 CFR 200.

Revised Expenditure Reports. NIH requires all financial expenditure reports (domestic and foreign) to be submitted using the Payment Management System. This includes the initial FFR and any FFR

revisions being submitted or re-submitted to NIH. In some cases the recipient may have to revise or amend a previously submitted annual or final FFR. When the revision results in a balance of \$20,000 or greater due to NIH, the recipient must submit a revised report whenever the overcharge is discovered, no matter how long the lapse of time since the original due date of the report, and post the refund to the PMS document if the funds have not expired and are reconciled and closed in PMS. All refunds under \$20,000 on closed PMS documents should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. PMS refund instructions may be found on the [Program Support Center webpage](#). Revised expenditure reports representing additional expenditures by the recipient that were not reported to NIH within the 90-day time frame may be submitted electronically with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the recipient to preclude similar situations in the future. This should be done as promptly as possible, but no later than one year from the due date of the original report for annual FFRs and no later than 60 calendar days from the due date of the original report for final FFRs (i.e., 180 days from the project end date).

8.4.1.5.3 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. (See [Administrative Requirements—Changes in Project and Budget](#) for NIH approval authorities for unobligated balances.) Using the principle of “first in-first out,” unobligated funds carried over are expected to be used before newly awarded funds.

Upon receipt of the annual FFR for awards other than those with authority for the automatic carryover of unobligated balances, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget period with the NIH share of the approved budget for the current budget period. If the funds available exceed the NIH share of the approved budget for the current budget period, the GMO may select one of the following options:

- In response to a written request from the recipient, revise the current NoA to authorize the recipient to spend the excess funds for additional approved purposes.
- Offset the current award or a subsequent award by an amount representing some or all of the excess.

8.4.1.5.4 Recipient Reporting of Subrecipient Data and Executive Compensation Information for Federal Funding Accountability and Transparency Act (FFATA)

A component of Public Law 109-282, the [Federal Funding Accountability and Transparency Act of 2006](#) as amended (FFATA), requires most recipients of new Federal funds to report on sub-awards/subcontracts/consortiums equal to or greater than \$30,000. This includes awards that are initially below \$30,000 but subsequent grant modifications result in an award equal to or greater than \$30,000.

Subaward reports are submitted in SAM.gov with subaward data ultimately distributed for publication and display on [www.USASpending.gov](#). Recipients are required to register with SAM.gov, collect the necessary data from subrecipients, and file subaward reports by the end of the month following the month in which the pass-through entity awards any subaward greater than \$30,000.

FFATA specifies the data that should be captured for each pass-through entity and first-tier subrecipient of Federal awards, regardless of award type. To promote data consistency and reduce reporting burdens, existing agency data sources will be leveraged to pre-populate reports for pass-through entities as well as for subrecipients when available. Recipients are responsible for confirming the pre-populated data and providing any additional required information.

Included in these requirements is the need to report the names and total compensation of the five most highly compensated officers of the entity if the entity as part of their registration profile in SAM in the preceding fiscal year: 1) received 80 percent or more of its annual gross revenues in Federal grants, subawards, contracts, and subcontracts; and 2) received \$25,000,000 or more in annual gross revenues from Federal grants, subawards, contracts, and subcontracts; and 3) had gross income, from all sources, of \$300,000 or more; and 4) the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1). Additionally, recipient organizations may be required to verify the following information in SAM.gov:

- Organization UEI
- Name and Address of organization
- Parent UEI
- Assistance listing number
- [FAIN](#)
- Federal Awarding Agency of the grant

8.4.1.6 Invention Reporting

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR 401.14. The requirements also are specified in [Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources](#).

In addition to complying with Bayh-Dole-related regulations, each NIH competing grant application and non-competing continuation progress report must indicate whether or not any subject inventions were made during the preceding budget period. If inventions were made, the recipient must also indicate whether they were reported.

The recipient also must submit an annual invention utilization report for all subject inventions to which title has been elected and inventions that have been licensed but not patented (research tools). The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

A recipient's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights or a withholding of grant funds or other enforcement actions, including the imposition of specific terms and conditions.

Bayh-Dole regulations allow recipients to report inventions electronically (37 CFR 401.16). NIH requires electronic reporting through an Internet-based system, [Interagency Edison](#). To meet the objectives of the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107), recipients are required to submit invention reports to NIH using iEdison. The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, are on the iEdison site. Recipients also may contact the [Division of Extramural Inventions and Technology Resources Branch, OPERA, OER](#). See Part III for contact information.

8.4.1.7 Financial Conflict of Interest Reports

Information related to FCOI reporting requirements can be found within [Public Policy Requirements -- Financial Conflict of Interest](#).

8.4.1.8 Research Securities

In alignment with the CHIPS and Science Act of 2022 (P.L. 117-167) and National Security Presidential Memorandum-33 (NSPM-33), NIH has established a series of requirements to strengthen research security across NIH-funded projects.

8.4.1.9 NIH Disclosure Requirements

As part of the application preparation and submission process, and annual progress report submission, all individuals designated in an application as senior/key personnel are required to certify and submit information to assist reviewers and NIH staff in making informed recommendations and funding decisions.

Details on all required disclosures can be found in the [NIH Disclosure Table](#). It is vital that submission of such disclosure information be taken seriously. Failure to comply with terms and conditions related to disclosure requirements may cause NIH to take action(s) to remedy non-compliance, such as disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action (see Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).. Further, violations that are potentially criminal will be referred to the NIH Office of Management Assessment for consultation with the HHS Office of Inspector General, the Department of Justice, or other law enforcement agencies, as appropriate.

8.4.1.10 Malign Foreign Talent Recruitment Program

In accordance with the CHIPS and Science Act of 2022 (P.L. 117-167) , individuals who are a current party to a Malign Foreign Talent Recruitment Program (MFTRP) are not eligible to serve as a senior/key person on an NIH grant or cooperative agreement.

8.4.1.11 Research Security Training

In accordance with the CHIPS and Science Act of 2022 (P.L. 117-167), each senior/key personnel listed on an NIH grant application must certify that they have completed Research Security Training (RST) within 12 months of the date of application submission. This individual certification is required at the time of the application submission, through the Biographical Sketch in SciENcv.

The Act also requires applicant institutions to certify that each covered individual who is employed by the institution and listed on the application has completed RST. The AOR, via their signature on the face page of the application, certifies the applicant institution's compliance with this requirement.

Completion of RST and the individual and institutional certifications is required for applications submitted for due dates on or after May 25, 2026.

8.4.2 Record Retention and Access

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. For awards under SNAP (other than those to Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH.

Federal institutions must retain records for 3 years from the date of submission of the annual FFR to NIH. See 2 CFR Part 200.334 for exceptions or qualifications to the 3-year retention requirement exist (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period), the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Maintain the information for the retention period for other types of grant-related records, including indirect cost proposals and property records. See 2 CFR Part 200.334 and 2 CFR Part 200.337 for record retention and access requirements for contracts under grants.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

NIH, pass-through entities, Inspectors General, the Comptroller General of the United States, or any of their authorized representatives, must have the right of access to any records of the recipient or sub-recipient pertinent to the NIH award, to perform audits, execute site visits, or for any other official use. This right also includes timely and reasonable access to the recipient's or subrecipient's personnel for the purpose of interview and discussion related to such documents or the NIH award in general. NIH's rights of access are not limited to the required retention period of this part but lasts as long as the records are retained. Pass-through entities must not impose any other access requirements upon subrecipients.

8.4.3 Audit

An audit is a systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of the following:

- Financial operations are properly conducted.
- Financial reports are timely, fair, and accurately.
- The entity has complied with applicable laws, regulations, and other grant terms.
- Resources are managed and used economically and efficiently.
- Desired results and objectives are being achieved effectively.

NIH recipients (other than Federal institutions) are subject to audit requirements in 2 CFR Part 200 Subpart F and in the NIHGPS (for types of organizations to which 2 CFR Part 200, Subpart F-Audit Requirements do not directly apply). In general, 2 CFR Part 200, Subpart F- Audit Requirements requires a State government, local government, or non-profit organization (including institutions of higher education) that expends \$1,000,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts are required to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS). The audit requirements for foreign recipients and for-profit recipients are addressed in the chapters of this NIHGPS that provide specific requirements for those types of recipients. In accordance with 2 CFR 200.101(a)(2), HHS has established for-profit audit requirements at 2 CFR 300.218. See NIHGPS 18.4.5 for details on NIH's implementation of the for-profit audit requirements.

As specified in the NoA, all awards issued by NIH meet the definition of "Research and Development" at 2 CFR Part 200.1. As such, NIH grant awards are subject to the R&D cluster of program requirements in the compliance supplement. NIH recognizes that some awards may have another classification for

purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Exhibit 10. Summary of Audit Requirements

Recipient Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Colleges & Universities (IHEs)	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Non-Profits	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Hospitals	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
For-Profits	NIH Grants Policy Statement	Audit Resolution Division (See contact information in Part III)
Foreign	NIH Grants Policy Statement (same as For-Profits)	Audit Resolution Division (See contact information in Part III)

When a recipient procures audit services, the procurement must comply with the procurement standards of 2 CFR Part 200, as applicable, including obtaining competition and making positive efforts to use small businesses, minority-owned firms, women’s business enterprises, and veteran-owned enterprises. Recipients should ensure that comprehensive solicitations made available to interested firms include all audit requirements and specify the criteria to be used for selection of the firm. Recipients’ written agreements with auditors must specify the rights and responsibilities of each party.

2 CFR Part 200, Subpart F-Audit Requirements explains in detail the scope, frequency, and other aspects of the audit. Some highlights of this regulation are as follows:

- Covered organizations expending \$1,000,000 or more per year in Federal awards are required to have an audit performed in accordance with the regulation. However, if the awards are under one program, the organization can have either a single organization-wide audit or a program-specific audit of the single program, subject to the provisions of 2 CFR Part 200.507. NIH identifies one program as all awards funded by one IC. Prior to electing a program-specific audit, the recipient must obtain written prior approval from the relevant NIH awarding IC. Covered organizations expending less than \$1,000,000 in any year are exempt from these audit requirements in that year but must have their records available for review as required by [Administrative Requirements—Monitoring—Record Retention and Access](#).

- The reporting package must contain the following:
 - Financial statements and schedule of expenditures of Federal awards.
 - Independent auditor's report, including an opinion on the financial statements and the schedule of expenditures of Federal awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements.
 - A schedule of findings and questioned costs.
 - If applicable, a summary of prior audit findings and a corrective action plan.
- An audit under 2 CFR Part 200, Subpart F-Audit Requirements is in lieu of a financial audit of individual Federal awards. However, Federal agencies may request additional audits necessary to carry out their responsibilities under Federal law or regulation. Any additional audits will build upon work performed by the independent auditor.
- The data collection form (SF-SAC) and a copy of the Single Audit reporting package must be submitted electronically to the [FAC](#) at the address provided in Part III.
- A senior level representative of the auditee (e.g., state controller, director of finance, chief executive officer, or chief financial officer) must sign a statement to be included as part of the data collection that says that the auditee complied with the requirements of this part, the data were prepared in accordance with this part (and the instructions accompanying the form), the reporting package does not include protected personally identifiable information, the information included in its entirety is accurate and complete, and that the FAC is authorized to make the reporting package and the form publicly available on a web site. Exception: An auditee that is an Indian tribe or a tribal organization (as defined in the Indian Self- Determination, Education and Assistance Act (ISDEAA), 25 U.S.C. 450b(l)) may opt not to authorize the FAC to make the reporting package publicly available on a web site, by excluding the authorization for the FAC publication. If this option is exercised, the auditee becomes responsible for submitting the reporting package directly to any pass-through entities through which it has received a Federal award and to pass-through entities for which the summary schedule of prior audit findings reported the status of any findings related to Federal awards that the pass-through entity provided. Unless restricted by Federal statute or regulation, if the auditee opts not to authorize publication, it must make copies of the reporting package available for public inspection.

If the schedule of findings and questioned costs discloses an audit finding related to an HHS or NIH award or if the schedule of prior audit findings reports the status of any audit finding relating to an HHS or NIH award, the FAC will provide copies of the audit report to NEARC, OIG, HHS. NEARC will, in turn, distribute them within HHS for further action, as necessary. Audit reports should not be sent directly to the GMO. The threshold for reporting questioned costs is described in 2 CFR Part 200.516.

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of a Federal audit or a recipient-initiated audit. Recipients usually are allowed 30 days from the date of request to respond to the responsible audit resolution official (Action Official) concerning audit findings. Failure to submit timely responses may result in cost disallowance or other actions by NIH or HHS. At the completion of the audit resolution process, the recipient will be notified of the Action Official's final decision. The recipient may appeal this decision if the adverse determination is of a type covered by NIH or HHS grant appeals procedures (see [Administrative Requirements—Grant Appeals Procedures](#)). Refunds owed to the Federal government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official or OFM.

It is imperative that recipients submit required 2 CFR Part 200, Subpart F audits within the time limits specified in the regulation. If recipients are delinquent in complying with the provisions of the regulation, NIH will take one or more actions that may result in the loss of Federal funds. No audit costs will be allowed either as indirect costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of 2 CFR Part 200, Subpart F.

See [Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost](#) for the allowability of audit costs.

8.5 SPECIFIC AWARD CONDITIONS AND REMEDIES FOR NONCOMPLIANCE (SPECIFIC AWARD CONDITIONS AND ENFORCEMENT ACTIONS)

A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the recipient an opportunity to correct the deficiencies before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing specific conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

8.5.1 Specific Award Conditions: Modification of the Terms of Award

During grant performance, the GMO may include specific award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When specific conditions are imposed, the GMO will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR Part 52.9 and 2 CFR Part 200.339.

The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case, the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel.

Generally, the decision to modify the terms of an award (e.g., by imposing specific award conditions) is discretionary on the part of the NIH awarding IC and is not appealable.

8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

NIH may implement specific award conditions if a recipient or subrecipient fails to comply with the U.S. Constitution, Federal statutes, regulations, or the terms and conditions of award. When NIH determines that noncompliance cannot be remedied by imposing specific conditions, NIH may take one or more of the following actions:

Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference and post-conference follow-up, usually 1 year. A conference grant made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic may be awarded for up to a total of 5 years and will be funded annually, based on the availability of funds. Continued funding beyond the first year will be contingent on a report of satisfactory progress submitted in accordance with SNAP instructions. A change in conference focus requires NIH awarding IC prior approval.

14.9 ACKNOWLEDGMENT OF FUNDING SOURCE AND DISCLAIMER

When a conference is funded by an NIH grant or cooperative agreement, recipients must include the following statement on conference materials (including promotional materials, agenda, and internet sites):

“Funding for this conference was made possible (in part) by (Insert Grant/Cooperative Agreement #) from (insert name of NIH IC). The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of NIH; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government.”

Appropriate use of the NIH or HHS logo on conference materials is of particular importance. Neither logo should be displayed if it would cause confusion as to the source of the conference or give the false appearance of government endorsement. Accordingly, unless specifically authorized by the award, any use of the HHS and/or NIH logo requires prior approval. Unauthorized use of the HHS or NIH name or logo may result in imposition of civil monetary penalties (as provided in 42 CFR Part 1003).

14.10 ALLOWABLE AND UNALLOWABLE COSTS

The following highlights allowable and unallowable costs under conference grants. No costs other than those specified in this subsection as allowable, including any qualifications on their allowability, are permitted under conference grants.

14.10.1 Allowable Costs

In general, consistent with 2 CFR Part 200.432, conference hosts/sponsors must exercise discretion and judgment in ensuring that conference costs are appropriate, necessary and managed in a manner that minimizes costs to the Federal award.

Conference Services. Grant funds may be used for necessary recording of proceedings, simultaneous translation, and subsequent transcriptions.

Consultant Services. Grant funds may be used to pay consultant fees, including travel and supporting costs (per diem or, where applicable, subsistence).

Equipment Rental. Grant funds may be used for the rental of necessary equipment.

Federal Employees. See [Grants to Federal Institutions and Payments to Federal Employees under Grants](#) chapter.

Meals. When meals are justified by the applicant as an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. See [Travel](#) below.