Contacts Meeting

December 15, 2015
National Institutes of Health (NIH) Updates
NOT-OD-16-004
Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications for NIH and AHRQ
NOT-OD-16-004: Other Relevant Notices

- **NOT-OD-16-029**: Application guides available for Application due dates on and between January 25 and May 24, 2016
- **NOT-OD-16-012**: Implementing Rigor and Transparency in NIH and AHRQ CDAs
- **NOT-OD-16-011**: Implementing Rigor and Transparency in NIH and AHRQ Research Grant Applications
- **NOT-OD-16-010**: Change in NIH definition of Children in Clinical Research
- **NOT-OD-16-009**: Upcoming change in font guidelines
- **NOT-OD-16-008**: Announcement of the PHS Assignment Request Form
- **NOT-OD-16-007**: Transition to new research training data table formats and release of xTRACT system
- **NOT-OD-16-006**: Simplification of the VAS
- **NOT-OD-16-005**: Upcoming changes to post award forms and instructions
The planned changes focus on the following areas:

- Rigor and transparency in research
- Vertebrate animals
- Inclusion reporting
- Data safety monitoring
- Research training
- Appendices
- Font requirements
- Biosketch clarifications

Some of the new policies require additional data collection and updates to our application forms.

The new upcoming policy and guidance changes will occur in two phases.

- **Phase 1**: Implements a subset of the policy changes using existing (FORMS-C) forms and updated instructions and will impact due dates on or after **January 25, 2016**.
- **Phase 2**: Completes the implementation with the introduction of new (FORMS-D) forms and instructions and will impact due dates on or after **May 25, 2016**.
Rigor and Transparency changes:

- NIH is changing application requirements and review language to enhance reproducibility of research findings through increased scientific rigor and transparency.
- New updated requirements focus on four areas deemed important for enhancing rigor and transparency:
  - 1) the scientific premise forming the basis of the proposed research,
  - 2) rigorous experimental design for robust and unbiased results,
  - 3) consideration of relevant biological variables, and
  - 4) authentication of key biological and/or chemical resources.

Changes specifically focus on:
- Updates to application guide instructions for preparing the research strategy
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment (uploaded in Other Attachments section of R&R Other Project Information form)
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

- See NOT-OD-16-011 and NOT-OD-16-012.
Vertebrate Animal Section changes:

NIH is removing redundancy with the IACUC review while meeting the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals.

Changes include:

- Updated guidance on criteria to be addressed (description of procedures; justifications; minimization of pain and distress; and euthanasia)
- A description of veterinary care is no longer required
- Justification for the number of animals has been eliminated
- A description and justification of the method of euthanasia is required only if the method is not consistent with AVMA Guidelines for the Euthanasia of Animals

Definition of Children:

NIH is redefining the age of a child for the purposes of NIH's inclusion policy to individuals under 18 years old instead of under 21 years old.

- Note: These change do not apply to AHRQ applications.
NOT-OD-16-004: Research Training

• NIH is updating requirements and instructions on the PHS 398 Research Training Program Plan form to reflect recent policy guidance and reduce applicant burden.

• Changes include:
  • "Recruitment and Retention Plan to Enhance Diversity" - applicants will be asked to focus on recruitment
  • "Human Subjects" and “Vertebrate Animals” - applicants must describe how the institution will ensure that trainees only participate in exempt human subjects research, non-exempt human subjects research that has IRB approval, or vertebrate animal research that has IACUC approval; it is no longer necessary to provide a list of potential grants trainees may work on and associated IRB/IACUC information
  • "Progress Report" - requirement to report on publications that arose from work conducted by the trainee while supported by the training grant will be moved to the Just-in-Time process
• New Forms, SF424 Forms D, will be coming out for Application due dates on and after May 25, 2016

• HS SPPO will be conducting more in-depth training sessions on new forms as they become available

• On November 5, NIH started sending email notifications to applicants indicating reviewers found one or more biosketches that did not comply with the current biosketch format. Hundreds of letters have already gone out. If you've received one of these notifications, **DON’T PANIC!**

• If you've received a warning letter, please take a few minutes to correct the biosketches! Eventually, these warning letters will be replaced with notifications that applications have been removed from consideration. **You've been warned** (queue foreboding music in your head).

Thank YOU Sheri Cummins, NIH OER, for this friendly reminder!
What should the current Biosketches include?

- **Four sections** (A - Personal Statement; B – Positions and Honors; C – Contributions to Science; D – Research Support or Scholastic Performance)

- Include no more than 5 contributions to science with no more than 4 citations per contribution

- Ensure that if you include the optional link to a full list of your published work in a site like My Bibliography that the URL is public, accessible without providing any login or personal information, and doesn't link to websites that may violate page limit rules

- Refrain from including information, such as preliminary data, that belongs elsewhere in the application

- **Follow NIH guidance** on font type, font size, paper size, and margins (See section 2.6 of application guide)
NOT-OD-16-007: NIH & AHRQ Announce Transition to New Research Training Table Formats for 2016 and Upcoming Release of the xTRACT System

• What is xTRACT?
  
  • Extramural Trainee Reporting and Career Tracking
    
    • A pre-submission tool within eRA Commons used to create research data training tables for RPPRs and institutional training grant applications
    
    • For T32, TL1, T90/R90, and T15 applications and RPPRs
    
    • T35, R25, K12/KL2 awards can use it on a pilot basis. You may wish to wait for future editions of the system, which will include features tailored to their specific types of awards.
    
    • T34 awards should not use the xTRACT system at all at this time
  
  • Table formats, instructions, and a completed set of tables with sample data may be found on the NIH website at: http://grants.nih.gov/grants/funding/424/datatables.htm.
NIH & AHRQ Announce Transition to New Research Training Table Formats for 2016 and Upcoming Release of the xTRACT System

• Implementation:
  • For RPPRs due prior to December 1, 2015, and applications submitted for due dates prior to May 25, 2016, applicants are advised to continue to use previously issued training data table formats.
  
  • New training data table formats must be used for RPPRs due December 1, 2015, and after and applications submitted for due dates on or after May 25, 2016. Applicants may create tables for their applications and RPPRs either by using fillable tables in MS Word or via the xTRACT system.
NIH & AHRQ Announce Transition to New Research Training Table Formats for 2016 and Upcoming Release of the xTRACT System

- Complete list of New Data Tables:
  - **Table 1.** Census of Participating Departments and Interdepartmental Programs
  - **Table 2.** Participating Faculty Members
  - **Table 3.** Federal Institutional Research Training Grant and Related Support Available to Participating Faculty Members
  - **Table 4.** Research Support of Participating Faculty Members
  - **Table 5A/B/C.** Publications of Those in Training: Predoctoral/Postdoctoral/Undergraduate
  - **Table 6A/B.** Applicants, Entrants, and their Characteristics for the Past Five Years: Predoctoral/Postdoctoral
  - **Table 7.** Appointments to the Training Grant for Each Year of the Current Project Period (renewal/revision applications only)
  - **Table 8A/B/C/D.** Program Outcomes: Predoctoral/Short-Term/Postdoctoral/Undergraduate
Note: xTRACT Module is now available via eRA Commons on a Pilot Basis ONLY

- xTRACT is being integrated with eRA Commons, some of the data for training tables and reports will be prepopulated, using xTrain appointment and related data. This data includes:
  - Trainee names
  - Selected characteristics
  - Institutions
  - Grant Numbers and subsequent NIH and other HHS awards.
  - Data manually entered in xTRACT for one training table submission will be available for reuse in xTRACT, when preparing data for subsequent training table submissions.
NOT-OD-16-017: Significant Changes in the FY 2016 NIH Grants Policy Statement

• The Significant Changes document summarizes the notable grants policy changes and clarifications that will be implemented in the FY 2016 NIHGPS.

• Anticipate that the FY 2016 NIHGPS will be available in November.

• The document may be found at the following location: http://grants.nih.gov/grants/policy/nihgps/Significant_Changes_NIHGPS_Oct2015.pdf
HSSPPO Holiday Closure and January Timelines

• During the holiday season, the HS SPPO will be closed from December 24th through January 3rd, reopening on January 4th, 2016.

• AIDS and AIDS-Related Application Proposals due January 7th:
  • Complete review copies of AIDS and AIDS-Related Application proposals should be received by HS SPPO no later than December 15th (it is okay to exclude the science sections at this stage of the proposal review). The finalized, ready to submit version of the proposal should be received no later than January 5th.
Any Questions?