

RESEARCH ADMINISTRATION & FINANCE

Lunch & Learn

October 21, 2015

Discussion Topics

eRA Enhancements:

- Updates in eSubmission
- Updates in ASSIST
- Updates in eRA Commons

DHHS – NIH & AHRQ:

Planned changes to policies, forms and instructions for DHHS applications in 2016

NSF:

Revision to: *Proposal & Award Policies & Procedures Guide (PAPPG), (NSF16-1)*

Webinars:

Hosted by NIH and NSF

Highlights of eRA Commons' October Software Release

Updates in eSubmission

NIH has made several changes to enhance the usability of the Application Submission System & Interface for Submission Tracking (ASSIST) solution:

- **Diversity Administrative Supplements Now Require Credentials**
 - When submitting Diversity Admin Supplements (Type 3) applications, all Senior/Key Persons are required to have valid eRA Commons credentials.
- **Updates in ASSIST**
 - Fellowship applications (Fs) will be able to be submitted using ASSIST (see [Target Timeline for Single-Project ASSIST](#)).
 - Ability to Submit Most Competing Programs
 - Starting in September, ASSIST was opened to most competing single-project applications (See [NOT-OD-15-044](#) for more information).
 - The use of ASSIST is not required. It is provided as an option for submission.

Updates in eRA Commons

NIH has added several new features to eRA Commons

- **eRA Help Desk Now *eRA Service Desk***

- Commons users will see this change on screens, email notifications, web pages, and other resources.

- **New Final Invention Statement Notification(s) to Institutions**

- Institutions will now receive email notifications that Final Invention Statements (FIS) are ready for acceptance by a Signing Official (SO) and submission to agency.
- eRA Commons will send an initial email after a PI or SO has uploaded an FIS and it is in a status of *Awaiting SO Verification*.

- **Security Precautions added to DOB and SSN Fields**

- eRA has added extra security to the Personal Profile for the Date of Birth and Social Security Number (SSN) fields.

- **Confirmation Checkbox Added to the Extension Screen**

- Users submitting a No-Cost Extension (NCE) will notice a new checkbox that verifies that the terms of the NCE have been read and are understood.

- **Introducing xTRACT**

- The xTRACT module will be available via the eRA Commons.
- It will allow applicants, grantees, and assistants to create research training tables for progress reports and institutional training grant applications.
- Initially, xTRACT will support the following training grant award mechanisms: T32, TL1, T90/R90, and T15 for both progress reports and grant applications.
- As part of NIH's [Biomedical Research Workforce](#) (BMW) initiative, xTRACT will allow NIH and other agencies to capture data on the careers of trainees (students and post-docs) and provide more information on training program outcomes.

- **NOTE:** xTRACT can be used on a pilot basis for creating data tables for those mechanisms for Research Performance Progress Reports due Dec. 1, 2015 or later and applications submitted for the May 25, 2016 due date and after (See Guide Notice [NOT-OD-16-007](#)).

NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications

- **Notice Number: NOT-OD-16-004**
- **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. We have received approval from the Office of Management and Budget to make the needed form updates and we expect to have system support and guidance for these updates in place by March 25, 2016 ([NOT-OD-15-146](#)).

- In order to move forward with the subset of policies which must remain consistent for all research applications in a funding year, we will implement the policy and guidance changes 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.

Policy & Guidance Changes - Phase 1

- **Timing**

Effective for applications submitted for due dates on or after January 25, 2016

- **Application Forms**

FORMS-C (current forms; already available)

- **Instructions**

By November 25, 2015, we will update the general and small business (SBIR/STTR) application guides used with FORMS-C application forms. Instructions for individual fellowship applications will be incorporated into the general application guide and no longer maintained as a separate document. These application guides must be used for due dates on or after January 25, 2016, and before May 25, 2016.

CHANGES *(Phase 1)*:

Topic	Change
Rigor and Transparency*	<p data-bbox="614 425 1696 753">We are changing application requirements and review language to enhance reproducibility of research findings through increased scientific rigor and transparency. These changes will take effect for most research grant applications (including small business and complex research grant applications), but will not impact institutional training and individual fellowship applications until Phase II.</p> <p data-bbox="614 789 929 825">Changes include:</p> <ul data-bbox="672 861 1696 1239" style="list-style-type: none"><li data-bbox="672 861 1696 953">• Updates to application guide instructions for preparing your research strategy attachment<li data-bbox="672 961 1696 1139">• 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)<li data-bbox="672 1146 1696 1239">• Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications <p data-bbox="614 1275 1392 1310">See NOT-OD-16-011 and NOT-OD-16-012.</p>

Vertebrate Animals*	<p>We are removing redundancy with Institutional Animal Care and Use Committee review while meeting the requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals.</p> <p>Changes include:</p> <ul style="list-style-type: none">• 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 <p>See NOT-OD-16-006.</p> <p>Note: This change does not apply to AHRQ applications.</p>
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Research Training	<p>We are updating requirements and instructions for several attachments on the PHS 398 Research Training Program Plan form to reflect recent policy guidance and reduce applicant burden.</p> <p>Changes include:</p> <ul style="list-style-type: none">• "Recruitment and Retention Plan to Enhance Diversity" - applicants will be asked to focus on recruitment• "Human Subjects" - applicants must describe how the institution will ensure that trainees only participate in exempt human subjects research or non-exempt human subjects research that has IRB approval; no longer necessary to provide a list of potential grants trainees may work on and associated IRB information• "Vertebrate Animals" - applicants must describe how the institution will ensure that trainees only participate in vertebrate animal research that has IACUC approval; no longer necessary to provide a list of potential grants trainees may work on and associated 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
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Definition of Child*

We are 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.

See [NOT-OD-16-010](#).

Note: This change does not apply to AHRQ applications.

Policy & Guidance Changes - Phase 2

- **Timing**

Effective for applications submitted for due dates on or after May 25, 2016

- **Application Forms**

FORMS-D: Our updated forms, identified by a Competition ID of "FORMS-D", must be used for all applications submitted for due dates on or after May 25, 2016.

- All active Funding Opportunity Announcements (FOA) will be reissued or updated to include "FORMS-D" forms at least 60 days prior to the first due date on or after May 25, 2016.
- FORMS-C application packages will be set to expire after the May 7, 2016 AIDS due date. During a short transition period, you will need to select the appropriate application package based on due date.

- **Instructions**

.By March 25, 2016, we will provide new application guides to be used with FORMS-D application forms for due dates on or after May 25, 2016.

<p>Rigor and Transparency*</p>	<p>We are extending Phase 1 changes to include institutional training and individual fellowship applications.</p> <p>We are adding a new "Authentication of Key Biological and/or Chemical Resources" attachment to the following forms in FORMS-D application packages:</p> <ul style="list-style-type: none"> • PHS 398 Research Plan • PHS 398 Career Development Supplemental Form • PHS Fellowship Supplemental Form <p>New "Plan for the Instruction in Methods for Enhancing Reproducibility" attachment will be added to the PHS 398 Research Training Program Plan form in FORMS-D application packages.</p>
<p>Vertebrate Animals*</p>	<p>We are extending Phase 1 changes to include institutional training and individual fellowship applications.</p> <p>See NOT-OD-16-006.</p> <p>We are adding new questions regarding euthanasia to the following forms in FORMS-D application packages to replace the euthanasia criteria in the vertebrate animals section:</p> <ul style="list-style-type: none"> • PHS 398 Research Plan • PHS Fellowship Supplemental Form <p>Note: These changes do not apply to AHRQ applications.</p>

<p>Inclusion Forms*</p>	<p>We are adding an optional PHS Inclusion Enrollment Report form to FORMS-D application packages.</p> <p>The new form, with additional study descriptors, will replace the optional Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms found in FORMS-C application packages.</p> <p>We will provide more details about these changes prior to release of the updated forms.</p>
<p>Data Safety Monitoring Plans</p>	<p>We are adding a new “Data Safety Monitoring Plan” to the following forms in FORMS-D application packages:</p> <ul style="list-style-type: none"> • PHS 398 Research Plan • PHS 398 Career Development Supplemental Form • PHS Fellowship Supplemental Form • PHS 398 Research Training Program Plan <p>This new attachment must be included with all applications involving clinical trials.</p> <p>Although the requirement of a data and safety monitoring plan for clinical trials is not new, the use of a separate attachment to collect this information will emphasize its importance and facilitate systematic enforcement of its presence.</p>

Research Training	<p>We are changing the research training data table format.</p> <p>Changes include:</p> <ul style="list-style-type: none">• Reducing the number of tables from 12 to 8• Minimizing the reporting of individual-level information• Extending the tracking of trainee outcomes from 10 to 15 years <p>NIH's xTRACT system to help applicants prepare the new tables will be available October 16, 2015.</p> <p>See NOT-OD-16-007.</p>
Appendix Policy	<p>We are reevaluating the current appendix policy. A notice describing specific appendix policy changes will be issued by spring 2016.</p>
New PHS Assignment Request Form	<p>We are adding an optional PHS Assignment Request Form to FORMS-D application packages to provide a consistent way to collect application referral information, including:</p> <ul style="list-style-type: none">• Awarding component (NIH institute) assignment preference• Study Section preference• List of potential reviewers in conflict, and why• List of scientific expertise needed to review the application• <p>See NOT-OD-16-008.</p>

New Font Guidelines	<p>We are providing additional flexibility regarding the fonts allowed in PDF attachments included in grant applications.</p> <p>Although we will continue to recommend specific fonts, we will also allow other fonts (both serif and non-serif) as long as they comply with specific type density and line spacing guidelines.</p> <p>See NOT-OD-16-009.</p>
Biosketch Clarifications	<p>We are clarifying biosketch instructions.</p> <p>Clarifications include:</p> <ul style="list-style-type: none">• Indicating that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography• Allowing publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections• Explicitly stating that graphics, figures and tables are not allowed

Font guidelines

- Text in PDF attachments must follow these minimum requirements:
 - **Font size:** must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)
 - **Type density:** must be no more than 15 characters per linear inch (including characters and spaces)
 - **Line spacing:** must be no more than six lines per vertical inch
 - **Text Color:** must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable as long as it is legible)
- The following fonts are recommended, although other fonts (**both serif and non-serif**) are **acceptable** if they meet the above requirements.
 - **Arial**
 - **Garamond**
 - **Georgia**
 - **Helvetica**
 - **Palatino Linotype**
 - **Times New Roman**
 - **Verdana**
- Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

Upcoming Changes to Post-Award Forms and Instructions

Forms	Title	Planned Changes	Targeted Effective Date
RPPR	PHS Research Performance Progress Report (RPPR)	New training data tables are in use. See NOT-OD-15-112 and NOT-OD-16-007 .	12/1/2015
		Updates Coming to the Screens in the Inclusion Management System (IMS). More information will be posted in a separate Guide Notice just prior to when the changes will be implemented.	1/22/2016
		Addition of clarifying rigor language. See NOT-OD-16-011 and NOT-OD-15-012 .	1/25/2016
PHS 2271	Statement of Appointment	Editorial clarifications to form items and instructions. New list of Field of Training codes. Reporting of tuition/fees and travel eliminated for NIH trainees. Updated list of Specialty Boards.	1/22/2016
PHS 416-7	NRSA Termination Notice	Editorial clarifications to form items and instructions. Instructions for fellows sponsored by Federal or foreign institutions updated to reflect current payment policies.	1/22/2016
PHS 2590	Noncompeting Continuation Progress Report	Updates Coming to Inclusion Enrollment Report Forms. More information will be posted in a separate Guide Notice just prior to when the changes will be implemented.	3/25/2016
Final Progress Report	Final Progress Report Instructions	Updates Coming to Inclusion Enrollment Report Forms. More information will be posted in a separate Guide Notice just prior to when the changes will be implemented.	3/25/2016

No changes or minimal editorial clarifications:

Forms	Title	Changes
PHS 6031-1	NRSA Annual Payback Activities Certification	No changes.
HHS 568	Final Invention Statement and Certification	No changes.
PHS 3734	Official Statement Relinquishing Interest and Rights in a PHS Research Grant	No changes.
SBIR/STTR Phase II Final Progress Report	Format for SBIR/STTR Phase II Final Progress Report	No changes.
Training Diversity Report	Training Diversity Report	Editorial clarifications.
SBIR Life Cycle Certification	Certifications for SBIR/STTR grantees to confirm continuing compliance with program requirements	Editorial clarifications.
STTR Life Cycle Certification	Certifications for SBIR/STTR grantees to confirm continuing compliance with program requirements	Editorial clarifications.



National Science Foundation
WHERE DISCOVERIES BEGIN



Revised version of NSF *Proposal and Award Policies and Procedures Guide* (NSF 16-1) has been issued.

- The new PAPPG will be effective for **proposals submitted, or due, on or after January 25, 2016**. Significant changes include:
- Enforcement of 5:00 PM submitter's local time across all NSF funding opportunities;
- Implementation of NSF's Public Access Policy;
- Submission of proposal certifications by the Authorized Organizational Representative (AOR) concurrently with proposal submission;
- NSF's implementation of the US Government Policy for Institutional Oversight of Life Sciences on Dual Use Research of Concern;
- Provision of Collaborators and Other Affiliations information as a new single-copy document, instead of as part of the Biographical Sketch;

- Submission of Biographical Sketches and Current and Pending Support separately for each senior personnel;
- Electronic signature and submission of notifications and requests by the AOR only;
- Revision of timeframe for submission of final project reports, project outcomes reports and financial closure of awards to 120 days after the award end date; and
- Numerous clarifications throughout the document.

In the interim, the guidelines contained in the current PAPPG (NSF 15-1) continue to apply until January 25, 2016 and will remain on the NSF website.

Webinars for Applicants and Grant Administrators:

What You Need to Know About NIH Application Submission and Review

- [Notice Number: NOT-OD-15-154](#)

Webinar Focus	Date
University Research Administrators	November 5, 2015
Research Project Grants (R01)	November 6, 2015

All of the webinars will run from 2:00 to 4:00 p.m. EST, including a 30 minute Q&A period.

Viewers Will See Presentations by Five CSR/NIH Experts

- The Review of Your NIH Grant Application Begins Here
- What You Need to Know about Application Receipt and Referral
- How Your Application Is Reviewed
- Key Things to Know About the NIH Grants Program
- Jumpstart Your Career with CSR's Early Career Reviewer Program (R01 webinar only)

How to Participate in the Webinar

- Go to www.csr.nih.gov/webinar to register for the webinar you wish to join by **Monday, October 29**. You will not need to download special software. You will just need a reliable Internet connection and browser.
- **Submit questions for the Q&A session before or during the webinar** by sending them to the moderator at AskExperts@csr.nih.gov.
- Go to www.csr.nih.gov/webinar on the day/time your webinar is scheduled. Click on the link that will be provided there to view it.