

NIH Update

Federal Demonstration Partnership

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**Samuel Ashe, Director, Division of Grants Policy
Office of Policy for Extramural Research Administration**



National Institutes of Health

FY 2018 NIH Grants Policy Statement

The updated NIHGPS was posted on October 12.

- 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



Reminder – Changes Coming in January

- **Effective for due dates on/after January 25, 2018.**
 - “Forms-E” grant application should be used – includes new Human Subjects and Clinical Trials Information Form ([NOT-OD-17-119](#))
 - All applications involving one or more clinical trials must be submitted through a FOA specifically designated for clinical trials ([NOT-OD-18-106](#)) – *Note any new review criteria!*
 - Multi-site studies involving non-exempt human subjects research funded by the NIH, are expected to use a single Institutional Review Board (sIRB)
 - Additional implementation guidance ([NOT-OD-18-004](#)) and information on exceptions ([NOT-OD-18-003](#)) is now available.

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.



Certificates of Confidentiality

21st Century Cures Act required changes to NIH CoC Policy

Issue	Previous Authority	Current Authority
How to get one	Issued upon approval of application	<ul style="list-style-type: none">• NIH-funded – automatic• Non-NIH funded – upon application
Disclosure	PI/ Institution could voluntarily disclose	Disclosure is prohibited unless specifically allowed by statute or with consent
Admissibility as evidence	Information protected by a CoC could be used in a legal proceeding if disclosed	Protected information cannot be used in a legal proceeding even if it is disclosed elsewhere
Copies of information	Unclear; typically advised to amend or extend	All information, including copies, is protected



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.



Closeout Enforcement

Reminder that NIH continues to enforcement its longstanding closeout requirements.

- NIH has consistently reminded recipients of their responsibility to submit timely, accurate closeout reports:
 - Reports are late after 120 calendar days.
 - Recipient responsibility to reconcile FFR and FCTR data.
- As a reminder, HHS policy requires NIH to close grants as soon as possible after the end of the period of performance, and no later than 270 days after the project period end date.
 - When no FFR is submitted, HHS policy directs NIH to close the grant using the last accepted FCTR.



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.



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.



SAVE THE DATE: 2018 REGIONAL SEMINARS

Spring Regional Seminar:

Washington, DC

May 2-4, 2018

Registration now open!

See [NOT-OD-18-013](#)



QUESTIONS?

