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# NIH Grants Updates

PRESENTED BY THE  
OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION

**October 29, 2024**



# AGENDA

- **UPDATES:**
  - Budget
  - Policy
  - System Process
  - Compliance Updates
- **Policy Reminders**
- **Resources**
- **Q&A**



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# BUDGET UPDATES

# FY25 Budget Updates

- On September 26, 2024, President Biden signed the Continuing Appropriations and Extensions Act, 2025 ([Public Law 118-83](#)).
- This Act (CR) continues government operations through December 20, 2024, at the Fiscal Year (FY) 2024 enacted level, with no reduction.
- The following FY 2024 notices remain in effect under this CR:
  - Legislative Mandates (see [NOT-OD-24-110](#))
  - Salary Limitation for Grants and Cooperative Agreements (see [NOT-OD-24-057](#))\*
  - Ruth L. Kirschstein National Research Service Award predoctoral and postdoctoral stipend levels and tuition/fees as described in [NOT-OD-24-104](#).

# \*Legislative mandates – Salary Limitation

- Effective October 1, 2024, the [HHS policy](#) on salary rate limitation outlines that the legislative mandate limiting salary to Executive Level II applies to
  - Direct salaries (individuals working directly on NIH projects) and
  - Indirect salaries (executive salaries in various cost pools)
- This policy change applies to new, competing renewals, non-competing continuations and supplemental awards.
- For recipients that do not have an updated or approved indirect cost rate agreement, the HHS salary rate limitation requirement applies, and recipients may not charge or recover funds for salaries above the salary limitation.

# Childcare Cost Updates for NRSA Fellows and Trainees

- Effective in FY 2024 NIH increased the childcare support to \$3,000 for applicable NRSA individual fellowships and institutional training awards.
  - For fellows, each NRSA fellow may request \$3,000 per budget period to defray childcare costs.
  - For trainees, NIH will provide an annual \$3,000 per each full-time predoctoral or postdoctoral NRSA trainee appointment slot at the time the new, renewal, or continuation award is made.
- Effective in FY2025, NIH intends to provide childcare cost support to individuals supported as full-time recipients of Predoctoral to Postdoctoral Fellow Transition Award (F99/K00) programs during the F99 phase of the award.

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# NIH POLICY UPDATES

# NIH Implementation of 2 CFR Part 200 - Overview

- In April 2024, the Office of Management and Budget issued [revisions](#) to the Uniform Administrative Requirements for Federal Financial Assistance, located at 2 CFR Part 200.
- NIH plans to implement the OMB administrative flexibilities and partially implementing the updated administrative requirements that are outlined throughout 2 CFR Part 200. NIH is working closely with HHS and the other HHS Operating Divisions.
- Currently, the [Research Terms and Conditions](#) (RTCs) are not being updated. However, NIH is working with other Federal research agencies to update the prior approval matrix and national policy requirements.

# Single Audit Requirements for Foreign Recipients and Subrecipients

- [NOT-OD-24-151](#) clarified the NIH single audit requirements for foreign recipients and subrecipients.
- Effective October 1, 2024, foreign recipients that expend \$750,000 (cumulative amount) or more in Federal awards during their fiscal year are required to conduct either a single audit, or program-specific audit (as required by the terms and conditions of award).
- A program-specific audit may not be elected unless all the Federal awards expended were received from NIH. The recipient must request prior approval from the funding Institute or Center prior to conducting a program-specific audit.

# Common Forms for Biographical Sketch and Current and Pending (Other) Support: NIH Implementation

- In accordance with the implementation plan submitted to the Office of Science and Technology Policy (OSTP) in May 2024, NIH issued [NOT-OD-24-163](#).
- Effective for all applications and RPPRs submitted for due dates **on or after May 25, 2025**.
- NIH will implement the Common Forms without change to any collection fields.
- NIH plans to continue collecting three required agency specific data elements
  - Personal Statement
  - Contributions to Science
  - Honors) to assess qualifications
- These data elements will be collected separately from the Common Forms on a new NIH Biographical Sketch Supplement.

Learn more: [NOT-OD-24-163](#)

# Common Forms for Biographical Sketch and Current and Pending (Other) Support: SciENcv/ORCID Implementation

- NIH will **require** the use of Science Experts Network Curriculum Vitae ([SciENcv](#)) to complete Common Forms and the NIH Biographical Sketch Supplement to produce digitally certified PDF(s) for use in application submission.
- NIH will **require** all Senior/Key Personnel to enter their ORCID ID into SciENcv in the Persistent Identifier (PID) section of the Common Forms.
  - NIH will **require** all Senior/Key Personnel to link their ORCID ID to their eRA Commons Personal Profile.
  - For information on linking an ORCID ID to the eRA Commons Personal Profile see the [ORCID ID topic](#) in the eRA Commons online help.

# Decision Matrix for Assessing Potential Foreign Interference for Covered Individuals or Senior/Key Personnel

- On 8/15/24 NIH [published a decision matrix](#) for assessing potential foreign interference.
- NIH strongly supports properly conducted and principled international collaborations that are integral for our country to remain competitive.

## NIH Decision Matrix for Assessing Potential Foreign Interference for Covered Individuals or Senior/Key Personnel (Use for Initial Assessment)<sup>1,2,3</sup>

Consistent with NSPM-33, NSPM-33 Implementation Guidance, and 2 C.F.R. 200.206, NIH has developed this Matrix as a guide to assist NIH in reviewing grant applications and ongoing awards for signs of potential foreign interference, and in appropriately mitigating risk. The rows below describe conditions in which NIH will contact the grant applicant or recipient for further information, and in which mitigation may be required, recommended, or not needed. NIH is making this document public to be transparent about the types of behaviors the NIH finds problematic and to provide NIH-funded researchers a better understanding about how their applications and disclosures may be received and reviewed.

Rating	Factor 1: Foreign Talent Recruitment Program <sup>4,5</sup>	Factor 2: Foreign Funding <sup>6,7</sup>	Factor 3: Affiliation with Foreign Institutions or Entities <sup>6,8</sup>
<p><b>Mitigation measures required.</b></p> <p><b>Contact recipient institution for more information.</b></p>	<p>Indicators of active (ongoing) participation in a malign foreign talent recruitment program (MFTRP) meeting any of the criteria in Sec. 10638(4)(A)(i)-(ix) of the CHIPS and Science Act of 2022.</p> <p>[Note: this factor/rating is automatically disqualifying]</p>	<p>Indicators of undisclosed or incompletely disclosed active (ongoing) funding from a Foreign Country of Concern (FCOC) or an FCOC-connected entity</p>	<p>Indicators of an undisclosed or incompletely disclosed active (ongoing) affiliation with an institution or entity located in or connected to a Foreign Country of Concern (FCOC).</p>
<p><b>Mitigation measures recommended.</b></p> <p><b>Contact recipient institution for more information.</b></p>	<p>Within the past 5 years: Indicators of past participation in a malign foreign talent recruitment program (MFTRP) meeting any of the criteria in Sec. 10638(4)(A)(i)-(ix) of the CHIPS and Science Act of 2022.</p> <p>Or</p> <p>Indicators of undisclosed or incompletely disclosed active (ongoing) participation in a</p>	<p>Within the past 5 years: Indicators of undisclosed or incompletely disclosed past funding from a Foreign Country of Concern (FCOC) or an FCOC-connected entity.</p> <p>Or</p> <p>Indicators of undisclosed or incompletely disclosed active (ongoing) funding from a foreign country or foreign entity that is</p>	<p>Within the past 5 years: Indicators of undisclosed or incompletely disclosed past affiliation with an institution or entity located in or connected to Foreign Country of Concern (FCOC).</p> <p>Or</p> <p>Indicators of an undisclosed or incompletely disclosed active (ongoing) affiliation with an</p>

# Reporting DMS Plan Activities in the RPPR

- Recipients must address [NIH Data Management and Sharing Policy](#) in annual RPPRs due on or after October 1, 2024.
- For awards for which the NIH DMS Policy applies, recipients will be asked:
  - Whether data has been generated to date and what type of data it is;
  - Whether data has been shared for use by others;
  - If data has been shared, in what repository and under what unique digital identifiers;
  - If data has NOT been shared, what is the status of data sharing (e.g., being prepared for submission, submitted to repository, not yet expected to be shared); and
  - If data has not been generated and/or shared as outlined in an approved DMS Plan, what corrective actions have or will be taken to comply with the approved Plan.
- The updated NIH RPPR Instruction Guide is posted to the [Research Performance Progress Report \(RPPR\)](#) page.

# Updated System Processes for Requesting Revisions to an Approved DMS Plan

- Under the final NIH Policy for Data Management and Sharing (DMS Policy), NIH requires a recipient to comply with the DMS Plan as approved by the funding NIH Institute, Center, or Office (ICO) as a term and condition of the award.
- If DMS Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), Plans should be updated by recipients and reviewed and approved by the NIH ICO.
- All requests for NIH awarding ICO prior approval must be submitted by the Authorized Organization Representative (Signing Official (SO) role in eRA Commons) at least 30 days in advance of the requested change, and the currently approved DMS Plan remains in effect for the award until the request is approved by the funding NIH ICO.

# Updated System Processes for Requesting Revisions to an Approved DMS Plan, Cont'd

- The processes for submitting requests and revised DMS Plans depend on where you are in the grant award cycle.
- **Pre-Award: Just-in-Time**
  - Before the award is made, applicants must use the “Data Management and Sharing Plan (DMSP) Revision” section of the [Just in Time \(JIT\) Screen](#) in eRA Commons, to submit a revised DMS Plan.
  - Note: SOs must no longer use the ‘Other File’ section in Just-in-Time to submit the revised DMS plan.
- **Post-Award: At Time of RPPR**
  - For changes being requested after the award is made, at the time of the RPPR (i.e., within 30 days of RPPR submission), in the [RPPR Module](#), recipients must use Section C.5.c to select “Upload Revised Data Management and Sharing Plan” and follow the instructions provided to complete the required entry. Refer to the [RPPR Instruction Guide](#).
- **Post Award: Off-Cycle Requests**
  - When revisions to the DMS Plans need to be requested off-cycle (other than at the time of the RPPR), recipients must Select “Prior Approval – DMS Request” in the [Prior Approval Module](#) to request the change.
  - Note: SOs must no longer use the ‘Other Request’ type in Prior Approval to submit the plan.

# NIH Guidance on Marking Changes in Resubmission Applications

- On February 13, NIH issued [NOT-OD-24-061](#), NIH Guidance on Marking Changes in Resubmission Applications. Effective May 25, 2024:
  - The use of markups should not be used to identify changes in Resubmission applications.
  - Changes made to a resubmission application should only be outlined in the Introduction attachment.
    - Must include a summary of substantial additions, deletions, and changes to the application.
    - Must include a response to weaknesses raised in the Summary Statement.
    - Unless otherwise indicated in the [Table of Page Limits](#), the Introduction may not exceed one page.

# Updated Guidance for Videos Submitted as NIH Application Materials

- On March 12, 2024, [NOT-OD-24-067](#) provided updated guidance on investigators submitting videos to submit their NIH applications.
- Major changes include:
  - NIH will no longer accept video files in CDs/DVDs/USBs format. Only digital video files submitted via email will be accepted.
    - AOR must send or concur to PD/PI sending videos and must be received by SRO no later than 30 days prior to peer review. No exceptions.
  - Combined size of videos per application must not exceed 35 MB
  - Key images and brief description of each video must be included within research strategy.
- Key reminders:
  - The only acceptable content for videos is demonstrations of devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time or demonstrates movement or change.
  - No demonstrations of data that could be feasibly presented in figures or tables will be accepted.

# Final Scientific Integrity Policy of the National Institutes of Health

- On September 20, 2024, [NOT-OD-24-178](#) issued the Final NIH Scientific Integrity Policy to promote a continuing culture of scientific integrity at NIH.
- Scientific integrity aims to make sure that science is conducted, managed, communicated, and used in ways that preserve its accuracy and objectivity and protect it from suppression, manipulation, and inappropriate influence.
- This Policy codifies NIH's long-standing expectations to preserve scientific integrity throughout all NIH activities, establishes key roles and responsibilities for those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms.



# FORMS-I



National Institutes of Health  
*Office of Extramural Research*

# Coming Soon: FORMS-I

- Effective for applications submitted for due dates **on or after January 25, 2025.**
- FORMS-I will incorporate updates related to multiple NIH initiatives:
  - Improvements to the NIH Fellowship Application and Review Process.
  - Updates to NRSA Training Grant Applications.
  - Adoption of the Common Forms for Biographical Sketch and Current and Pending (Other) Support for submission of applications and RPPRs **for due dates on or after May 2025.**
- FORMS-I application guide and forms packages will be available beginning in late October/November 2024.

# PHS Fellowship Supplemental Form

## PHS Fellowship Supplemental Form

[View Burden Statement](#)

OMB Number: 0925-0001  
Expiration Date: 01/31/2026

Introduction		
1. Introduction to Application (for Resubmission applications)	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
Candidate Section		
2. * Goals, Preparedness, and Potential	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
Research Training Plan		
3. * Training Activities and Timeline	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
4. * Research Training Project Specific Aims	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
5. * Research Training Project Strategy	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
6. Progress Report Publication List (for Renewal applications)	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
7. * Training in the Responsible Conduct of Research	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
Commitment to Candidate, Mentoring, and Training Environment		
8. Sponsor(s) Commitment	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
9. Letters of Support from Collaborators, Contributors, and Consultants	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
10. Description of Candidate's Contribution to Program Goals	<input type="text"/>	<a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>

# PHS 398 Research Training Program Plan

[View Burden Statement](#)

## PHS 398 Research Training Program Plan

OMB Number: 0925-0001  
Expiration Date: 01/31/2026

<b>Introduction</b>			
1. Introduction to Application (for Resubmission and Revision applications)	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
<b>Training Program Section</b>			
2. * Program Plan	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
3. Recruitment Plan to Enhance Diversity	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
4. Plan for Instruction in the Responsible Conduct of Research	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
5. Plan for Instruction in Methods for Enhancing Reproducibility	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
6. Multiple PD/PI Leadership Plan (if applicable)	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
7. Progress Report (for Renewal applications)	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
<b>Faculty, Trainees and Training Record Section</b>			
8. Participating Faculty Biosketches	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
9. Letters of Support	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>
10. Data Tables	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a> <a href="#">View Attachment</a>

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# **SIMPLIFIED REVIEW FRAMEWORK**

# NIH Peer Review – Simplified Review Framework

- [NOT-OD-24-010](#), Simplified Review Framework (SRF) for NIH Research Project Grant Applications. Effective for applications with **due dates on or after January 25, 2025**.
- Applies to most research project grant (RPG) activity codes.
- Reorganizes the five regulatory criteria into three factors to better focus peer reviewers on the key questions needed to assess the scientific and technical merit of proposed research points.
  - **Factor 1:** Importance of the Research (Significance, Innovation), scored 1-9
  - **Factor 2:** Rigor and Feasibility (Approach), scored 1-9
  - **Factor 3:** Expertise and Resources (Investigator, Environment), to be evaluated for sufficiency.

# Simplified Review Framework (SRF) Updates

- On April 4, 2024, NIH issued [NOT-OD-24-085](#), Simplified Review Framework for NIH Research Project Grant Applications - Update and Implementation Plans.
  - Updates applicable activity codes:
    - Added: R21/R33, UH2/UH3, UG3/UH3, R61/R33
    - Removed: DP1, DP2, DP3, DP4, and DP5
- No form changes associated with the SRF initiative; however, applicants will need to use FORMS-I packages for applications with **due dates on or after January 25, 2025**.
- New and reissued SRF NOFOs may be initially posted without an application forms package. In these cases, application forms and associated application instructions will be added at least 30 days and, frequently 60 days or more, prior to the first due date. See [NOT-OD-24-086](#).

Learn more: [NOT-OD-24-085](#) and [NIH Simplified Review Framework for Research Project Grants \(RPGs\): Implementation and Impact on Funding Opportunities Webinar](#).

# Changes to the NIH Fellowship Application and Review Process

- NIH issued [NOT-OD-24-107](#), Implementation of Revisions to the NIH Fellowship Application and Review Process.
  - Reorganizes the five current scored review criteria and redefines them in three scored criteria
  - Updates PHS Fellowship Supplemental Form to align with restructured criteria
  - Revises instructions for Reference Letters
- Effective for application submissions with due dates after **January 25, 2025**
- Applicable to programs using the activity codes: F30, F31, F32, F33, and F99/K00

# Updates on NIH Institutional Training Grant Applications

- NIH issued [NOT-OD-24-129](#), Updates to NIH Institutional Training Grant Applications for Due Dates on or After January 25, 2025.
  - The Recruitment Plan to Enhance Diversity will be its own attachment in the PHS 398 Research Training Program Plan Form.
  - Mentor training expectations will be more clearly defined in the parent T32 NOFO.
  - Institutional Training [data tables](#) will be updated to reduce burden and promote consistent information collection across training programs.
- Effective for application submissions with due dates after **January 25, 2025**
- Applicable to programs using the activity codes:
  - Institutional Training – T series, e.g., T15, T32, T34, T35, T37, T90/R90, TL1, TL4
  - International Institutional Training – D43, D71, U2R
  - Institutional Career Development – K12, KL2



# **SBIR/STTR UPDATES**

# SBIR and STTR Foreign Disclosure Requirements

- [NOT-OD-23-139](#) and [NOT-OD-24-029](#) outline the Implementation of the NIH Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Foreign Disclosure Pre-Award and Post-Award Requirements.
  - Due diligence program to assess security risks and denial of award when foreign relationships or commitments with countries of concern pose a significant risk as provided in the SBIR and STTR Extension Act of 2022.
  - Effective for competing SBIR and STTR applications submitted for due dates on or after September 5, 2023.
  - Disclosure of all funded and unfunded relationships with foreign countries is required for all owners and “covered individuals”.
  - Submitted via the “Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries” form during the Just-in-Time process.
  - Disclosure form is available on NIH’s [Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries web page](#).

# New SBIR and STTR Domestic Subaward Requirements

- On July 3, 2024, [NOT-OD-24-149](#) implemented a change in policy for domestic subawards for the SBIR Program and the STTR Program.
- SBIR and STTR recipients are now 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.
- If the new subaward results in any changes to the “Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries” form, the recipient must submit an updated form for review.
- *Reminder:* NIH continues to require prior approval when adding a foreign subaward to the project ([NIHGPS 8.1.2.10](#)).

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# SYSTEM PROCESS UPDATES

# Retirement of NIH's Automated Just-in-Time Email Notification

- The automated Just-In-Time (JIT) notification from [era-notify@mail.nih.gov](mailto:era-notify@mail.nih.gov) was retired effective October 1, 2024.
  - Email was sent for all applications with an overall impact score of 30 or less.
- The official email requesting JIT material(s) will continue to be sent directly by NIH staff from the awarding Institute/Center to those who are required to provide the material(s).
- The JIT link to submit materials, when requested, will still be available in eRA Commons until the application is awarded.
  - Note that either a PI or SO can upload and save Just-in-Time information; however, only the SO can submit it.

# Retirement of Commons Demo and Quick Queries Sites

- [NOT-OD-25-005](#): eRA Commons Demo, a sample environment to try out most of the capabilities of eRA Commons, was retired as of October 14, 2024.
  - The external extramural research community will have the option to use the non-production environment — the [User Acceptance Testing](#) (UAT) environment — for practice. See [steps to use UAT](#).
- [NOT-OD-24-111](#): eRA Commons Quick Queries, including Grants Pending Closeout, Progress Report Search by IPF number, IPF Number Search, and Issued Notice of (Grant) Award, was retired as of June 3, 2024.
  - We encourage you to take full advantage of other eRA tools in [Commons Status](#) and [Research Performance Progress Report \(RPPR\)](#) to access Award-related information. In addition, we encourage you to use [RePORTER](#) to obtain desired information related to organizations along with a variety of other grant related topics.

# Redesigned NIH Grants & Funding Site

- Launched September 24<sup>th</sup>
- Design based on analytics and user feedback
- Increased focus on new users
- Improved opportunity search
- Reorganized grants process content
  - Stronger integration with How to Apply – Application Guide
- Lots of URL changes
  - **Update your bookmarks, websites, and resources!**
  - Redirects in place for at least a year

Old grants.nih.gov home page



New grants.nih.gov home page



Learn more: [NOT-OD-24-171](#)



# COMPLIANCE UPDATES

# Continued Extension of Certain Flexibilities for BESH studies

- On May 6, 2024, [NOT-OD-24-118](#) extended interim registration and results reporting flexibilities for basic experimental studies with humans (BESH).
- NIH is extending the period of delayed enforcement for registration and results reporting, for BESH responsive to designated BESH NOFOs with application due dates through September 24, 2025.
  - Only applicable to BESH submitted to funding opportunities designated as BESH
- BESH responsive to designated BESH NOFOs with application due dates on or after September 25, 2025, are expected to register in ClinicalTrials.gov and report summary results information to either ClinicalTrials.gov or Regulations.gov
- For BESH projects, NIH continues to expect registration and results reporting, but with the additional flexibility to register and report results on alternative publicly available platforms.

# Review of Single Audits

- For FY25, NIH is streamlining our longstanding process for reviewing organizations' Single Audits as part of the pre-award risk assessment.
- Rather than delay awards solely pending corrective action on Single Audit issues, NIH will automatically add a Specific Award Condition (SAC), with associated funding restrictions as applicable per NIH Grants Policy Statement (GPS), [Section 8.5.1, Specific Award Conditions: Modification of the Terms of Award](#), to the award to incorporate as a term and conditions of award the resolution of audit concerns reported in the organization's most recent Single Audit report, including:
  - Corrective Action Plan pending implementation by the organization to address findings of significant deficiencies, material weaknesses or internal controls deficiencies that may impact NIH awards.
  - Delinquent submission of a required audit report
- The SAC, and any associated financial restrictions, will remain on the award until the recipient provides evidence of satisfactory resolution of the audit findings.
- This new process will apply to all competing and non-competing NIH awards in FY25
- Please note that NIH may unilaterally take administrative action to safeguard NIH funds in accordance with the NIH GPS, [Section 8.5.2 - Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support](#)
- The single audit determination threshold was increased from \$750,000 to \$1,000,000 in federal award expenditures during the non-Federal entity's fiscal year.

# Unilateral Closeout Reporting

- On January 23, 2024, NIH issued [NOT-OD-24-055](#), NIH Enforcement of Unilateral Closeout Reporting in the System for Award Management Responsibility/Qualification.
- NIH will initiate unilateral closeout for **all** awards that fail to meet closeout requirements within one year after the end of the project period end date.
- NIH is required to submit Responsibility/Qualification determinations for any entity that does not submit all required closeout reports within one year of the period of performance end date ([2 C.F.R. § 200.344\(i\)](#)).
- Recipients may comment on the report displayed on SAM.gov via the Contractor Performance Assessment Reporting System (CPARS) to provide a public statement in response to NIH's report ([2 C.F.R. § 200.341\(b\)\(4\)](#)).
- The Responsibility/Qualification record will remain in SAM.gov for 5 years.



# **POLICY REMINDERS**

# NIH OER Virtual Events

- [Upcoming NIH Grants Events](#)
  - Subscribe to NIH Grants Events to keep informed at [OER Listservs and RSS Feeds](#).



Virtual

Wednesday, November 13, 2024 / 1:00PM - 4:00PM

## NIH Grants Process Primer: Application to Award - Part One

Understanding NIH's overall structure and the foundation of the agency's grants process is vital to successfully applying for NIH funding. To help you on this journey, the NIH invites you to participate in a two-part webinar designed to help inform...



Virtual

Thursday, November 14, 2024 / 1:00PM - 4:00PM

## NIH Grants Process Primer: Application to Award - Part Two

Understanding NIH's overall structure and the foundation of the agency's grants process is vital to successfully applying for NIH funding. To help you on this journey, the NIH invites you to participate in a two-part webinar designed to help inform...

# Reminder: eRA Commons ID Requirement

- An eRA Commons ID must be entered in the “Credential, e.g. agency login” field for all Senior/Key Personnel, and Other Significant Contributors (OSCs) listed on the R&R Senior/Key Person Profile Form.
- Previously, applicants will encounter an eRA system warning if the “Credential, e.g. agency login” field is blank or does not contain a valid eRA Commons ID.
- The validation has been updated from a warning to an error in mid-January in advance of due dates on or after January 25, 2024.
- Applicants are encouraged to check that their Commons account is active well before the due dates.
  - Reminder: NIH encourages Senior/Key Personnel to link their ORCID ID to their eRA Commons Personal Profile. For information on linking an ORCID ID to the eRA Commons Personal Profile see the [ORCID ID topic in the eRA Commons online help](#).

# Reminder: NIH Policy for Subaward/Consortium Written Agreements

- On September 15, 2023, NIH issued [NOT-OD-23-182](#), NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements.
- Effective January 1, 2024:
  - For foreign subrecipients, the written agreement must include a provision requiring the foreign subrecipient to provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.
- The FY2024 NIH Grants Policy Statement (NIHGPS) has incorporated these requirements in [NIHGPS Section 15.2.1](#).

# Reminder: Timely Progress Reports

- Annual *Research Performance Progress Report (RPPR)* Format
- Due Dates
  - Non-SNAP: Approximately 60 days before the start of next budget period
  - SNAP: Approximately 45 days before start of the next budget period
  - Multi-Year Funded: on or before award anniversary date

# Reminder: Federal Financial Report and Financial Closeout Service Center Updated Guidance for Returning Grant Funds

- NIH recipients who need to return funds in the PMS for NIH grant awards that have ended, but funds have not yet expired (e.g., funds obligated from an annual appropriation within 5 years of current fiscal year).
- When recipients need to return funds on an NIH grant:
  - If the refund is \$20,000 or greater, NIH recipients must
    - (1) submit a revised FFR, and
      - (2) 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 at <https://pms.psc.gov/grant-recipients/returning-funds-interest.html>.
- A chart outlining the updated refund process for various scenarios may be found at <https://grants.nih.gov/policy/compliance.htm> under Compliance Resources.

# Reminder: Invention Reporting

- **Reporting of inventions through iEdison is mandatory.**
  - Reminder: Management of the iEdison system has transitioned from the NIH eRA to the NIST, U.S. Dept. of Commerce (DOC).
- Annually, in the progress report (RPPR Section C.4), identify any inventions, patent applications and/or licenses resulting from the award.
- A Final Invention Statement and Certification (HHS 568) must be submitted within 120 calendar days of the project period end date of all awards that support research. The Statement shall include all inventions which were conceived or first actually reduced to practice during the course of work under the grant or award, from the original effective date of support through the date of completion or termination.
- Failure to report all inventions may result in your organization's loss of rights in the invention or other actions as appropriate.

Learn more: [NIH GPS 8.2.4](#) and [NIH GPS 8.6.3](#)

About iEdison: [NIST FAQ](#); [NIST Training Opportunities](#); [NOT-OD-22-100](#); [NOT-OD-22-158](#)

# Reminder: Required Language for Government Support Clauses on Patented Intellectual Property

- Per the Bayh-Dole Act, The Government Support Clause is a statement acknowledging federal support of a subject invention that **MUST** be included in the specification of a U.S. patent application or a U.S. issued patent (35 USC 202(c)(6))
  - See: [NIH Grants Policy Statement, Section 8.2.4 “Inventions and Patents”](#)
- As a reminder, the Government Support Clauses must specifically identify “the National Institutes of Health” as the funding agency
- Sample: *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.*

# Reminder: Grant Closeout Requirements

- *Closeout of an award is the process by which NIH determines that all applicable administrative actions and all required work of an award have been completed by the recipient and NIH.*
- NIH continues to require and enforce longstanding closeout requirements **due within 120 days** of the project period end date:
  - **Final Research Performance Progress Report (RPPR)**
  - **Final Federal Financial Report (FFR) (SF 425)**
  - **Final Invention Statement and Certification (HHS 568)**
- NIH will initiate unilateral closeout (including potential enforcement actions) if recipients fail to submit final reports on time.

# Reminder Notifications for Final Federal Financial Reports (FFRs) in Rejected Status

- Beginning November 2023, NIH sends reminder email notifications to recipients with Final FFRs in rejected status.
- Reminder: Revised Final FFRs must be resubmitted in a timely manner in accordance with NIH [GPS 8.6](#) and [8.6.1](#) to ensure all administrative and financial closeout requirements are conducted within the required time frames. (See [2 CFR Part 200.344](#) and NIH GPS [8.6](#)).
- Please direct all inquiries to OPERA FFR Reconciliation and Financial Closeout Support Center ([ODOPERARejectedFFR@od.nih.gov](mailto:ODOPERARejectedFFR@od.nih.gov)).

# Resources

TOPIC	LINKS
<b>Application Submission</b>	<ul style="list-style-type: none"><li>• Grant Application Basics: <a href="https://grants.nih.gov/grants/grant_basics.htm">https://grants.nih.gov/grants/grant_basics.htm</a></li><li>• Find Grant Funding- NIH Guide for Grants and Contracts: <a href="https://grants.nih.gov/funding/searchguide/index.html#/">https://grants.nih.gov/funding/searchguide/index.html#/</a></li><li>• How to Apply - Application Guide: <a href="http://grants.nih.gov/grants/how-to-apply-application-guide.htm">http://grants.nih.gov/grants/how-to-apply-application-guide.htm</a></li><li>• Annotated SF424 (R&amp;R) Application Forms: <a href="https://grants.nih.gov/grants/how-to-apply-application-guide/resources/annotated-form-sets.htm">https://grants.nih.gov/grants/how-to-apply-application-guide/resources/annotated-form-sets.htm</a></li><li>• eRA Training: Video Tutorials: <a href="https://www.era.nih.gov/era-training/era-videos.htm">https://www.era.nih.gov/era-training/era-videos.htm</a></li><li>• How we check for application completeness: <a href="https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/how-we-check-for-completeness.htm">https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/how-we-check-for-completeness.htm</a></li></ul>
<b>eRA</b>	<ul style="list-style-type: none"><li>• eRA Commons: <a href="https://www.era.nih.gov/">https://www.era.nih.gov/</a></li><li>• eRA Commons Help &amp; Tutorials: <a href="https://www.era.nih.gov/help-tutorials/era-commons/user-guide.htm">https://www.era.nih.gov/help-tutorials/era-commons/user-guide.htm</a></li><li>• Self Help Resources and eRA Service Desk: <a href="https://www.era.nih.gov/need-help">https://www.era.nih.gov/need-help</a></li></ul>
<b>General</b>	<ul style="list-style-type: none"><li>• NIH Grants &amp; Funding web page: <a href="https://grants.nih.gov/">https://grants.nih.gov/</a></li><li>• NIH Grants Policy Statement: <a href="https://grants.nih.gov/policy/nihgps/index.htm">https://grants.nih.gov/policy/nihgps/index.htm</a></li><li>• NIH Extramural Nexus – newsletter for the extramural community: <a href="https://nexus.od.nih.gov/all/">https://nexus.od.nih.gov/all/</a></li><li>• NIH Frequently Asked Questions (FAQs): <a href="https://grants.nih.gov/faqs#/">https://grants.nih.gov/faqs#/</a></li><li>• Research Portfolio Online Reporting Tools (RePORT): <a href="https://report.nih.gov/">https://report.nih.gov/</a></li><li>• RePORT Expenditures &amp; Results (RePORTER): <a href="https://reporter.nih.gov/">https://reporter.nih.gov/</a></li></ul>
<b>RPPR</b>	<ul style="list-style-type: none"><li>• RPPR Webpage, including links to the NIH RPPR Instruction Guide, RPPR Guide Notices, FAQs, Training, and Contacts: <a href="https://grants.nih.gov/grants/rppr/index.htm">https://grants.nih.gov/grants/rppr/index.htm</a></li></ul>

# NIH Listservs

- NIH Guide for Grants and Contracts (The official publication for NIH Grant Policies, Guidelines & Funding Opportunities):  
<https://grants.nih.gov/grants/guide/listserv.htm>
- Office for Human Research Protections (OHRP):  
<https://www.hhs.gov/ohrp/index.html>
- Office of Laboratory Animal Welfare (OLAW): <https://olaw.nih.gov/>
- eRA News: <https://www.era.nih.gov/about-era/get-connected.htm>
- Virtual NIH Grants Events: <https://grants.nih.gov/news-events>

# Questions

- Division of Grants Policy: [GrantsPolicy@mail.nih.gov](mailto:GrantsPolicy@mail.nih.gov)
- Division of Grants Compliance & Oversight: [GrantsCompliance@mail.nih.gov](mailto:GrantsCompliance@mail.nih.gov)
- Systems Policy Branch: [OPERAsystemspolicy@mail.nih.gov](mailto:OPERAsystemspolicy@mail.nih.gov)
- Division of Extramural Inventions and Technology Resources: [Inventions@nih.gov](mailto:Inventions@nih.gov)
- OPERA FFR Center: [OPERAFFRInquiries@od.nih.gov](mailto:OPERAFFRInquiries@od.nih.gov)

