Summary of Changes to NIH/AHRQ Application form packages:

NIH is changing policies, forms, and instructions for grant applications submitted in 2016. These changes will take phase in two phases.

- **Phase 1:** Effective for applications submitted for due dates on or after January 25, 2016.
- **Phase 2:** Effective for applications submitted for due dates on or after May 25, 2016.


**FORMS-C** - This is the current application forms which are already available. Use for all application due before May 25, 2016. Revised application guide will be available by November 25, 2016. The guide will include instructions for individual fellowship application; there will no longer be a separate document.

**FORMS-D** - These forms will be used for applications due on or after May 25, 2016. The application guide will be available late March.

*Please note that 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.*

In mid-March FOAs will be updated to reference FORMS-D. Training and development FOAs will be reissued.

**Rigor and Transparency**

**Phase 1: January 25, 2016**

- Applicable to research grants.
- NIH is changing application requirements and review language to enhance reproducibility of research findings through increased scientific rigor and transparency. PIs will address in the Research Strategy.
- There is a new mandatory “Authentication of Key Biological and/or Chemical Resources” attachment. For FORMS C PIs will upload attachment to Other Attachments section of the R&R Other Project Information form.
- RPPRs submitted January 25, 2016 or later will be expected to emphasize rigorous approaches taken to ensure robust and unbiased results. Rigor should be addressed in the RPPR for any grant that funds research or training in research; grants that support other activities do not need to address rigor. The RPPR instructions will be updated by January 25, 2016.

**Phase 2: May 25, 2016**

- Extending Phase 1 changes to include institutional training and individual fellowship applications.
- FORMS D will have a new attachment field on PHS 398 Research Plan form for “Authentication of Key Biological and/or Chemical Resources”
**Vertebrate Animals**  
*Not applicable to AHRQ.*

**Phase 1: January 25, 2016**

- Applicable to research grants.
- 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 2: May 25, 2016**

- Extending Phase 1 changes to include institutional training and individual fellowship applications.
- FORMS D will have new questions regarding to replace the euthanasia criteria in the vertebrate animals section.

**Definition of Child**  
*Not applicable to AHRQ.*

**Phase 1: January 25, 2016**

- Child is redefined to under age 18 instead of under 21. This will align it with the typical age of consent and perception of childhood, which will allow less confusion in implementation of inclusion policy while emphasizing children as a vulnerable population that need particular attention.

**Research Training proposals**

**Phase 1: January 25, 2016**

NIH is 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.

- 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

**Phase 2: May 25, 2016**

- NIH is changing the research training data table format. NIH’s xTRACT system to help applicants prepare the new tables. There will be fewer tables with less reporting on the individual-level, but the tracking of trainee outcomes will be extended to 15 years.
Inclusion Forms

Phase 2: May 25, 2016

- FORMS-D application packages will have an optional PHS Inclusion Enrollment Report form that will replace the Planned Enrollment Report and the Cumulative Inclusion Enrollment Report. Guidelines are pending.

Data Safety Monitoring Plans

Phase 2: May 25, 2016

- New attachment in FORMS-D application packages. This will be required for all applications involving clinical trials.

PHS Assignment Request Form

Phase 2: May 25, 2016

- New attachment in FORMS-D application packages. Use to make review assignment requests. NIH will no longer check the Cover Letter Attachment for requests pertinent to the assignment and review of applications.

Fonts

Phase 2: May 25, 2016

- While there will be NIH-recommended fonts, NIH will allow additional flexibility in font choice. Fonts must meet requirements for: Font size, type density, line spacing, text color.

Biosketches

Phase 2: May 25, 2016

- Instruction will be clarified:
  - Optional URL for publication list must be to a government website.
  - Publications and products may be cited in both Personal Statement and Contributions to Science.
  - Graphics, figures, and tables are not allowed.

Appendix

- NIH is reevaluating policy and will a notice by Spring 2016.

October 27, 2015