Changes to NIH Policies, Instructions, and Forms for 2016

UPCI Basic Research Faculty Meeting
January 29, 2016
• **ASSIST** is now an option for submitting most grant applications. We highly recommend using ASSIST as we have noted a lot less errors during the submission process.

• **COI Superform for 2016** must be completed by April 15, 2016. The 2015 forms will be accepted until April 14th.

• **CITI Training- Conflict of Interest, Responsible Conduct of Research, Human Subjects Research** expires every 3 years. Please be sure to update. Many of these forms were completed in late 2012/early 2013 and are due to be updated.

• **CITI COI and current COI Superform** must be completed before the Office of Research will submit grants on your behalf. Be sure they are up to date!!
Reminder:
Investigators whose proposed work involves the generation or use of large-scale genomic data should:
• state this in the cover letter
• include a genomic data sharing plan in your application
  ➢ NIH Guidance in Developing Genomic Data Sharing Plans

Investigators who plan to use controlled-access human genomic data from NIH-designated data repositories as a secondary user, include the following in the Research Plan of your application:
• a brief plan for requesting access to the data
• state your intention to abide by the NIH Genomic Data User Code of Conduct

See NOT-OD-14-124 and NOT-OD-15-027 for further guidance
### NIH Implementing New Forms & Policies in Phases

**Form Implementation**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Form Type</th>
<th>Forms Available</th>
<th>Must Use</th>
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<tbody>
<tr>
<td>Phase I</td>
<td>Implements a subset of policy changes to existing FORMS-C</td>
<td>Released 11/25/15</td>
<td>On or After 01/25/16, but before 05/25/16</td>
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<tr>
<td>Phase II</td>
<td>Implements remaining policy changes and <strong>new</strong> FORMS-D</td>
<td>By 03/25/16</td>
<td>On or After 05/25/16</td>
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UPCI Fiscal will initiate the correct form/application in ASSIST and/or provide the correct grants.gov files.

**NOT-OD-16-004** summarizes the changes for 2016 grant applications.

Revised  **NIH Grants Policy Statement (Rev. 11/2015)** effective for all awards with budget periods beginning on or after October 1, 2015.
# Key Policy Changes and Phases

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<tr>
<th>Change</th>
<th>Phase I</th>
<th>Phase II</th>
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<td>Rigor and Transparency in Research</td>
<td>X</td>
<td>X</td>
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<td>Vertebrate Animals</td>
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<td>X</td>
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<td>Definition of Child</td>
<td>X</td>
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<td>Requirements for PHS 398 Research Training Program Plan</td>
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<td>Inclusion Reporting</td>
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<td>Data Safety Monitoring Plans</td>
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<td>Institutional Training Grants- new tables required</td>
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<td>New PHS Assignment Request Form</td>
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<td>Font Requirements</td>
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<td>Biosketch Clarifications</td>
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<tr>
<td>Rigor &amp; Transparency requirements for institutional training grants, institutional career development awards, &amp; individual fellowships</td>
<td></td>
<td>Delayed until FY 2017</td>
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Rigor & Transparency in Research – Phase I

• Changes made to both application instructions & review guidelines

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

• Changes will take effect for most research grant applications (including small business and complex research grant applications) and Career Development Awards with due dates on/after January 25, 2016

• Will not impact institutional training and individual fellowship applications until early FY 2017
Changes include:

• Updates to application guide instructions for preparing your Research Strategy attachment
  ➢ Page limits for the Research Strategy section remain the same

• Required use of new Authentication of Key Biological and/or Chemical Resources attachment
  ➢ Required for all February 5th R01s
  ➢ Upload in Other Attachment section on R&R Other Project Information form

• Reviewers will be given additional rigor and transparency questions to consider when reviewing applications

• See NOT-OD-16-011 and NOT-OD-16-012 for further guidance
Updates focus on 4 areas deemed important for enhancing rigor and transparency:

1. Scientific Premise of Proposed Research
2. Rigorous Experimental Design for robust & unbiased results
3. Consideration of Relevant Biological Variables, such as sex
4. Authentication of Key Biological and/or Chemical Resources
Rigor & Reproducibility Resources

For further guidance refer to the following websites:

- **NIH- Research & Training- Rigor & Reproducibility**

  Resources include:
  - Principles and Guidelines
  - Publications
  - Training
  - Meetings and Workshops
  - Expanded Guidelines
  - Application Instructions

Rigor Reproducibility FAQS:

**FAQS- Rigor & Reproducibility**

FAQS on Forms Changes:

**Form Updates 2016 - FAQS**
Vertebrate Animals- Phase I

Changes made to remove redundancy with IACUC review.

The vertebrate animal attachment must address the following:

• Updated guidance on criteria to be addressed (description of procedures; justifications; minimization of pain and distress; and euthanasia)

• No longer require a description of veterinary care

• No longer need a justification for the number of animals

• A description and justification of the method of euthanasia is only required if the method is not consistent with AVMA Guidelines

• See NOT-OD-16-006 for further guidance
NIH lowered the age of a child for the purposes of its inclusion policy to individuals under 18 years old instead of under 21 years old.

See [NOT-OD-16-010](#) for further guidance.
Changes to Post Award Forms & Instructions

Newly revised forms and instructions will be posted on the NIH Forms & Applications page of the NIH website.

**RPPR (Progress Report, non-competing type 5) Changes:**

1. Addition of rigor language
   - Updates to Section B - Accomplishments
   - See **NOT-OD-16-011** & **NOT-OD-15-012** for further guidance

2. New training data tables are in use
   - See **NOT-OD-15-112** and **NOT-OD-16-007** for further guidance

3. Updates coming to the screens in the Inclusion Management System
   - IMS online help guide was revised 1/21/16
   - More information will be posted in a separate guide notice
   - IMS changes for Noncompeting Continuation Progress Report (PHS 2590) and Final Progress Report Instructions (Final Progress Report)
Effective for due dates on or after May 25, 2016

- FORMS-C application packages will expire after the May 7, 2016 AIDS due date
- New FORMS-D Instructions will be released by March 25, 2016
- New FORMS-D forms **must** be used for all applications
- New application guides to be used with FORMS-D forms will be provided by March 25, 2016
- NIH will reissue parent announcements, administrative supplements, research training, career development, individual fellowship, and multi-project FOAs that include Individual Career Development, Institutional Career Development or NRSA Training component types
- **FORMS-D** application packages will be added to all other active FOAs
Rigor and Transparency- Phase II

• New Authentication of Key Biological and/or Chemical Resources attachment will be added to the following forms in FORMS-D application packages:
  – PHS 398 Research Plan
  – PHS 398 Career Development Supplemental Form
  – PHS Fellowship Supplemental Form

• New Plan for the Instruction in Methods for Enhancing Reproducibility attachment will be added to
  – PHS 398 Research Training Program Plan form in FORMS-D application packages
Vertebrate Animals- Phase II

- NIH will extend Phase I changes to include institutional training and individual fellowship applications.

- New questions regarding euthanasia will be added to the following forms in FORMS-D application packages to replace the euthanasia criteria in the vertebrate animals section:
  - PHS 398 Cover Page Supplement
  - PHS Fellowship Supplemental Form

- See NOT-OD-16-006 for further guidance.
Inclusion Forms- Phase II

- An optional **PHS Inclusion Enrollment Report** form will be added to FORMS-D application packages.

- The new form will replace the optional Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms found in FORMS-C application packages.

- More details will be provided about these changes prior to release of the updated forms.
Data Safety Monitoring Plans - Phase II

• New **Data Safety Monitoring Plan** will be added to the following forms in FORMS-D application packages:
  – PHS 398 Research Plan
  – PHS 398 Career Development Supplemental Form
  – PHS Fellowship Supplemental Form
  – PHS 398 Research Training Program Plan

• This new attachment **must** be included with all applications involving clinical trials.
• NIH is reevaluating the current appendix policy.

• A notice describing specific appendix policy changes will be issued by spring 2016
New PHS Assignment Request Form

• Applicants who want to communicate requests pertinent to the assignment and initial peer review of applications must use a new **PHS Assignment Request Form**

• This **optional** form will be added to FORMS-D application packages to provide a consistent way to collect application referral information, including:
  – 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](#) for further guidance.
Font Guidelines Phase II

• Additional flexibility will be provided regarding the fonts allowed in PDF attachments included in grant applications.

• Specific fonts will continue to be recommended.

• Applicants will be allowed to use other fonts (both serif and non-serif) as long as they comply with specific type density and line spacing guidelines.

• See [NOT-OD-16-009](https://example.com/not-od-16-009) for further guidance.
Biosketch Instruction Clarifications include:

- A URL leading to a publication list is optional but if provided, it must lead to a government website (.gov) like My Bibliography.

- Allowing publications (peer-reviewed or not) and research products to be cited in both the Personal Statement and the Contributions to Science sections.

- Explicitly states that graphics, figures, and tables are not allowed.

- Must follow exact format, instructions, and page limits, or application could get rejected.

- See [NOT-OD-15-024](#) and [NOT-OD-16-004](#) for further guidance.
Thank You