



Changes to NIH Policies, Instructions, and Forms for 2016

UPCI Basic Research Faculty Meeting
January 29, 2016



University of Pittsburgh
Cancer Institute
Partner with UPMC CancerCenter



INTERNAL REMINDERS

- **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!!

NIH Genomic Data Sharing Policy

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

Phase	Form Type	Forms Available	Must Use
Phase I	Implements a subset of policy changes to existing FORMS-C	Released 11/25/15	On or After 01/25/16, but before 05/25/16
Phase II	Implements remaining policy changes and new FORMS-D	By 03/25/16	On or After 05/25/16

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

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

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

Rigor and Transparency- Phase I - continued

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

Rigor and Transparency- Phase I - continued

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

Definition of Child- Phase I

- NIH lowered the age of a child for the purposes of it's 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)

Policy & Guidance Changes-Phase II

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.

Appendix Policy – Phase II

- 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](#) for further guidance.

Biosketch Clarifications – Phase II

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



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