Office of Research Services

Winter 2018
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NIH Clinical Trial Updates

NIH is making significant changes to the way it funds clinical trials for opportunities due on or after January 25, 2018: As of January 25th, NIH will only fund clinical trials in response to funding opportunities that explicitly state they will accept clinical trials.

NIH is implementing these changes to enhance their capability to identify clinical trials and help them to ensure collection of critical elements, as well as provide more standard reviews of clinical trials.

In support of this change, NIH has revised its definition of clinical trials as follows:
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavior outcomes.

These updates to the clinical trial funding process are implemented concurrently with the update to the new NIH Application Packages, FORMS-E. In the new forms, Clinical Trial Protocols will not be accepted as Appendix material for any of the Parent FOAs. Protocols and other clinical-trial–specific material will ONLY be allowed when required by the clinical-trial–specific FOA.

For more information, see: https://grants.nih.gov/policy/clinical-trials/why-changes.htm

We're moving on up!

On January 29, ORS staff will begin their work days in our new office space, located on the 5th floor of the Franklin Building. The relocation of the Office of Research Services is one of several moves that will occur within the building through early Spring 2018.

Construction work that began in September 2017 will soon reveal a transformed inner space. Renovation work includes the public restrooms, which will now have fully accessible, ADA-compliant stalls.

Compliance with NIH Biographical Sketch Format

NIH Biosketches are required for all key personnel on new and competing renewal proposals and when there is a change in key personnel. In some circumstances, biosketches are also required on progress reports.

In September of 2017, NIH updated the biosketch format. Prior to the update, the biosketch had an expiration date of 10/31/2018. The updated biosketch has an expiration date of 03/31/2020. Both may be used until 10/31/2018, after which only the September 2017 version will be accepted.

What makes a biosketch compliant with NIH guidelines?

The first page of the biosketch must match the format as shown below:

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STU

NOTE: Do not delete the header (OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)) to bypass formatting guidelines.

Personal Statement

A brief statement that is specific to the project, not a broad statement of the investigator's overall research. As such, the Personal Statement should vary from one project/proposal to another.

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B. Positions and Honors

A chronological list of the positions the investigator has held that are relevant to the application. If the investigator is not currently at Penn, the expected start date and position should be indicated. Additionally, any relevant academic and professional achievements/honors should be listed. Some examples would be:

Contributions to Science

NIH allows up to 5 contributions. They should be brief and not exceed one half page (the page limit for the biosketch in total is no more than 5 pages), including citations. Each listed contribution may have no more than 4 publications or research products. (NOTE: Providing a link to a full list of published work is not required. However, if included, it must be to a Federal Government website with a ".gov" suffix. NIH will not click on any URL that does not contain the .gov suffix.)

Additional Information: Research Support and/or Scholastic Performance

Research Support: This section is not the same as Other Support information. The Research Support should contain two sections (as applicable): Ongoing Research Support and Completed Research Support. Total direct cost amounts and calendar month effort should not be included in the Research Support section. This section is used to highlight accomplishments as scientists.

Scholastic Performance: This section pertains to predoctoral applicants/candidates and postdoctoral applicants. In summary, it is an unofficial transcript of all coursework completed by the applicant/candidate.

REMINDER: The reviewers at NIH *do* read biosketches. Adhering to the biosketch formatting guidelines shows the reviewers that care and attention was given to meet programmatic requirements of the application per the FOA and NIH Applications Guides.

HELPFUL LINKS: Biosketch Format Pages, Instructions, and Samples:
https://grants.nih.gov/grants/forms/biosketch.html

NIH Application Form Instructions:
https://grants.nih.gov/grants/how-to-apply-application-guide.html

Recent Research Inventory System Subaward Module Updates and Advice

You may have noticed that many of your subawards are on new FDP subaward templates. Less noticeable but more importantly, RIS has been upgraded and now has the ability to generate these agreements by auto populating many of the fields that were previously entered manually. This is just one of several initiatives undertaken to reduce turnaround time for subaward processing.

Subaward requests that arrive in ORS with accurate and complete information can be turned around quickly. Unfortunately, many requests have issues that slow the completion process.

The importance of accuracy of subaward institution contacts cannot be overstated. If an identified recipient has a new email address, has left the institution, or if there is a typo/misplaced period in an email address, the agreements may be routed to a dead-letter box, notifications of which are not returned through RIS. Errors are discovered only after ORS sends multiple follow-up emails or a subrecipient contacts us (or the BA directly) to complain about a missing subaward. Requests for information that go unanswered are a significant impediment to the timely issuance of agreements.

Take advantage of the Notes Section in the Subaward Request Form to tell ORS staff things about the project that might not be evident at first glance. For example, a new record entry (-00) should note any previous agreements it is intended to amend, such as paper-based agreements not captured by RIS, or agreements issued under old Institution Numbers. Other pertinent information: Is the subaward to be funded by a supplemental award to our main grant? Is the project currently in a non-HSR stage? Absent clear direction, valuable time is often lost searching Penn ERA, NIH Commons, or our On Base archive for clues.

ORS endeavors to issue subawards as efficiently as possible. But our subaward agreements--and turnaround time--are only as good as the information we receive. Your assistance is invaluable and appreciated.

Common obstacles that slow subaward processing:

Missing documentation of **sponsor approva**l (i.e., approval to rebudget, replace a PI, or to subaward), if required.

Lack of **IRB documentation**; lack of IRB Reliance Agreement information; IRB protocols that don't match the project; IRB documents in foreign languages.

Requested periods of performance not within the currently funded award period; budgets that don't match the requested agreement's Period of Performance or requested amount.

Scopes of Work referring to a PI's former institution or no-longer involved personnel; outdated Scopes of Work when the current budget represents a substantial change.

Budgets that have math errors or are too broad.

A Reminder about Sponsor Prior Approvals

As a member of the Federal Demonstration Partnership, Penn is permitted to make some changes to grants without prior sponsor approval. If these expanded authorities are applicable, that information will be included in the Notice of Award for the grant. When they are not, and for most contracts and some grants, prior approval from the sponsor is required prior to making changes to the grant activities.

The following chart may be useful to the Penn research community in determining if a particular change generally requires prior sponsor approval when NIH or NSF is the sponsor. Even if prior approval is not required, it is sometimes prudent to consult with the sponsor prior to making changes in grant spending, particularly for unbudgeted activities near the end of the award period. If you have questions as to whether or not prior approval is required or if a charge is appropriate to a grant, please contact the Office of Research Services for guidance.

Activity	NIH Prior Approval Required?	NSF Prior Approval Required?
Adding a subaward or contract that was not included in the original proposal	No	Yes
Adding an international component or foreign travel	Yes	No
Change in scope of project or program	Yes	Yes
Rebudgeting to purchase equipment	Yes	Yes
Change in key personnel	Yes	Yes
Disengagement from project more than 3 months or 25% reduction by approved PI/PD and other key personnel	Yes	Yes
Adding human subjects activities	Yes	Yes
Adding animal subjects activities	Yes	Yes
Transfer of funds to Participant support costs	Yes	No
Transfer of budgeted Participant support to other categories	No	Yes
Changes in approved cost sharing or matching	Yes	Yes

Remember – even with this general applicability, it is important to review the notice of award that takes precedent over the general agency terms and conditions!

NSF UPDATE: Revised Proposals & Award Policies & Procedures Guide (PAPPG)

The National Science Foundation (NSF) has issued a new Proposals & Award Policies & Procedures Guide (PAPPG) effective for proposals submitted on or due after January 29, 2018. Highlights of changes in the 2018 PAPPG include:

Proposals:

Project Description must contain a separate section specifically identified as "Intellectual Merit."

Collaborators and Other Affiliations (COA) standard template implemented.

Budget justification page limit increased from 3 to 5 pages (for both proposers and subawardees).

Results from Prior NSF Support clarifies the timeframe during which any PI or Co-PI that has received NSF support must report on such funding.

Eligibility subcategory for proposal submission was added for international branch campuses of U.S. institutions.

Awards:

Prior Written Approvals section has been updated to reference the Research Terms and Conditions Appendix A, which is the authoritative source of NSF prior approval requirements.

Final Project Report has been updated to reflect that when PIs submit the report, they are indicating that the scope of work is complete and no further administrative actions are anticipated on the grant.

Intellectual Property has been updated to specify that NSF subject inventions are required to be reported via iEdison and NSF now reserves option to require annual utilization reports or a final invention statement and certification.

If you have questions related to the preparation of an NSF proposal or managing an NSF award, please contact the Office of Research Services for additional clarification or to make any requests to the NSF.

NIH FORMS-E Are Coming

NIH has announced that new FORMS-E will replace the existing application FORMS-D. All proposals for the deadline of January 25, 2018, or later will be required to use the new forms. The latest NIH Notice can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-009.html. It contains links to other NIH sites providing information about these new forms, especially the updated Application Guide, which is now available.

> ***Important Note**:* FORMS-E applies to applications ***DUE*** on or after 1/25/2018, regardless of when that application is submitted. For example, submitting an application prior to 1/25 with a due date of 2/5 still requires that FORMS-E be used. FORMS-E cannot be used for any submission with a due date prior to 1/25. Continue to use FORMS-D for those deadlines.

PennERA Proposal Development (PD) will be configured with the new forms in November. All users will be notified of that date. More detail will be provided at that time, but the PennERA Team has some preliminary information about this update.

- Applications already created using FORMS-D that will need to use FORMS-E will be able to be updated.
- NIH has begun publishing new or updated Funding Opportunity Announcements. Please be sure to select FORMS-D for now, even if a FORMS-E option is available for selection.

Please contact PennERAhelp@lists.upenn.edu if you have any questions.

Please see a companion article in this newsletter from ORS Pre-Award about FORMS E content changes.

Summary of changes to PennERA

Detailed information will be provided by the PennERA Help Team when the environment is upgraded to encompass these changes.

- NIH Pre-Submission Validation Web Service will be available.
  Users will be able to view and ***fully*** validate their applications at NIH ***prior to submitting them from PennERA***.
- More information about the Grants.gov status of an application will be available in each PennERA record on the finalize screen.
- Consolidation of human subjects, inclusion enrollment, and clinical trial information into one form.
  Pieces of this information are currently contained in various locations in the forms package but will now be located in one form.
  New form page entitled "PHS Human Subjects and Clinical Trials Information" added to PennERA record incorporates all information into this one form.
  This form is required by NIH in most applications, as it now contains the basic Human Subjects question, "Are Human Subjects involved?"
- In most applications, including some non-NIH federal agencies, Other Project Info will become one screen in the record.
  For example, PennERA currently has several screens for data entry and uploads that are combined to create the Other Project Information form, including Project Summary, Project Narrative, References Cited, Other Attachments, etc.
  As a result of the forms upgrade, any PD record created for an agency using the new version of this form (v1.4) will have just one screen for this information.

Reminder about U.S. Sanctions and International Travel

The Department of Treasury, Office of Foreign Assets Control (OFAC), broadly regulates and restricts transactions with embargoed countries, including academic exchanges and research collaborations. Currently, some of the most comprehensive controls apply to Cuba, Iran, North Korea, and Syria. Here, we provide general guidance to the Penn community for Iran and Cuba travel.

To whom does this apply?

OFAC regulations apply to U.S. persons, which is defined as any U.S. citizen, permanent resident alien, entity organized under the laws of the United States, or any person in the United States.

The regulations apply to U.S. citizens and permanent residents wherever located, and to foreign nationals located inside the United States. Individuals with dual U.S. citizenship are considered "U.S. persons."

Anyone traveling on behalf of Penn, regardless of nationality or passport used, is subject to the OFAC regulations and may require a license from the U.S. government before engaging in certain activities.

IRAN

BEFORE YOU GO

If you are planning to travel to Iran or engage in a collaboration with an Iranian institution, please contact the Export Compliance Office (expctrl@lists.upenn.edu, or 215-573-8817) before you:

- Travel to Iran to attend or participate in a conference or workshop
- Travel to Iran to engage in activities that are not listed under Iran General License G
- Travel to Iran with anything other than personal belongings, equipment covered by an OFAC license, or equipment allowed under Iran General License D-1

  Note that if personal belongings include any controlled item, a license will still be necessary
  Penn-owned equipment and material may require a specific license

- Provide Iranian nationals that reside in Iran, or Iranian institutions, technical assistance or analysis
- Import from Iran or export to Iran

If you are contemplating any of these activities, a license may be required. Depending on the activity, license applications for Iran can sometimes take several months to process, so please contact the Export Compliance Office well in advance of your expected travel dates.

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CUBA

IMPORTANT UPDATE

On November 9, 2017, the U.S. State Department published a list of entities associated with Cuba, *including hotels, shops, restaurants, and travel agencies*, with which direct financial transactions are generally prohibited under the OFAC Cuba regulations: https://www.state.gov/e/eb/tfs/spi/cuba/cubarestrictedlist/275331.htm.

If you have completed at least one travel-related transaction (e.g., purchased a flight or reserved accommodation) with an entity on this list prior to November 9, 2017, those travel-related transactions remain authorized provided that they are consistent with OFAC's regulations.

In addition, the OFAC regulations stipulate that Penn faculty, staff, and students traveling to Cuba under University of Pennsylvania sponsorship should carry an appropriate authorization letter printed on University letterhead and signed by the designated representative for Penn. Please contact expctrl@lists.upenn.edu or 215-573-8817 for assistance in obtaining the required letter.

Remember: Travel to Cuba is generally restricted and must fall under into one of 12 categories of authorized travel. If you are contemplating Cuba travel, please contact the Office or Research Services or the Global Support Services Office for more information and assistance.

For questions related to OFAC sanctions, licensing, or export control regulations in general, please contact expctrl@lists.upenn.edu or 215-573-8817.

New Audit Process for FY17 Annual Federal, State, & City Audits

A new process has been implemented to streamline the annual federal, state, and city audits of sponsored award projects. The new audit process allows more efficient and effective management of audit work, both for Penn and for our external auditors. This new process, detailed below, was proposed through the Research Shared Governance Board and accepted by its members.

City, State, and Uniform Guidance (Federal) Audit Process:

- External auditors will identify all testing samples.
- ORS will pull information available from systems and provide it to the auditor.
- ORS will make documentation requests to the responsible BA, copying the school's point of contact, providing a firm due date for responses (2 weeks).
- ORS will maintain a record of the requests made and track departmental responses.
- If information is not received by the original due date, a follow up email will be sent to the school point of contact, copying Missy Peloso and MaryFrances McCourt, with a FINAL due date (1 week or less).
- If there is no response by the FINAL due date, ORS will assume there is no additional documentation and the school will be responsible for resolution of any preliminary audit finding(s).

Additionally, ORS will provide monthly progress reports on the audits to the RSGB during the audit season (typically May-February).

The primary point of contact by school for audit requests is listed below:

School	Point of Contact
Annenberg	Patricia Lindner
GSE	Helen Mitchell-Sears
PSOM	Chanika Pratt
SAS	Elyse Saladoff
SDM	John Manuel
SEAS	Christopher Bristow
SON	Charlotte Liu
SVM	Stephanie Mahan