Current Issues at NIH

NIH OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION
Budget News

• On September 30, 2021, President Biden signed the Extending Government Funding and Delivering Emergency Assistance Act (Public Law 117-43).

• NIH remains funded under a Continuing Resolution (CR) through December 3rd and NIH continues operations at the FY 2021 enacted level.

• Consistent previous NIH practices, NIH Institutes and/or Centers may, at their discretion, issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award.
Legislative Mandates

- All legislative mandates that were in effect in FY 2021 remain in effect under this CR:
  - NOT-OD-21-057, FY 2021 Salary Cap
    - Effective Jan 3, 2021: $199,300
  - NOT-OD-21-056, FY 2021 Legislative Mandates
  - NOT-OD-21-049, FY 2021 NRSA Stipend Levels
    - Effective for all FY21 NRSA awards
  - NOT-OD-21-058, Notice of Fiscal Policies in Effect for FY 2021
Updates to the Non-Discrimination Legal Requirements for NIH Recipients

• NIH has updated and implemented HHS language on the Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance, to comply with 2 CFR Part 200.300 and to ensure that NIH is promoting equity in its grant awards.

• NIH is updating its Funding Opportunity Announcement (FOAs) and terms and conditions of award.
  • No policies have changed – just updated language.

• This language will be incorporated into the NIH Grants Policy Statement (GPS) upon its next publication.

See details: NOT-OD-21-181
Reminder: Grants Policy Related Inquiries

- Inquiries are best directed to the:
  - recipient or applicant organization’s internal grants administration contacts (e.g., Office of Sponsored Programs),
  - NIH contacts named in the Funding Opportunity Announcement (FOA),
  - NIH grants management contact at the awarding Institute or Center (IC).

- Inquiries regarding general grants-policy matters are best directed first to the recipient’s Office of Sponsored Programs; specifically, the AOR.

See details: NOT-OD-21-151
NRSA Childcare Costs for Fellowships

• NIH began providing childcare support to recipients of NRSA fellowships on April 8, 2021
• Applies to full-time NIH-NRSA-supported fellowship positions.
  • Each fellow is eligible to receive $2,500 per budget period
  • For households where both parents are NRSA fellows, each parent is eligible to receive $2,500.
• Costs are permitted for dependent children living in the eligible fellow’s home from birth under the age of 13, or children who are disabled and under age 18.
  • Childcare costs do not apply to elder or non-child dependent care costs.

See details and application instructions: NOT-OD-21-074
NRSA Childcare Costs for Training Grants

• NIH will begin providing childcare support to recipients of NRSA training grants awarded (continuation, new, or renewal) in FY 2022
• Applies to full-time NIH-NRSA-supported trainees.
  • Each trainee is eligible to receive $2,500 per budget period
  • For households where both parents are NRSA trainees, each parent is eligible to receive $2,500.
• Costs are permitted for dependent children living in the eligible fellow’s home from birth under the age of 13, or children who are disabled and under age 18.
  • Childcare costs do not apply to elder or non-child dependent care costs.

See details: NOT-OD-21-177
Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel

- Targeting due dates on or after January 25, 2022
- An eRA Commons ID must be entered in the “Credential, e.g. agency login” field for all Senior/Key Personnel listed on the R&R Senior/Key Person Profile (Expanded) Form
- Senior/Key Personnel (NIH defined in NIH GPS 1.2)
  - The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.
- Applicants will encounter an eRA system validation if the “Credential, e.g. agency login” field is blank or does not contain a valid eRA Commons ID. Currently, this is a warning.

See details: NOT-OD-21-109
What is commitment transparency?

Transparency and reporting of all research activities, domestic and foreign

- Openness and transparency enables productive collaboration and helps ensure appropriate disclosure of potential conflicts of interest and commitment
- Failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, threatens to distort decisions about the appropriate use of NIH funds
Inter-Agency Areas of Focus

• Some foreign governments are working vigorously to illicitly acquire, and in some cases outright steal, U.S. research and technology.

• Key Issues:
  • **Conflicts of Interest:** An individual, their spouse, or dependent children have a financial interest/relationship which could directly and significantly affect the design, conduct, reporting, or funding of research.
  • **Conflicts of Commitment:** An individual accepts or incurs conflicting obligations between or among multiple employers or entities.
  • **Talent Recruitment Programs**

For Details visit [OSTP Blog](https://ostp-blog.example.com)
Issues Seen at NIH

• Failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments and businesses, which threatens to distort decisions about the appropriate use of NIH funds and accurate evaluation of commitment of effort to US-supported research;

• Diversion of proprietary information included in grant applications or produced by NIH-supported biomedical research to other entities, including other countries; and

• Failure by some peer reviewers to keep information in grant applications confidential; including, in some instances, disclosure to foreign entities or other attempts to influence funding decisions.
Our Approach

• To support the need for full transparency, NIH has updated forms and instructions

• Collaborated with OSTP and with other research agencies to implement NSPM-33 and NDAA 233

• Institutions and researchers need to fully disclose, and institutions must have policies to ensure that they are aware of all research endeavors

• Form updates ensure that NIH is receiving all the information needed to support sound funding decisions
Implementation of Changes to the Biographical Sketch and Other Support Format Page

- NIH expects 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).

- NIH will require the use of the updated format pages on and after January 25, 2022.
  - Electronic signatures and supporting documentation will be required beginning January 25, 2022.
  - Failure to follow the appropriate formats on or after January 25, 2022, 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](#)
FAQs - Biosketch

• Has the page limit changed?
  • No. The page limit remain 5 pages

• Is an updated SciENcv template available?
  • Yes! An updated table was posted in March 2021

• The Biosketch instructions state that all positions and scientific appointments must be provided. Does this refer to active positions and appointments, or all positions a researcher has ever held?
  • The Biosketch must include all current positions and scientific appointments.

Send any questions to: nihosbiosketch@nih.gov
FAQs – Other Support

• Do outside consulting activities have to be reported in Other Support?
  • Consulting activities that involve research and fall outside of an individual’s appointment, separate from institution’s agreement, must be disclosed as Other Support.

• Does NIH require disclosure of recently completed support in Other Support submissions?
  • No, NIH does not require disclosure of recently completed support in Other Support submissions, only current and pending resources.

Send any questions to: nihosbiosketch@nih.gov
Update – Implementation of Requirement to Submit SF-425/FFR via Payment Management System

- Recipients have reported a significant increase in errors in submitting reports via a single-entry point since January 1.
- Errors mainly caused because the system does not allow recipients to submit reports that do not reconcile expenditure versus quarterly cash transaction data.
- Given the significant impact, agencies will provide leniency, as appropriate, where these challenges prevent recipients from submitting timely FFRs.
  - Notify the Grants Management Official of any delays and retain all documentation related to this flexibility in the event of an audit finding.
- Beginning in March 2021, on behalf of NIH, PMS began converting all NIH Final FFRs to Interim Annual FFRs in order to relax the validations on a weekly basis.
- Recipients should indicate in the Remarks section that this is a Final FFR. The FFRs will be reviewed by NIH OFM staff as Final FFRs.

Learn more: NOT-OD-21-060, NOT-OD-21-128, NOT-OD-21-138
Update – Process for Submission of FFRs for Closed PMS Subaccounts

- Recipients are unable to submit FFRs on closed PMS subaccounts (e.g. “C” status).
- When a recipient identifies a need to revise an FFR for a closed PMS subaccount, the recipient should contact the NIH Office of Financial Management (OFM). Recipients should email the OFM staff member assigned to their account. These assignments may be found at [https://ofm.od.nih.gov/Pages/Grants-FFRS0.aspx](https://ofm.od.nih.gov/Pages/Grants-FFRS0.aspx).
  - In that email, the recipient should provide the grant number, PMS document number, details on the FFR revisions needed, and a request to re-open the subaccount.
- Upon receipt, OFM will review the information, and submit a transaction in the NIH financial system to re-open the subaccount. OFM will notify the recipient when the action is complete, and the recipient must then submit the revised FFR in PMS for NIH review and approval.
  - Any questions or issues should be sent to the OFM-GAB Branch Chief – Don Geiger don.geiger@NIH.gov.

Mandatory Submission of SF-425/FFR via Payment Management System - Points of Contact

- Direct all systems policy inquiries to:
  - NIH Office of Policy for Extramural Research Administration (OPERA) Systems Policy Branch
    Email: OPERAsystemspolicy@nih.gov

- 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.

- PMS Training opportunities will be posted at: https://pms.psc.gov/training/gr-ffr-training.html

Update – Process for Requesting Drawdowns Outside of the Liquidation Period

- Recipients must submit timely, accurate grant expenditure reports, and reconcile cash transaction reports submitted to the PMS with expenditure reports submitted to NIH.

- 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 circumstances where recipients are unable to complete drawdowns in a timely manner, the recipient must submit a prior approval request to the IC GMS BEFORE submitting the payment request in PMS.
  - The request must provide the PMS subaccount (e.g. award document number), NIH grant number, the amount of funds being requested, and a justification for the late payment request. The recipient must also describe what action is being taken by the recipient to preclude similar situations in the future.
  - The IC will review the request and if it is determined that the justification is adequate, will notify the recipient of the approval. Once approved, the recipient may submit the payment request in PMS.

- Requests will be 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). When submitting the FFR through PMS, the Authorized Organization Representative (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.

Learn more: NOT-OD-15-135, NOT-OD-21-102, NOT-OD-21-149
FORMS-G

• Effective for application due dates on or after January 25, 2022.
• FORMS-G Application Guide publication and posting of FORMS-G application forms package to active FOAs will begin in late October 2021.
• Additional guidance and final implementation details will be provided in Fall 2021.
• Substantive form changes (i.e. new/deleted/modified fields):
  • SF424 R&R
  • R&R Senior/Key Person Profile (Expanded)
  • R&R Budget and Associated Subaward Budget Attachment(s) Form
  • Project/Performance Site Location(s)
  • PHS 398 Training Budget and Associated Subaward Budget Attachment(s) Form
  • PHS Additional Indirect Costs
  • PHS Fellowship Supplemental Form
  • PHS Human Subjects and Clinical Trials Information
  • SBIR/STTR Information

Learn more: NOT-OD-21-169
FORMS-G Key Changes

- Federal-wide transition from the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number to the new government-owned Unique Entity Identifier (UEI). See NOT-OD-21-170.
- Federal-wide adoption of the Grants.gov updated country and state lists
- Expansion requirement for eRA Commons IDs to all Senior/Key Personnel. See NOT-OD-21-109.
- New budget section for requesting childcare costs on the PHS Fellowship Supplemental Form. See NOT-OD-21-074.
- See High-level Summary of Form Changes in FORMS-G Application Packages for full list of changes.

Learn more: NOT-OD-21-169
Update- Adjusted Timeline for Requiring Two-Factor Authentication to Access eRA Modules Using Login.gov or InCommon Federated Accounts

- In December 2020, NIH announced that eRA users were required to transition to the use of a two-factor authentication service provider, specifically Login.gov, by September 15, 2021.

- To ensure a smooth transition and to respond to feedback from users, the timeline for implementing the requirement is being adjusted to phase in the requirement for most users and introduce another supported two-factor authentication service to support InCommon Federated institutions.

- Adjusted Timeline and Approach:
  - Starting September 15, 2021, eRA will begin a phased approach for requiring the use of two-factor authentication for user accounts. The new timing of enforcement depends on the type of user account.
  - This phased approach applies to all scientific account holders but excludes administrative accounts until early 2022. (See also ERA Commons User Roles)
  - Triggering event: All PIs and key personnel associated with an application or Research Performance Progress Report (RPPR) will be required to transition to the use of two-factor authentication 45 days after the submission of their competing grant application (Type 1 or 2) or their RPPR.

- Creating a Login.gov account and associating it with your eRA account is a simple, one-time, three-step process that should only take a few minutes. See step-by-step instructions, FAQs, video tutorials and more at the Access eRA Modules via Login.gov webpage.

- For further information about using an InCommon Federated account see the Access eRA Modules Via an InCommon Federated Account webpage.

Learn more: NOT-OD-21-040, NOT-OD-21-172
Upcoming Change in Federal-wide Unique Entity Identifier Requirements

- In March 2019, the General Services Administration (GSA) announced that the U.S. Government is moving to a new government-owned Unique Entity Identifier (UEI) which will replace the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number in all systems.
- By April 2022, the federal government will stop using DUNS to uniquely identify entities registered in SAM.
- Entities currently registered in SAM will automatically be issued a UEI.
- Note: Entities registering prior to April 2022 must still obtain a DUNS prior to SAM registration.

Learn more: [NOT-OD-19-098](#), [NOT-OD-21-170](#)
UEI Implementation

• Mid-FY 2021- All entities registered in SAM will automatically be issued a UEI.
  • Note: DUNS still required for new registrants prior to April 2022.

• Beginning October 2021-
  • eRA pulling UEI data for organizations in eRA Commons registered in SAM.gov. No action is required by the entity.
  • NIH recipients’ UEI will be populated on Page One of the Notice of Award
  • NIH recipients’ UEI will be transmitted in award data reported to HHS TAGGS and USASpending.gov.

• Organizations will begin to see their UEI in the eRA Commons IPF early in January 2022.

• For applications due on or after January 25, 2022, applicants must have a UEI at the time of application submission. Application forms and packages required for application submission will be updated to reflect UEI instead of DUNS (FORMS-G).

Learn more: NOT-OD-19-098, NOT-OD-21-170
NIH STANDING POLICY REMINDERS
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: https://public.era.nih.gov/chl/public/search/progressReportByIpf.era*
Timely Financial Reporting

• Federal Financial Report (FFR) (SF-425) Expenditure Data – Must be submitted in PMS!
• Submitting accurate data
• Recipients must reconcile cash transaction reports submitted to the HHS Payment Management System (PMS) with expenditure reports submitted to NIH

• 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
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.

See NOT-OD-16-066
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
Questions?

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

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

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
RPPR Resources

• RPPR Webpage: http://grants.nih.gov/grants/rprp/

• Includes links to:
  • RPPR Guide
  • RPPR Guide Notices
  • Frequently Asked Questions
  • Training
  • Contacts
Frequently Asked Questions

FAQs –searchable websites for:

• Application/progress report preparation, funding initiatives, policies, human subjects, sIRB, clinical trials, animals, disaster response, PMS Subaccounts, Core Facilities, FCOI, etc....

http://grants.nih.gov/grants/frequent_questions.htm
Summary of Helpful NIH Web Pages

• Office of Extramural Research (OER) Web Page:
  • http://grants.nih.gov/grants/oer.htm

• NIH Grants Policy Statement:
  • http://grants.nih.gov/grants/policy/nihgps/

• NIH Extramural Nexus – newsletter for the extramural community:
  • http://nexus.od.nih.gov/all/nexus-by-date/

• Grant Application Basics:
  • http://grants.nih.gov/grants/grant_basics.htm

• eRA Training: Video Tutorials
  http://era.nih.gov/era_training/era_videos.cfm
Summary of Helpful NIH Web Pages – App Instructions

- How to Apply - Application Guide:

- Annotated SF424 (R&R) Application Forms (General and Small Business and Multi-project):

How we check for application completeness:

Self Help Resources page:
Summary of Helpful NIH Web Pages - eRA

• eRA Commons Web pages:

• eRA Commons User Guides:
  • [http://era.nih.gov/commons/user_guide.cfm](http://era.nih.gov/commons/user_guide.cfm)

• Intellectual Property Policy:

• Research Portfolio Online Reporting Tools (RePORT):

• RePORT Expenditures & Results (RePORTER):
  • [http://projectreporter.nih.gov/reporter.cfm](http://projectreporter.nih.gov/reporter.cfm)
NIH OER Listservs

- NIH Guide for Grants and Contracts:
  Official publication for NIH Grant Policies, Guidelines & Funding Opportunities

- Office for Human Research Protections (OHRP):
  [http://www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)

- Office of Laboratory Animal Welfare (OLAW):

- eSubmission:
  Separate listservs available for scientists and administrators
Points of Contact

- General Application Questions:
  - E-Mail: GrantsInfo@nih.gov
  - Phone: 301-945-7573

- Grants.gov Customer Support:
  - E-Mail: support@grants.gov
  - Webpage: http://grants.gov/
  - Phone: 1-800-518-4726

- eRA Commons Helpdesk:
  - Web: https://grants.nih.gov/support/index.html
  - Toll-free: 1-866-504-9552
  - Phone: 301-402-7469
  - Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time