NIH Update

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Federal Demonstration Partnership
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National Institutes of Health

FY 2018 NIH Grants Policy Statement

The updated NIHGPS will be available on October 6, 2017.

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

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!!!

Biomedical Research Workforce Policy Updates

Research Career Development Salary Supplementation Update

Significant Policy Change!!

For effort not directly committed to a Career "K" award, NIH will allow recipients to devote effort, with compensation, on Federal or non-Federal sources as the Program Director/Principal Investigator (PD/PI) or in another role (e.g., co-Investigator).

- **Recipients may devote effort while serving in these roles as long as the specific aims of the other supporting grants(s) differ from those of the "K" award.**

See NOT-OD-17-094 for additional information.

Additional Guidance on "Full-Time Training" for NRSA Awards

NIH recognizes that NRSA fellows and trainees may seek part-time employment incidental to their training program to offset their expenses.

Therefore, NIH issued additional guidance clarifying that fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) conducting the following activities part time:

- Research
- Teaching, or
- Clinical employment

As long as the activities do not *interfere with, or lengthen*, the duration of their research training.

See NOT-OD-17-095 for additional information.

Clinical Trial Reform Policy Reminders

Good Clinical Practice Training Requirement

Effective January 1, 2017 – NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP)

Good Clinical Practice training establishes:

- ✓ Standards for clinical trial implementation, data collection, monitoring, and reporting
- ✓ Responsibilities of investigators, sponsors, monitors, and institutional review boards

See NOT-OD-16-148 for additional information.

Funding Opportunity Announcements (FOAs) for Clinical Trials

Effective for due dates on/after January 25, 2018 - All grant applications involving one or more clinical trials must be submitted through an FOA *specifically designated for clinical trials.*

Clinical Trial-specific FOAs allow NIH to:

- ✓identify proposed clinical trials
- ✓ensure that key pieces of clinical trial-specific information are submitted with each application
- ✓uniformly apply clinical trial-specific review criteria

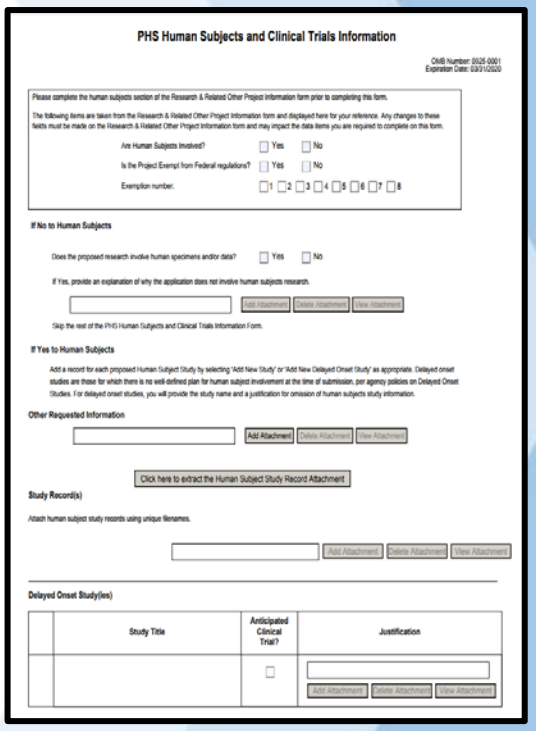
Learn more at https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm

See NOT-OD-17-043 for additional information.

New Human Subjects & Clinical Trials Information Form

A primary component of NIH's clinical trial reform is the creation of a new application form that:

- ✓ **Consolidates** human subjects, inclusion enrollment, and clinical trial information into one form
- ✓ Collects information at the **study-level**
- ✓ Uses **discrete form fields** to capture clinical trial information and provide the level of detail needed for peer review
- ✓ Presents key information to reviewers and staff in a **consistent format**
- ✓ **Aligns** with ClinicalTrials.gov (where possible) for future data exchange with ClinicalTrials.gov


PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project information form prior to completing this form.

The following items are taken from the Research & Related Other Project information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

If No to Human Subjects

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment | Delete Attachment | View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting "Add New Study" or "Add New Delayed Onset Study" as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment | Delete Attachment | View Attachment

See NOT-OD-17-062 for additional information.

Single Institutional Review Board (sIRB) Policy for Multi-site Research

Effective for due dates on/after January 25, 2018 – NIH expects that all multi-site studies which involve non-exempt human subjects research funded by the NIH, will use a *single Institutional Review Board (sIRB)* to conduct the ethical review required for the protection of human subjects.

sIRB policy aims to:

- ✓ Streamline IRB review process to enhance research efficiency
- ✓ Reduce unnecessary administrative burdens and inefficiencies

Learn more at https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

See NOT-OD-17-076 for additional information.

National Institutes of Health

NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

Effective January 18, 2017 – All NIH-funded awardees and investigators conducting clinical trials must register and report the results of their trial in ClinicalTrials.gov

NIH dissemination policy:

- ✓ Extends previous HHS policies to apply to **all** NIH-funded clinical trials instead of defining a subset of "applicable clinical trials"
- ✓ Increases the availability of information to the public about clinical trials

Learn more at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

See NOT-OD-16-149 for additional information.

SAVE THE DATE:
2017 NIH REGIONAL SEMINARS

Fall Regional Seminar

Baltimore, MD

October 25th – 27th

See NOT-OD-17-073 for details.

QUESTIONS ?