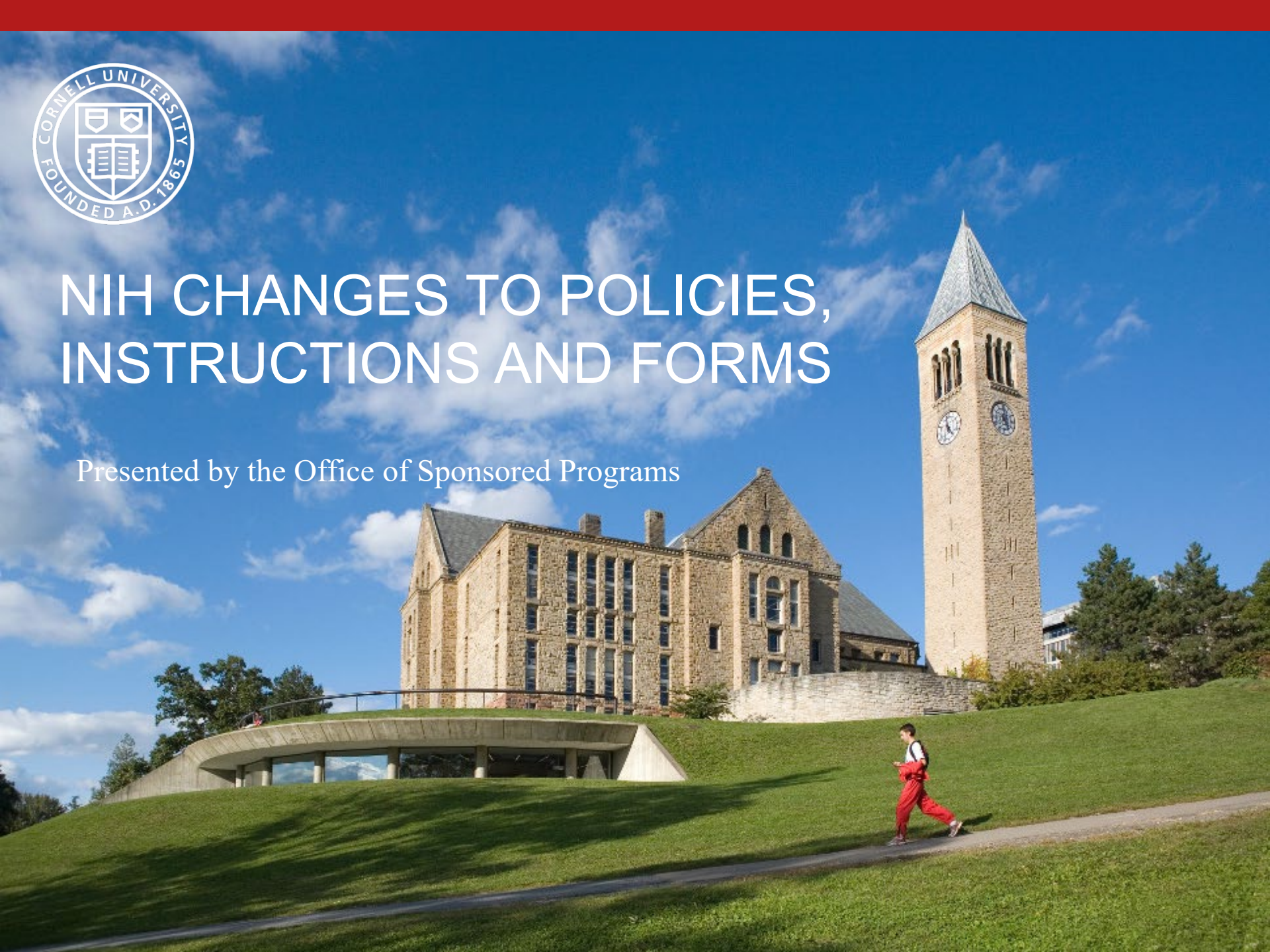


NIH CHANGES TO POLICIES, INSTRUCTIONS AND FORMS

Presented by the Office of Sponsored Programs





NIH CHANGES

- Phase 1 – For due dates on or after January 25, 2016
- Phase 2 – For due dates on or after May 25, 2016

See: [NOT-OD-16-004](#)



PHASE 1:

- Applies to FORMS-C application forms
- Required for due dates on or after January 25, 2016
- Implements the following policy changes:
 - Rigor and Transparency
 - Vertebrate Animals
 - Definition of Child
 - Research Training



Rigor and Transparency

- Revisions to application guide instructions for preparing your research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

See: [NOT-OD-16-011](#) and [NOT-OD-16-012](#)



Rigor and Transparency – 4 main focus areas

- 1) the scientific premise forming the basis of the proposed research
- 2) rigorous experimental design for robust and unbiased results
- 3) consideration of relevant biological variables
- 4) authentication of key biological and/or chemical resources



Authentication of key biological and/or chemical resources

Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

- Key biological and/or chemical resources may or may not be generated with NIH funds and:
 - 1) may differ from laboratory to laboratory or over time
 - 2) may have qualities and/or qualifications that could influence the research data
 - 3) are integral to the proposed research
- Can include: Cell lines, specialty chemicals, antibodies, other biologics
- Doesn't include: Standard laboratory reagents, buffers, common chemicals
- Reviewers will be asked to assess this information
- Information in this section must focus only on authentication and/or validation of key resources to be used in the study



Rigor and Transparency - Research Strategy Updates

- **SIGNIFICANCE**

- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application

- **APPROACH**

- Describe the experimental design and methods proposed and how they will achieve robust and unbiased results
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex

There are some activity code exceptions to this policy, and some grants that will be subject to this policy only with the implementation of Phase II



Rigor and Transparency- RPPR

- Research Performance Progress Reports (RPPR) 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. This includes non-competing continuation reports (Type 5) for grants reviewed and awarded before implementation of the policy.



Vertebrate Animals

Vertebrate Animals section should include:

- Description of the procedures
- Justifications of the species in relation to the proposed work
- Minimization of Pain and Distress
- Euthanasia (If consistent with AVMA guidelines, only need to state as such, otherwise need entire justification)

Summary of Changes:

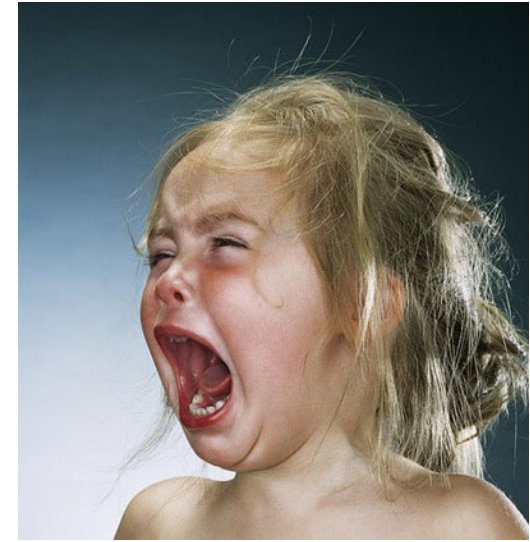
- A description of vet care no longer required
 - No justification of number of animals required
 - Full description of euthanasia method required only if not consistent with AVMA guidelines
-
- For all applications EXCEPT F series and T series grants implemented during Phase I

Does not apply to AHRQ applications!

See: NOT-OD-16-006



Definition of Child



- For proposals submitted for due dates on or after January 25, 2016, the age of a child will be defined as individuals under 18 years old instead of under 21 years old
- Applicants for NIH funding will still be expected to justify the age range of the proposed participants in their clinical research, with particular attention paid to addressing the inclusion (or exclusion) of children (or subsets of children)

Does not apply to AHRQ applications!

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



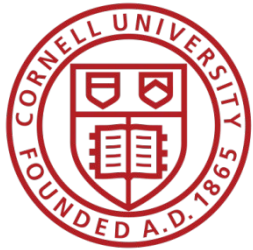
Research Training

- "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



PHASE 1

QUESTIONS?



PHASE 2:

- Applies to FORMS-D application forms
- Required for due dates on or after May 25, 2016
- Implements the following changes:
 - Rigor and Transparency
 - Vertebrate Animals
 - Inclusion Forms
 - Data Safety Monitoring Plans
 - Research Training
 - Appendix Policy
 - New PHS Assignment Request Form
 - New Font Guidelines
 - Biosketch Clarifications



Rigor and Transparency

- Extending Phase 1 changes to include institutional training and individual fellowship applications.
- Adding a new "Authentication of Key Biological and/or Chemical Resources" attachment 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 the PHS 398 Research Training Program Plan form in FORMS-D application packages.



Vertebrate Animals

- Extending Phase 1 changes to include institutional training and individual fellowship applications.
- See NOT-OD-16-006.
- Adding 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.



Inclusion Forms

- Adding an optional PHS Inclusion Enrollment Report form to FORMS-D application packages.
- 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.
- Provide more details about these changes prior to release of the updated forms.



Data Safety Monitoring Plans

- Adding a new “Data Safety Monitoring Plan” 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.
- 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.



Research Training

- Changing the research training data table format.
- Changes include:
 - 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
- NIH's xTRACT system to help applicants prepare the new tables became available as of October 16, 2015.
- See [NOT-OD-16-007](#).



Appendix Policy

- Reevaluating the current appendix policy. A notice describing specific appendix policy changes will be issued by spring 2016.



New PHS Assignment Request Form

- Adding an optional PHS Assignment Request Form 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](#).



New Font Guidelines

- Providing additional flexibility regarding the fonts allowed in PDF attachments included in grant applications.
- Although NIH will continue to recommend specific fonts, they will also allow 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](#).



Biosketch Clarifications

- Clarifying biosketch instructions.
- Clarifications include:
 - 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



PHASE 2

Questions?



Resources

- NOT-OD-16-004 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html>
- NOT-OD-16-031 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-031.html>
- NOT-OD-16-029 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-029.html>
- NOT-OD-16-012 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-012.html>
- NOT-OD-16-011 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html>
- NOT-OD-16-010 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html>
- NOT-OD-16-009 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-009.html>
- NOT-OD-16-008 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-008.html>
- NOT-OD-16-007 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-007.html>
- NOT-OD-16-006 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html>
- NOT-OD-16-005 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-005.html>
- NOT-OD-15-146 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-146.html>
- NOT-OD-15-112 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-112.html>



Contact your Grant and Contract Officer

Tammy Custer, tjb3, 255-5066

Kim Holloway, jkh44, 255-6841

Linda Griswold, lag13, 255-7280

Brenda Truesdail, bmt2, 255-7124

Chris Ashdown, Federal Team Lead, cma20, 255-3843

THANK YOU!