Welcome

Please help yourself to breakfast.
Agenda

8:00 - 8:45am Registration and Breakfast
8:45 - 8:55am Welcome
8:55 - 9:25am Samuel Ashe, NIH
9:25 - 9:55am Q&A and Discussion
9:55 - 10:00am Closing
Current Issues at the NIH

George Washington University Grants Management
Breakfast Forum
May 2018 – Washington D.C

Presenter:
Samuel Ashe, Director, Division of Grants Policy
Office of Policy for Extramural Research Administration, OER, NIH
Guidance on Salary Limitation for Grants and Cooperative Agreements for FY 2018

Limited to Executive Level II – increased from $187,000 to $189,600, effective as of January 7, 2018.

See NOT-OD-18-137
FY 2018 NIH Grants Policy Statement

The updated NIHGPS was posted on October 12, 2017.

• The revised Grants Policy Statement is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2017.

• A summary of the significant changes is available online.

NIH continues to publish interim grants policy changes through the issuance of NIH Guide Notices via the NIH Guide for Grants and Contracts.

See NOT-OD-18-005
Administrative Relief for Hurricane-Affected Areas

NIH has worked with OMB and HHS to identify short-term administrative relief actions for areas affected by Hurricanes Harvey, Irma and Maria

- Extension of Financial and other Reporting
- Prior Approval reminder – prior approval is not required for rebudgeting, unless there will be a change in scope
- Extension of currently approved F&A Rates
- Extension of Single Audit Submission
- Alternatives for record retention and cost documentation
- Expenditure of award funds for salaries – *must follow your organization’s policies*
- Extension of Closeout

See [NOT-OD-18-114](#)
Policy Updates
21st Century Cures
Certificates of Confidentiality

• Section 2012 of the 21st Century Cures Act – Requires the Secretary of HHS to issue Certificates of Confidentiality (CoCs) to investigators or institutions engaged in:
  • Biomedical
  • Behavioral, or
  • Other research in which identifiable, sensitive information is collected

• CoCs protect researchers from being forced to disclose their research information in response to subpoenas or other legal requests

See NOT-OD-17-109
Certificates of Confidentiality

21st Century Cures Act required changes to NIH CoC Policy

<table>
<thead>
<tr>
<th>Issue</th>
<th>Previous Authority</th>
<th>Current Authority</th>
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<tbody>
<tr>
<td>How to get one</td>
<td>Issued upon approval of application</td>
<td>• NIH-funded – <strong>automatic</strong></td>
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<td></td>
<td></td>
<td>• Non-NIH funded – upon application</td>
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<tr>
<td>Disclosure</td>
<td>PI/ Institution could voluntarily disclose</td>
<td>Disclosure is prohibited unless specifically allowed by statute or with consent</td>
</tr>
<tr>
<td>Admissibility as evidence</td>
<td>Information protected by a CoC could be used in a legal proceeding if disclosed</td>
<td>Protected information cannot be used in a legal proceeding even if it is disclosed elsewhere</td>
</tr>
<tr>
<td>Copies of information</td>
<td>Unclear; typically advised to amend or extend</td>
<td>All information, including copies, is protected</td>
</tr>
</tbody>
</table>

See [NOT-OD-17-109](#)
“Type 2” Policy Change

In order to maximize transparency, NIH has updated its renewal application policy.

- **NIHGPS Chapter 8.6.2** no longer states that “whether funded or not” the progress report contained within the renewal application may serve in lieu of a separate final progress report.

This change aligns NIH’s final performance reporting requirement with the requirements of other Federal research awarding agencies.
**RPPR Implementation**

- **Annual RPPR** – describes a grant’s scientific progress, identifies significant changes, and describes plans for the subsequent budget period.

- **Interim RPPR** – use when submitting a renewal (Type 2) application. If the Type 2 is funded, the Interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. The data elements collected on the Interim RPPR are the same as for the Final RPPR, including project outcomes.

- **Final RPPR** – Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR, except budget and plans for the upcoming year.

Reminder – Final RPPRs are now required for all grants. NIH is no longer accepting the Final Progress Report format!

See [NOT-OD-17-022](#) and [NOT-OD-17-085](#)
Project Outcomes

NIH will publish the Project Outcomes Section of all Final and Interim RPPRs submitted on or after October 1, 2017.

• Will be available to the general public via the NIH RePORTER.

• Reviewed and approved by NIH staff to ensure the narrative is written for the general public in clear and comprehensible language.

• Should not include any proprietary, confidential information or trade secrets.

• Allow recipients to provide the general public with a concise summary of the cumulative outcomes or findings of the project.

See NOT-OD-18-103
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
Documentation of Personnel Expenses

NIH has clarified the applicability and flexibility of the requirements for documentation of personnel expenses for its grants and cooperative agreement recipients.

- Charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed.

- Budget estimates alone do not qualify as support for charges, but may be used for interim accounting purposes.

- Records may reflect categories of activities expressed as a percentage distribution of total activities.

- When recording salaries and wages charged to Federal awards for Institutes of Higher Education, a precise assessment of factors that contribute to costs is not always feasible, nor is it expected.

See [NOT-OD-18-108](#)
Inclusion Policy Changes

Individuals of all ages, including children, must be included in all human subjects research conducted or supported by NIH, unless there are ethical reasons not to include them.

• Applies to all competing grant applications for due dates on or after January 25, 2019.

• Policy has been expanded to include individuals across the lifespan.

• Clinical research studies are expected to submit individual level data on sex/gender, race, ethnicity and age at enrollment with annual progress reports.

See NOT-OD-18-116
Federal Policy for the Protection of Human Subjects

The Final Rule (45 CFR part 46) is intended to enhance protections for human research participants, facilitate valuable research, and reduce burdens for investigators, research institutions, and Institutional Review Boards (IRBs)

***HHS has announced an Interim Final Rule that delays the effective date and general compliance date to July 19, 2018.***

• Studies that have not undergone initial IRB review will be subject to the new Final Rule requirements.
• Research ongoing on that date will continue to be subject to the current Common Rule requirements

Note: The NIH policy on the use of single IRBs in multi-site studies took effect in January 2018.

See NOT-OD-17-038 and NOT-OD-17-040
Integrity in Peer Review

Maintaining integrity in the peer review process is essential. Officials at applicant organizations, PIs, and other individuals named in applications or proposals:

• Should not contact reviewers on the study section evaluating their application. The only acceptable process for communication is through the NIH Scientific Review Officer or Contracting Officer.
• Should not send information or data directly to a reviewer on the study section evaluating his/her application.
• Should immediately contact the SRO if contacted by a reviewer or other individual named in another application, outside of the channels described above.

See NOT-OD-18-115
Integrity in Peer Review

- Each peer reviewer must read the NIH Confidentiality and Non-Disclosure Rules, and certify that he or she fully understands and will comply with the confidential nature of the review process.
- When certifying the Confidentiality Agreements, each peer reviewer agrees, under penalty of perjury, 18 U.S.C. §1001, to maintain confidentiality in peer review.
- If NIH determines that a situation involves a breach of integrity, NIH may take action including, but not limited to:
  - Notifying the individuals and institutions involved
  - Terminating the reviewer’s or Council member’s service
  - Pursuing a referral for government-wide suspension or debarment
  - Referring the matter to the NIH Office of Management Assessment and possibly to the HHS Office of Inspector General, which could result in criminal penalties, fines, imprisonment, and/or other actions

See NOT-OD-18-115
Electronic Submission & eRA Commons
Advance Notice of Transition to the xTRACT System for Preparing Research Training Data Tables

NIH anticipates mandating that required training data tables submitted with applications and progress reports for the following activity codes be created via the xTRACT system:

- T32
- TL1
- T90/R90
- T15

In late FY 2019, NIH will provide further guidance about the implementation of this expected requirement. At this time, applicants who have not yet taken advantage of the xTRACT system to create training data tables are encouraged to begin exploring its functionality, and may wish to start by using the system to create Data Table 8, to accompany an RPPR.

See NOT-OD-18-133
Diversity Supplements

Effective January 25, 2018, all applications for (single and multi-project) diversity supplements must be submitted electronically.

- Options available to submit electronically include NIH ASSIST, Institutional system-to-system (S2S), Grants.gov Workspace and streamlined system through eRA Commons

- Within Section D.1 of the RPPR, recipients are required to identify whether an individual that has worked on the award is supported by a Diversity Supplement.
  - Institutions with a non-competing continuation award that includes diversity supplement support will be required to identify at least one participant that is supported by the diversity supplement.

See NOT-OD-18-111
Automated Post Award Changes

Effective March 2, 2017, recipients of NIH awards can submit the following prior approval requests electronically through eRA Commons.

Prior Approval Request for Change of PD/PI
SOs can initiate the request for a Change of Program Director/Principal Investigator (PD/PI) electronically through eRA Commons via Prior Approval.

Prior Approval Request for No Cost Extension (NCE)
SOs will be able to request NCEs (in addition to the requests made under expanded authority) electronically through eRA Commons via Prior Approval.

For additional details please see eRA Commons Online Help
Tips for e-Submission Success

Register Early!

- Required registrations
  - System for Award Management (SAM)
  - Grants.gov
  - eRA Commons
  - DUNS
  - SBA (for small business applicants only)
- Submit early, and correct any errors before due date
- View your application in Commons
  - If you can’t VIEW it, NIH can’t REVIEW it!
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:
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
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 & FAQ
Helpful NIH Resources
RPPR Resources

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

Includes links to:

• RPPR Application 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, animals, disaster response, PMS Subaccounts, Core Facilities, FCOI, sIRB, 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. 10/17):
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:

Do I have the right electronic forms for my NIH application?:

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: 301-435-0714

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
Questions?