Upcoming NIH Changes

Presented by

Sponsored Projects Administration (SPA)
Implementing New Forms and Policies in Phases

<table>
<thead>
<tr>
<th>Phase</th>
<th>Form Type</th>
<th>Forms Available On...</th>
<th>Must Use By...</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>FORMS-C</td>
<td>Now</td>
<td>Before 1/25/16</td>
</tr>
<tr>
<td>Phase I</td>
<td>FORMS-C (enhanced): with updated instructions</td>
<td>Released 11/25/15</td>
<td>On or after 1/25/16, but before 5/25/16</td>
</tr>
<tr>
<td>Phase II</td>
<td>FORMS-D (updated forms)</td>
<td>By 3/25/16</td>
<td>On or after 5/25/16</td>
</tr>
</tbody>
</table>

Need to be careful downloading forms from the FOAs. There may be overlap between FORMS C and D. Make sure to download appropriate form set based on proposal due date.
Key Changes

Changes focus on the following areas, but implementation is divided into phases:

• Rigor and transparency in research – both Phases I & II
• Vertebrate animals – both Phases I & II
• Definition of Child – Phase I
• Requirements for PHS 398 Research Training Program Plan - Phase I
• Inclusion reporting – Phase II
• Data safety monitoring – Phase II
• Institutional Training Grants - new tables required Phase II
• Font requirements – Phase II
• Biosketch clarifications – Phase II
Rigor & Reproducibility Resources

  - PLEASE refer to this website!
  - See the training resources and application instructions.
- Email questions to [reproducibility@nih.gov](mailto:reproducibility@nih.gov)
Rigor & Reproducibility

• Identified need for rigorously designed published preclinical studies.

• **Rigor** - ensures robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.

• **Reproducibility** – if results are reproduced by multiple scientists, it validates the original results and readiness to progress to the next phase of research – in particular clinical trials.

• NIH worked with 30 basic/preclinical science journals - identifying the common opportunities in the scientific publishing arena to enhance rigor and further support research that is reproducible, robust, and transparent. Many additional journals are endorsing this.
## Four Key Areas to Address Rigor & Transparency in Applications

<table>
<thead>
<tr>
<th>Key Area</th>
<th>Application Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Premise</td>
<td>Research Strategy: Significance (scored)</td>
</tr>
<tr>
<td>Scientific Rigor</td>
<td>Research Strategy: Approach (scored)</td>
</tr>
<tr>
<td>Consideration of Relevant Biological Variables, such as sex</td>
<td>Research Strategy: Approach (scored)</td>
</tr>
<tr>
<td>Authentication of Key Biological and/or Chemical Resources</td>
<td>New Attachment (not scored): to be saved as a single file named “Authentication of Key Resources Plan” attached as Item 12, Other Attachments, on the Other Project Information form.</td>
</tr>
</tbody>
</table>

**Phase I:** These new Rigor and Transparency instructions apply to *Research* grants and *Career Development Awards* due on or after **January 25th, 2016**.

**Phase II:** These new instructions apply to *Individual Fellowships* and *Institutional Training Grants* due on or after **May 25th, 2016**.
Page Limitations are still the Same!

• The page limits for the Research Strategy section are still the same. See the following table:


• Note that the application instructions in specific Funding Opportunity Announcement (FOA) *supersedes* the SF 424 Application Instructions, in case there are conflicts.

• Note that instructions differ slightly for Career Development, Fellowships and Institutional Training Grants. Read the new instructions carefully.
Phase I Form Changes

Rigor & Transparency

- affects most RESEARCH and CAREER DEVELOPMENT grants

- to enhance reproducibility of research findings through increased scientific rigor and transparency

- See NOT-OD-16-011 and NOT-OD-16-012.

- Updates to application instructions for preparing the research strategy attachment

- New "Authentication of Key Biological and/or Chemical Resources" attachment

- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications
Phase I Form Changes

Vertebrate Animals

See NOT-OD-16-006.

Nothing NEW – criteria reduced and simplified

VAS guidance: http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm

- 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
**Phase I Form Changes**

<table>
<thead>
<tr>
<th>Definition of Child</th>
<th>Redefining the age of a child for the purposes of NIH's inclusion policy to individuals under <strong>18 years old</strong> instead of under 21 years old.</th>
</tr>
</thead>
<tbody>
<tr>
<td>See <strong>NOT-OD-16-010</strong>.</td>
<td>Note: This change does not apply to AHRQ applications.</td>
</tr>
</tbody>
</table>

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Phase I Form Changes

Institutional Training Grants:

- "Recruitment and Retention Plan to Enhance Diversity" - new focus on recruitment

- "Human Subjects" - 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" - 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
Phase II

• All active FOAs will be reissued or updated to include "FORMS-D" by March 25th, 2016

• NIH will reissue parent announcements, administrative supplements, research training, career development, individual fellowship and multi-project FOAs that include "Indiv Career Dev", "Inst Career Dev" or "NRSA Training" component types, plus all other active research FOAs.

• 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.

• New FORMS-D Instructions to be released by March 25th
# Phase II Form Changes

<table>
<thead>
<tr>
<th>Rigor &amp; Transparency</th>
<th>• New &quot;Authentication of Key Biological and/or Chemical Resources&quot; attachment to the following forms in FORMS-D application packages:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• New requirements extends to institutional training grants and individual fellowships</td>
<td>• PHS 398 Research Plan</td>
</tr>
<tr>
<td>• See <a href="NOT-OD-16-011">NOT-OD-16-011</a> and <a href="NOT-OD-16-012">NOT-OD-16-012</a>.</td>
<td>• PHS 398 Career Development Supplemental Form</td>
</tr>
<tr>
<td></td>
<td>• PHS Fellowship Supplemental Form</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
Phase II Form Changes

Vertebrate Animals

New requirements extends to institutional training grants and individual fellowships

See NOT-OD-16-006.

• New questions regarding euthanasia to the following forms in FORMS-D application packages to replace the euthanasia criteria in the vertebrate animals section:
  • PHS 398 Research Plan
  • PHS Fellowship Supplemental Form

Note: These changes do not apply to AHRQ applications.
Phase II - New Forms

• Inclusion Forms - will replace the optional Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms. More info to come.

• New “Data Safety Monitoring Plan” - must be included with all applications involving clinical trials. Now a separate attachment.

• Appendix Policy is changing – no info yet

• New PHS Assignment Request Form – Optional
  • 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
  • See NOT-OD-16-008.
Phase II - New Font Guidelines!

• See NOT-OD-16-009

• Additional flexibility

• Will also allow other fonts (both serif and non-serif) as long as they comply with specific type density and line spacing guidelines.
  • Recommended fonts - Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana

• **Font size:** must be 11 points or larger

• **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
Phase II - NIH Biosketch Clarifications effective 5/25/16

• 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.

• Must follow exact format, instructions and page limits, or could get application rejected.
Resources for the Changes

**The new application guide for FORMS VERSION C, updated 11/25/2015, to be used for applications due on and between 1/25/2016 and 5/24/2016.**


- Announcement of Policy changes:
- NOT-OD-16-004:

- List of FORMS-D changes:

- Forms Updates FAQs:

- Do I have the right forms?
# NIH & AHRQ Post-Award Forms

<table>
<thead>
<tr>
<th>Forms</th>
<th>Title</th>
<th>Planned Changes</th>
<th>Targeted Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHS 2271</td>
<td>Statement of Appointment</td>
<td>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.</td>
<td>1/22/2016</td>
</tr>
<tr>
<td>PHS 416-7</td>
<td>NRSA Termination Notice</td>
<td>Editorial clarifications to form items and instructions. Instructions for fellows sponsored by Federal or foreign institutions updated to reflect current payment policies.</td>
<td>1/22/2016</td>
</tr>
<tr>
<td>PHS 2590</td>
<td>Noncompeting Continuation Progress Report</td>
<td>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.</td>
<td>3/25/2016</td>
</tr>
<tr>
<td>Final Progress Report Instructions</td>
<td>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.</td>
<td>3/25/2016</td>
<td></td>
</tr>
</tbody>
</table>
The following forms have either no changes or minimal editorial clarifications. Effective immediately, new forms will be available on the NIH Forms & Applications page.

<table>
<thead>
<tr>
<th>Forms</th>
<th>Title</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHS 6031-1</td>
<td>NRSA Annual Payback Activities Certification</td>
<td>No changes.</td>
</tr>
<tr>
<td>HHS 568</td>
<td>Final Invention Statement and Certification</td>
<td>No changes.</td>
</tr>
<tr>
<td>PHS 3734</td>
<td>Official Statement Relinquishing Interest and Rights in a PHS Research Grant</td>
<td>No changes.</td>
</tr>
<tr>
<td>SBIR/STTR Phase II Final Progress Report</td>
<td>Format for SBIR/STTR Phase II Final Progress Report</td>
<td>No changes.</td>
</tr>
<tr>
<td>SBIR Life Cycle Certification</td>
<td>Certifications for SBIR/STTR grantees to confirm continuing compliance with program requirements</td>
<td>Editorial clarifications.</td>
</tr>
<tr>
<td>STTR Life Cycle Certification</td>
<td>Certifications for SBIR/STTR grantees to confirm continuing compliance with program requirements</td>
<td>Editorial clarifications.</td>
</tr>
</tbody>
</table>
Extramural Trainee Reporting And Career Tracking (xTRACT)

- New training table required for RPPRs due on or after 12/1/2015 (was Table 12, now called Table 8)
- New and competing applications must use new training grant tables for due dates on or after 5/25/2016
- Can use xTRACT on a pilot basis (not required)
- Available in the eRA Commons
- New Tables can be found here:
  - Columbia was involved with the pilot testing of xTRACT. More communications to come for PIs and administrators of training grants.
Welcome to xTRACT!

xTRACT may be used to prepare data tables for submission with NIH and other Public Health Service agency institutional research training grant applications and progress reports.

For FY 2016, xTRACT is available on a pilot basis for T32, TL1, T90/R90, and T15 training grants, to create data tables for Research Performance Progress Reports due December 1, 2015 or later and applications submitted for the May 25, 2016 due date and after.
NIH Proposal Preparation Options

NIH ASSIST:
- Quick Guide (single-project)
- Multi-Project Training – contact SPA Project Officer to set up a training, if needed

InfoEd Proposal Development (PD):

Adobe Forms still an option
Questions

• Contact your Sponsored Projects Administration (SPA) Project Officer

• Contact Stephanie Scott, Communications & Outreach Director, for general policy questions, information about xTRACT, or ASSIST
  • sfs2110@columbia.edu

• Contact SPA-eBiz@columbia.edu for questions concerning InfoEd or the eRA Commons.