On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (Public Law 117-328), into law.

NIH is currently issuing several important fiscal policy Guide Notices:

- **NOT-OD-23-056**: FY 2023 Salary Cap ($212,100), released Jan. 13, 2023
- **NOT-OD-23-072**: Notice of Legislative Mandates in Effect for FY 2023, released Feb. 3, 2023
- **NOT-OD-23-076**: Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2023, released Feb. 3, 2023
POLICY UPDATES
The NIH Grants Policy Statement (GPS) was published on December 23, 2022. The latest version of the NIH GPS is available on the NIH.gov website, along with a significant changes table.

Previous versions of the NIH GPS remain applicable as standard terms and conditions of award for all NIH grants and cooperative agreements with budget periods that began prior to October 1, 2022.

NIH will continue to publish interim grants policy changes and clarifications through the issuance of NIH Guide Notices, available here.

New this year, NIH posted a Federal Register Notice announcing the updates. Future updates to the NIH GPS will be posted in the Federal Register prior to implementing updates.
Reminder of Changes to the Biographical Sketch and Other Support Format Page

• NIH requires applicants and recipients to use the updated Biosketch and Other Support format for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs).
  • Electronic signatures and supporting documentation are required.
  • Failure to follow the appropriate formats may cause NIH to withdraw applications from or delay consideration of funding.
• Applicants and recipients remain responsible for disclosing all research endeavors regardless of the version of the forms used.

Learn more: NOT-OD-21-110
Learn More: Biosketch FAQs & Other Support FAQs
Send inquiries to: nihosbiosketch@nih.gov
Updated Requirements for NIH Notification of Removal or Disciplinary Action Involving PDs/PIs or other Senior/Key Personnel

- NIH GPS Section 8.1.2.6 states NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions.

- Notification must be provided by the AOR within 30 days of the removal or disciplinary action and submitted through a dedicated web form.

- This disclosure requirement does not replace the existing requirements to obtain prior approval for any significant change in the status of the PD/PI or other Senior/Key Personnel specifically named in the notice of award.

- For more information about how NIH addresses institutional notifications of harassment, bullying, retaliation, or hostile working conditions, see Institutional Reporting.

- For more information on the NIH commitment to supporting a safe and respectful workplace at institutions that receive NIH funding, please visit our website.

- Resources on reporting allegations of harassment, including sexual harassment, discrimination, and other forms of inappropriate conduct that can result in a hostile work environment at your institution are available here.

- Please contact NIH for any incidents that occurred prior to the release of this update.
New Data Management and Sharing (DMS) Policy (NIH GPS Section 8.2.3.1)

• Effective January 25, 2023, the DMS Policy requires:
  • researchers to prospectively plan for how scientific data will be preserved and shared through submission of a DMS Plan (replaces 2003 Data Sharing Policy).
  • submission of a DMS Plan outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.
  • compliance with the recipient’s plan as approved by the NIH Institute and Center (IC).

• Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data.

Learn more: Data Management & Sharing Policy Overview, DMS FAQs, and an optional DMS Plan format page.
NIH Data Management and Sharing
Online Resources

Website: [NIH Scientific Data Sharing](#)

FAQs: [DMS Policy FAQs](#)

Email Box: [Sharing@nih.gov](#)

Webinar Series: [NIH DMS Policy Implementation](#)
NIH Efforts to Reduce Administrative Burden: The DMS Demonstration Pilot Project – Collab with Federal Demonstration Partnership (FDP)

- Goals of the DMS Demonstration Pilot:
  - Generate greater consistency in DMS Plan requirements across NIH ICs and programs.
  - Mitigate the administrative burden for researchers associated with DMS Plan development and implementation.

- 2 Phases
  - DMS Plans Templates
  - Costing Policies
Phase 1: DMS Plan Templates

Phase 1: DMS Plan Templates

• **Federal Demonstration Partnership (FDP)** pilot project to test structured templates and tools for DMS Plan submission

• 2 Templates have been selected for testing
  • Discussions underway with DMPTool

• Purpose is to generate greater consistency in DMS Plan requirements across ICOs and programs, while mitigating administrative burden for researchers.

• FDP has 15-20 participants signed on so far.

• Pilot participants will begin using the test templates starting March 1.
FDP Pilot Phase 2: Costing Policies

• Identify ways to
  • Analyze ways to maximize common cost principles
  • Identify types of costs required (e.g., key personnel, impact on budget caps/thresholds)
  • Determine how to identify additional/unforeseen costs that may be needed to meet the spirit of the DMS Policy
  • Determine feasibility of placing costs in a single category vs. throughout the budget line items
  • ...and MORE (i.e., subawards, and costs after the period of performance)!
NIH Natural Disaster Policies

• October 3, 2022 – **NOT-OD-22-221**: Reminder: NIH Natural Disaster Policy – Hurricanes Fiona and Ian

• On January 12, 2023, the OMB Single Audit Extension for Recipients in Major Disaster Areas (Alaska, Florida, South Carolina, North Carolina, Puerto Rico) – **(NOT-OD-23-022)**
  • Implements the OMB Memorandum on the Administrative Relief for Grantees Impacted by Hurricanes Fiona & Ian and the Alaska Flood & Landslide issued on December 23, 2022.

• January 25, 2023 – **NOT-OD-23-065**: OMB Administrative Relief for Recipients Impacted by Hurricanes Fiona and Ian and the Alaska Flood and Landslide
  • These flexibilities are time limited to 90 days after the OMB memo was issued and will therefore end on March 23, 2023.

• January 31, 2023 - **NOT-OD-23-069**: California Flooding, Landslides, and Mudslides and Alabama Storms, Straight-line Winds, and Tornadoes

Learn more: NIH Extramural Response to Natural Disasters and Other Emergencies
COVID-19 Public Health Emergency Expiration (NOT-OD-23-095)

- HHS declared public health emergency for COVID-19 will be terminated on May 11, 2023.
- Effective May 12, 2023, NIH will no longer issue emergency NOFOs related to COVID-19.
- All existing emergency flexibilities remain for the current competitive segments (ongoing awards).
Updates to the Non-Discrimination Legal Requirements for NIH Recipients

- On December 23, 2022, NIH issued **NOT-OD-23-047, Updates to the Non-Discrimination Legal Requirements for NIH Recipients**, to be aligned with 2 CFR 200.
- GPS will be updated to include the standard term for FY24.
- Provides the responsibilities for grant and cooperative agreement recipients for administering their awards in compliance with federal civil rights laws that prohibit discrimination.
- The requirements provided in NOT-OD-23-047 will be incorporated into all NIH Notices of Funding Opportunities (NOFOs) and Notices of Award (NoA) as a new term and condition:

Learn more: **NOT-OD-23-047**
Updates to the Non-Discrimination Legal Requirements for NIH Recipients (cont.)

• Section 3 of all new NIH NoAs will include:
  • Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws require taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

Learn more: NOT-OD-23-047
Small Business Innovation Research (SBIR) and Small Technology Transfer Research (STTR) Extension Act, 2022

- **Public Law No: 117-183**. SBIR and STTR Extension Act, 2022 was passed on September 30, 2022.
- Key provisions for Small Business Concerns (SBCs):
  - Defines applicant submission requirements, criteria for restricting awards and requiring repayment.
  - Federal agencies are now required to assess an SBC applicant’s foreign affiliation (currently assessed via the Other Support at the researcher level).
- NIH has issued the following policy guidance:
  - NOT-OD-23-092 and Federal Register Notice: Notice of Change to Minimum Performance Standards for SBIR and STTR Applicants
- Additional guidance will be issued over the next several months.
iEdison Transitioned from NIH eRA to National Institute of Standards and Technology (NIST)

- Management of the iEdison system has transitioned from the NIH eRA to the NIST, U.S. Dept. of Commerce (DOC). The new iEdison by NIST was launched August 9, 2022.

- The transition included several new capabilities and enhancements, including:
  - Ability to initiate discussions with the agency staff within an invention record using two-way communications.
  - Integration with the U.S. Patent and Trademark Office (USPTO) database to ensure accuracy and reduce recipient reporting burden.
  - Optional real-time email notifications to both recipient and agency users for notifications regarding certain required reporting and reviewing actions.
  - Enhanced security through Login.gov.

- All existing data and any attachments associated with individual invention and patent reports has been transferred to the new iEdison system. In addition, existing and active iEdison accounts have been associated with the new system.

- Reminder: There will be **no** changes to the longstanding NIH requirements for invention and patent reporting under the Bayh-Dole Act. The only change is the new iEdison system interface and associated Login.gov requirements for access.

Learn more: 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”

• 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.
Good Cause Extension Request Process and Criteria

- NOT-OD-23-080 was released February 8, 2023, to inform the research community that NIH has issued the Clinical Trials Results Information Submission: Good Cause Extension Request Process and Criteria document.
  - Outlines the process and criteria for requesting a good cause extension of the submission deadline for clinical trial results information under 42 CFR 11.44(e) of the Final Rule for Clinical Trials Registration and Results Information, section 402(j)(3)(E)(vi) of the Public Health Service Act, and the complimentary NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149).
  - Extension requests must be submitted electronically via the ClinicalTrials.gov Protocol Registration and Results System (PRS) prior to the date that results information would otherwise be due (i.e., the primary completion date + 12 months).
    - Must include a description of the reason(s) that the responsible party believes constitute good cause to justify an extension and an estimated date on which the results information will be submitted.

Learn more: NIST FAQ; NIST Training Opportunities; NOT-OD-22-100; NOT-OD-22-158.
Effective for due dates on or after January 25, 2023, applicants must use FORMS-H application packages.

Key forms change to add new “Other Plan(s)” single attachment to:
- PHS 398 Research Plan
- PHS 398 Career Development Award Supplemental Form
- PHS 398 Research Training Program Plan
- PHS Fellowship Supplemental Form


See High-level summary of FORMS-H application form changes for more information.
- Additional RPPR and other eRA system changes for DMS policy implementation (e.g., Grant folder and JIT module) are planned and will be communicated as details are finalized.

Learn more: NOT-OD-22-195, NOT-OD-23-012
New Other Plan(s) Attachment

**PHS 398 Research Plan**

**Introduction**
1. Introduction to Application (for Resubmissions and Revision applications)

**Research Plan Section**
2. Specific Aims
3. Research Strategy
4. Progress Report Publication List

**Research Plan Section**
5. Vertebrate Animals
6. Select Agent Research
7. Multiple PD/PI Leadership Plan
8. Consortium/Contractual Arrangements
9. Letters of Support
10. Resource Sharing Plan(s)
11. Other Plan(s)
12. Authentication of Key Biological and/or Chemical Resources

**Appendix**
13. Appendix
New NIH Federal Financial Report and Financial Closeout Service Center

• Effective August 2022, NIH established a central Federal Financial Report (FFR) and Financial Closeout Service Center under OER OPERA.

• FFR and Financial Closeout Service Center will address and prevent financial overdraws by recipients and encourage recipients to complete drawdowns and reconciliation before submitting FFRs to NIH. Activities include:
  • Receiving, reviewing and reconciling Annual and Final FFRs
  • Closing transactions (059) submitted to PMS as part of Final FFR reconciliation and processing
  • Reviewing Fellowship awards (FFR not required) after termination notice received. NIHs will submit closing transactions to PMS.
  • Ensuring all NIH awards are financially closed within 270 days of the performance period end date.

• FFR Process Improvements:
  • Reconcile FFR with PMS data
  • Coordinate reviews with ICs to minimize errors
NIH FFR Resources

• A central email inbox is now available for inquiries related to the submission and processing of FFRs and financial closeout.
  • OPERAFFRInquiries@od.nih.gov
  • Alan Whatley – Team Lead

• Other currently available resources related to FFR reporting requirements and grant closeout:
  • NIH Grants Policy Statement 8.4.1.5 Financial Reports
  • NIH Grants Policy Statement 8.6 Closeout; 8.6.1 Final Federal Financial Report
  • NIH Grants and Funding Closeout webpage
  • Grant Closeout Frequently Asked Questions (FAQs)
FFR Submission Help Desks

• Direct all eRA systems-related inquiries to:
  • eRA Service Desk
    Submit a web ticket: https://grants.nih.gov/support/index.html
    Toll-free: 1-866-504-9552
    Phone: 301-402-7469
  • The FFR due date and the data on Lines 1 thru 9 are populated by NIH eRA. If any of this data on the FFR is incorrect, please contact the eRA Service Desk directly.

• Direct all PMS systems-related inquiries to:
  • ONE-DHHS Help Desk
    Email: PMSSupport@psc.hhs.gov
    Toll-free: 1-877-614-5533
  • For all inquiries related to Line item 10a Cash Receipts, 10b Cash Disbursements and line item 10d Total Federal Funds Authorized, please contact PMS Helpdesk at 1.877.614.5533 or you can submit a ticket to PMS using the self-service web portal. Please ensure that you provide the Payee Account Number (PAN), PMS Document Number and Sub-account number and provide the details of the issue.

Reminder: Process for Requesting Drawdowns Outside of the Liquidation Period

- Recipients must submit timely, accurate grant expenditure reports, and reconcile drawdowns in PMS.
- Recipients may request payments from the Payment Management System (PMS) up to 120 days past the period of performance end date of the PMS subaccount.
- In rare circumstances where recipients are unable to complete drawdowns in a timely manner, the recipient must submit a detailed prior approval request to the IC GMS **BEFORE** submitting the payment request in PMS. See NOT-OD-23-086.
  - **After** receiving approval from the IC, the recipient may submit the payment request in PMS.
- Requests are reviewed and considered on a case-by-case basis. Recipients remain responsible for ensuring that information submitted to NIH in Federal Financial Reports (FFR) is accurate, complete, and consistent with the recipient's accounting system (see NIHGPS Section 8.4.1.5.2).
- These procedures apply to PMS documents in Open or Pending Close status. They do not apply to PMS documents in Closed status.
  - NIH will only consider late draw requests on closed PMS documents if they are related to a public health emergency, natural disaster, or similar event.

Ability to Bypass 2-Business Day Viewing Window for Administrative Supplements

- Effective October 27, 2022, NIH implemented a new functionality that offers option to bypass the full standard 2-business day application viewing window through a new ‘Verify’ action in eRA Commons Status and will expedite processing of eligible electronic administrative supplement requests.

- The optional Verify action to bypass the application viewing window for administrative supplement applications will be available to users with SO role in eRA Commons Status.

- The Verify action moves an application forward for agency processing without waiting for the viewing window to expire.

- Note that once this bypass option is used, the SO forfeits the organization’s ability to reject or make further changes to the application. Organizations must carefully review their applications prior to using the Verify action to mitigate the need for resubmissions.

- After the SO verifies they want to bypass the viewing window, NIH will automatically forward the request to the appropriate grants management and program staff for consideration.

Learn more: NOT-OD-23-011
Updates to xTrain Coming Soon!

- A redesign of the xTrain module in eRA Commons is anticipated to be released on March 30, 2023.
- The xTrain module will be redesigned to streamline workflows and present a more user-friendly interface, following extensive collaboration with both internal and external user groups.
- The module will also have the new visual appearance of other eRA modules along with added security and stability.
- **Highlights for xTrain External Users**
  - Enhanced Trainee Roster with a display of awarded slots and counts of the in-progress forms
  - Enhanced screen for business officials with a list of all forms routed to them
  - An updated screen for trainees

Learn more: NOT-OD-23-094
NIH Response to Registration Issues in SAM.gov

- GSA implemented a new process in SAM.gov to validate entities as a first step to requesting a UEI and for completing SAM.gov entity registration.

- If challenges are experienced that impact all applicants and recipients across the Federal government, NIH is making an exception to the Late Application Policy until the issue is resolved.

- If an applicant entity does not have a current SAM registration or renewal at the time of the application submission due date, NIH will accept late applications within the two-week late window as long as the entity has submitted all SAM registration or renewal documentation at least two weeks prior to the application due date and all other aspects of the application are compliant and consistent with the funding opportunity announcement requirements.
  - The entity's application Cover Letter must include documentation, such as a confirmation email or screenshot, demonstrating that the SAM registration or renewal request was submitted prior to the application due date.

- An automatic, 30-day extension was implemented for any existing SAM.gov entity registrations needing to be renewed with an expiration date ranging between Friday, April 29, 2022, and April 28, 2023. No action is required on the part of entity registrants.

- Organizations that do not have an active SAM registration will not receive an NIH award.

Learn More: See FSD FAQ
Timely Progress Reports

• Annual Progress Reports = 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 anniversary date

Searchable list to determine which progress reports are due:
Timely Financial Reporting

• Federal Financial Report (FFR) (SF-425) Expenditure Data – Must be submitted in PMS!

• Reminder: FFRs must be accurate, complete, and consistent with the recipient's accounting system (see NIHGPS Section 8.4.1.5.2).

• Annual (Non-SNAP Awards)
  • FFR submitted no later than 90 days after the end of the calendar quarter in which the budget period ended.

• Final (SNAP and Non-SNAP Awards)
  • FFR submitted within 120 days following the end of the project period.
  • Reminder: Expenditure data and drawdowns in PMS must be reconciled prior to FFR submission.
Invention Reporting

• NIH recipients must file the HHS 568 at the conclusion of an NIH award.
• All subject inventions reported on the HHS 568 must be reported in iEdison.
• Failure to report all inventions may result in your organization’s loss of rights in the invention or other actions as appropriate.
Administrative Closeout Requirements

- NIH continues to require and enforce longstanding closeout requirements.
- Recipients must submit timely, accurate closeout reports.
- Reports are LATE after 120 calendar day.
- Recipients must reconcile cash transaction reports submitted to the HHS Payment Management System (PMS) with expenditure reports submitted to NIH.
- When recipients fail to submit timely reports, NIH will initiate unilateral closeout.

See NOT-OD-18-107 and NOT-OD-21-149
Questions?

**Division of Grants Policy:**
- E-Mail: GrantsPolicy@mail.nih.gov

**Division of Grants Compliance & Oversight:**
- E-Mail: GrantsCompliance@mail.nih.gov

**Division of Grants Systems Integration- Systems Policy Branch:**
- E-Mail: OPERAsystemspolicy@mail.nih.gov

**Division of Extramural Inventions and Technology Resources:**
- E-Mail: Inventions@nih.gov
Helpful NIH Resources
OLAW Educational Outreach

OLAW free quarterly webinars series:
http://grants.nih.gov/grants/olaw/e-seminars.htm
  • Recordings of past webinars:
    http://grants.nih.gov/grants/olaw/educational_resources.htm

Disaster planning resources:
http://grants.nih.gov/grants/olaw/disaster_planning.htm
  • Disaster planning webinar & FAQs
Helpful NIH Web Pages

• **Application Resources:**
  - Annotated SF424 (R&R) Application Forms (General, Small Business, Multi-project):
  - eRA Training: Video Tutorials: [https://www.era.nih.gov/era-training/era-videos.htm](https://www.era.nih.gov/era-training/era-videos.htm)
  - Grant Application Basics: [https://grants.nih.gov/grants/grant_basics.htm](https://grants.nih.gov/grants/grant_basics.htm)
  - Self Help Resources page: [https://www.era.nih.gov/need-help](https://www.era.nih.gov/need-help)

• **eRA Resources:**
  - eRA Commons Web pages: [https://www.era.nih.gov/](https://www.era.nih.gov/)
  - eRA Commons User Guides: [https://www.era.nih.gov/help-tutorials/era-commons/user-guide.htm](https://www.era.nih.gov/help-tutorials/era-commons/user-guide.htm)
  - RePORT Expenditures & Results (RePORTER): [https://reporter.nih.gov/](https://reporter.nih.gov/)
Helpful NIH Web Pages

• General NIH Resources:
  • NIH Extramural Nexus – newsletter for the extramural community: https://nexus.od.nih.gov/all/
  • NIH Frequently Asked Questions: https://grants.nih.gov/faqs#/  
  • Office of Extramural Research (OER) Web Page: https://grants.nih.gov/faqs

• RPPR Resources:
NIH OER Listservs

• NIH Guide for Grants and Contracts: 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/

• eSubmission: Separate listservs available for scientists and administrators
  https://www.era.nih.gov/about-era/get-connected.htm