NIH Update

OFFICE OF POLICY FOR EXTRAMURAL RESEARCH
ADMINISTRATION, OER, NIH

National Institutes of Health
The updated NIH GPS will be available early in Fiscal Year 2020.

- The revised Grants Policy Statement will be applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2019.

Until publication, NIH will continue to publish interim grants policy changes through the issuance of NIH Guide Notices via the NIH Guide for Grants and Contracts.

Stay tuned for additional information!!!
NIH FORMS UPDATES

Coming Soon for applications due on or after
May 25, 2020 – Forms F

Stay tuned for additional information!!!
CHANGES TO NIH REQUIREMENTS REGARDING PROPOSED HUMAN FETAL TISSUE (HFT) RESEARCH

• For competing applications and competing revisions submitted after Sept. 25, 2019, NIH will require applicants/contract offerors to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant/contract officer will use HFT.

• HFT is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following:
  • human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
  • animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.
  • derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.
  • any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

See NOT-OD-19-128 and NOT-OD-19-137 for additional information
Changes to NIH Requirements Regarding Proposed HFT Research

- Applications that do not address all of the required information, including the detailed (non-modular) budget as specifically instructed, will be administratively withdrawn and not reviewed.
  - Specific guidelines for information and forms that must be included in applications are specified in the Guide Notices.
    - Note: If HFT are included in the proposed application, regardless of whether costs will be incurred, it must be noted as a single line item here. The line item must be titled Human Fetal Tissue Costs.
- Applications and proposals involving HFT that fall within a fundable scoring range will be assessed by an ethics advisory board comprised of scientists, bio-ethicists and others as specified in section 492A of the Public Health Service Act.

NIH POLICY ON OTHER SUPPORT

• Other Support has long been defined in the NIH Grants Policy Statement (1.2 Definitions and 2.5.1 Just-in-Time)
  • “All financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual’s research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards.”
• NIH issued NOT-OD-19-114 to clarify the existing Other Support requirements
• Our Goal: Facilitate the transparency of all research activities, both domestic and foreign not merely financial.

See NOT-OD-19-114 and the FAQs for additional information
WHAT ABOUT FCOI?

- Requirements found in 42 CFR Part 50, Subpart F
- Investigators must disclose their significant financial interests to their institution
- This requirement includes financial interests received from a foreign entity
- Separate and distinct from other support and foreign components

See [NOT-OD-19-114](#) and the [FAQs](#) for additional information.
Key measures for identifying foreign components are as follows:

- Is a portion of the project being conducted outside the US?
  - No – not a foreign component
  - Yes – are the activities being conducted outside of the US significant?
- Indicators include:
  - collaborations with investigators at a foreign site anticipated to result in co-authorship;
  - use of facilities or instrumentation at a foreign site; or
  - receipt of financial support or resources from a foreign entity.
- Foreign components require NIH prior approval
REQUIREMENT FOR ORCID ID BEGINNING IN FY 2020

• In October 2019, the requirement for ORCID identifiers will be incorporated into the appointment process for trainees, scholars, and participants supported by institutional research training, career development, and research education awards that require appointments through the xTrain system, including the following:
  • T03, T15, T32, T34, T35, T37, T42, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, RL9

• Beginning with receipt dates on or after January 25, 2020, the requirement for ORCID identifiers will be enforced at the time of application for individual fellowship and career development awards, including the following:
  • F05, F30, F31, F32, F33, F37, F38, F99/K00, FI2, K01, K02, K05, K07, K08, K18, K22, K23, K24, K25, K26, K38, K43, K76, K99/R00

• The ORCID identifier must be linked to the individual’s eRA Commons Personal Profile.

See NOT-OD-19-109
CENTRALIZED NOTIFICATIONS FOR UNFUNDED APPLICATIONS

• Centralized, streamlined process for official notification of unfunded applications
• Consolidated email listing all of the applications – sent by the NIH eRA system
• Approximately 14 months after the application’s council date

See NOT-OD-19-133
CHANGE OF PROCEDURE FOR REQUESTING EARLY STAGE INVESTIGATOR (ESI) EXTENSION

- Beginning on August 22, 2019, investigators will be able to request an extension to their ESI eligibility period through eRA Commons via an ESI Extension request button in the Education section of their Personal Profile.
- System will provide text fields to provide a justification for the proposed extension, and the ability to upload PDFs of supporting documentation.
- The request will be reviewed by the ESI Extension Committee.
- If approved by the Committee, the new ESI end date will appear in the Education section of their Personal Profile.
- Prior Extension request form and portal will be retired.

See NOT-OD-19-125
UPCOMING CHANGE IN FEDERAL-WIDE UNIQUE ENTITY IDENTIFIER REQUIREMENTS

• Federal-wide transition from the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) to a new Government-owned unique entity identifier (UEI).
  • Effective December 2020, the system for Award Management (SAM) will become the central repository for the new Unique Entity Identifier that will be incorporated into an institution’s SAM registration.

• The transition from DUNS to the Unique Entity Identifier is ongoing, and GSA will provide details to agencies related to the full implementation by December 2020.

• NIH will provide updates and guidance to recipients on changes to policies and procedures as additional information becomes available.

See NOT-OD-19-098
HHS REINVENT GRANTS MANAGEMENT

• Mission: Reduce administrative burden while increasing transparency, resource optimization, and efficiency across HHS grants management

• Current Initiatives
  • Standardized Notice of Award (NOA) Page One
  • SF-425/Federal Financial Report (FFR) Submission via the HHS Payment Management System (PMS)
REMINDER: ELIGIBILITY CHECKBOX IN COMMONS PROFILE

• If your institution gets a Global Validation Error that states your company is not eligible to submit to a FOA:

  • The signing official must access the company institutional eRA Commons Profile, where they will find a checkbox that needs to be checked, stating that they are eligible to apply.
  • Check this checkbox **annually**.

• **If the error persists, contact the eRA Commons Service Desk:**
  • Submit a Web Ticket: [https://public.era.nih.gov/submithelp](https://public.era.nih.gov/submithelp)
  • Toll-free: 1-866-504-9552
  • Phone: 301-402-7469
Don’t Miss the NIH Regional Seminar on Program Funding & Grants Administration in Phoenix, AZ

Nov 6-8, 2019

https://regionalseminars.od.nih.gov/phoenix2019/

New to Working with NIH? Consider this unique opportunity to hear from and visit with over 100 NIH experts.
Questions?
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


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 Enforcement

NIH is strengthening enforcement of longstanding closeout requirements.

• Recipients must submit timely, accurate closeout reports
• Reports are LATE after 120 calendar days
  • NIH may allow late submission with prior approval (i.e., acceptable written justification)
  • Cash transaction data is submitted directly to PMS
  • Recipient responsibility to reconcile FFR and FCTR data

When recipients fail to submit timely reports NIH will initiate unilateral closeout.

• When no FFR is submitted, HHS policy directs NIH to close the grant using the last accepted FCTR
• This could be considered a debt or result in disallowed costs

See NOT-OD-18-107
Educational Outreach
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 Resources
RPPR Resources

RPPR Webpage: http://grants.nih.gov/grants/rppr/

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 (Rev. 10/18):
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

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:
http://grants.nih.gov/support/index.html
Summary of Helpful NIH Web Pages

eRA Commons Web pages:
http://era.nih.gov/

eRA Commons User Guides:
http://era.nih.gov/commons/user_guide.cfm

Intellectual Property Policy:
http://grants.nih.gov/grants/intell-property.htm

Research Portfolio Online Reporting Tools (RePORT):
http://report.nih.gov

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

NIH Guide for Grants and Contracts:
Official publication for NIH Grant Policies, Guidelines & Funding Opportunities
http://grants.nih.gov/grants/guide/listserv.htm

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

Office of Laboratory Animal Welfare (OLAW):
http://grants.nih.gov/grants/olaw/references/list.htm

eSubmission:
Separate listservs available for scientists and administrators
Grants Information: Who to 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
Grants Policy: Who to Contact?

Division of Grants Policy:
- E-Mail: GrantsPolicy@mail.nih.gov
- Phone: 301-435-0949

Division of Grants Compliance & Oversight:
- E-Mail: GrantsCompliance@mail.nih.gov
- Phone: 301-435-0949

Division of Extramural Inventions and Technology Resources:
- E-Mail: Inventions@nih.gov
- Phone: 301-435-1986