Updates to NIH policies and guidelines

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Research Funding & Development Services
What is NIH worried about?

- Biomedical research is complex. It involves sophisticated instruments and hundreds of reagents—a reproducibility problem.

- Recent studies show that findings from a significant percentage of scientific papers cannot be reliably reproduced by other researchers (50 – 90%).

- To address this, NIH is implementing changes to enhance reproducibility of the research they fund, thereby ensuring scientific integrity, public accountability, and social responsibility.
Implementation Timeline

*Phase I* – Effective for applications due on or after **January 25, 2016**

*Phase II* – Effective for applications due on or after **May 25, 2016**

Training Grants and F series: Many changes scheduled for Phase II have been pushed to **FY2017** (further details to come)

**Phase I:**
- Rigor and transparency (research grants and contracts)
- Vertebrate animals (research grants and contracts)
- Definition of “child”

**Phase II:**
- Vertebrate animals (training, career dev, fellowship awards)
- Research training table format Fonts
- Clarification of biosketch instructions
- FORMS-D (replace FORMS-C)

**Phase III?**
- Rigor and transparency (training, career dev, fellowship awards)
- Changes to PHS forms

**New instructions for peer review will include criteria for rigor and transparency**
Rigor and Transparency

Four areas of focus:

• **Scientific Premise** – must describe the scientific premise of the proposed research including an evaluation of strengths and weaknesses of published research or preliminary data

• **Scientific Rigor** – full description of rigorous experimental design and methods

• **Consideration of Relevant Biological Variables** – including sex, age, weight, underlying health conditions, etc.

• **Authentication of Key Biological or Chemical Resources** – new PDF attachment that describes methods used to ensure the identity and validity of these key resources used in the proposed research

The first three required sections must be incorporated into the 12 page limit of the Research Strategy. The fourth is a separate attachment.
Authentication of key biological and/or chemical resources – new attachment

- Authentication of Key Resources Plan (≤ 1 page) under item 12, Other Project Information SF424 form

- Must provide a brief description of plan for authenticating resources such as established cell lines, antibodies and other biologics

- Standard laboratory reagents that do not vary do not need to be included (e.g. buffers and common chemicals)

- Authentication plan will not impact the review score. It will be reviewed and addressed prior to award.
New guidance on Research Performance Progress Reports

Phase I and beyond for research grants and contracts

Rigor and Transparency components must be included in performance reports effective Jan. 25

Updates to Section B – Accomplishments:

- **B.2 What was accomplished under these goals?**
  ✓ Include approaches taken to ensure unbiased results.

- **B.6 What do you plan to do for the next reporting period to accomplish these goals?**
  ✓ Discuss efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased.
Simplification of the Vertebrate Animals Section

• A description of veterinary care is no longer required.

• Justification for the number of animals has been eliminated.

• A description of the method of euthanasia is required only if the method is not consistent with AVMA guidelines.

Note: With the focus on rigor, these components must nevertheless be addressed in the Research Strategy section

Does not apply to AHRQ applications
NIH definition of Child

_Phase I and beyond for all applications_

- The age of a child is now 18 years old and younger instead of 21 and younger

Fonts

_Phase II and beyond for all applications_

New font guidelines:

- **Font size:** must be 11 points or larger (smaller text in figures, graphs, diagrams, and charts is acceptable as long as it is legible when the page is viewed at 100%)
- **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
- **Recommended fonts:** Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana
- **Color:** Black (color in figures, graphics, headings, etc. ok as long as it’s legible)
Clarification of biosketch instructions

*Phase II for all applications*

- A URL for a publication list is **optional** but, if provided, must be to a government website (.gov) e.g. *My Bibliography* or *SciENcv*

- Publications (peer-reviewed and non-peer-reviewed) and research products may be cited in both the personal statement and the contributions to science sections

- Graphics, figures, and tables are not allowed in biosketch
Unknowns

- How will reviewers interpret the new guidelines?

- Will an increased focus on rigor clash with innovative, high-risk, high-reward research?

- No clear consensus or protocols on how to validate or authenticate resources.
Resources

• Notice NOT-OD-16-004, Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (initial announcement)

• Notice NOT-OD-16-034, updated timeline for implementing formal instruction to enhance reproducibility for NIH and AHRQ training grants, career development awards, and individual fellowships.

• NIH Office of Extramural Research webpage on Guidance: Rigor and Reproducibility

• Notice NOT-OD-16-011: Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

• Notice NOT-OD-031: Updates regarding RPPRs to address Rigor and Transparency

• Principles and Guidelines for Reporting Preclinical Research

• Open Mike blog, Dr. Michael Lauer, NIH Deputy Director for Extramural Research

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