NIH Update

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Overview

National Institutes of Health

Two phases of changes:

- Phase 1: For due dates on or after **January 25, 2016**
  - Rigor and Reproducibility (excluding training and fellowships)
  - Vertebrate animals (excluding training and fellowships)
  - Definition of a child
  - Training grant applications
  - Genomic data sharing policy
- Phase 2: For due dates on or after **May 25, 2016**
  - Updated forms for all applications, FORMS-D

A full description of the changes can be found in NIH notice NOT-OD-16-004

Rigor and Reproducibility

NIH has revised their application instructions and review criteria to enhance the reproducibility of research findings through increased scientific rigor and transparency.

Focus will be placed on the following four areas:

1. Scientific Premise of Proposed Research
2. Rigorous Experimental Design
3. Consideration of Sex and Other Relevant Biological Variables
4. Authentication of Key Biological and/or Chemical Resources

Rigor and Reproducibility

1. Scientific Premise of Proposed Research

In the **Research Strategy, Significance** section:

- Describe the scientific premise for the proposed project, including the general strengths and weaknesses of the prior research being cited as crucial to support the application.
- This could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.

Rigor and Reproducibility

2. Rigorous Experimental Design

In the **Research Strategy, Approach section**:

- Describe how you will achieve robust and unbiased results when describing the experimental design and proposed methods.
- Robust results are obtained using methods designed to avoid bias and can be reproduced under well-controlled and reported experimental conditions.
- **RPPR's** submitted January 25, 2016 or later will be expected to emphasize rigorous approaches taken to ensure robust and unbiased results.

Rigor and Reproducibility

3. Consideration of Sex and Other Relevant Biological Variables

In the **Research Strategy, Approach section**:

Sex:

- NIH expects that sex as a biological variable will be factored into research design, analysis and reporting in vertebrate animal and human studies.
- Strong justification must be provided for applications proposing to study only one sex.

Rigor and Reproducibility

3. Consideration of Sex and Other Relevant Biological Variables

In the **Research Strategy, Approach section** **(Continued)**:

Other Relevant Biological Variables:

- Should also consider other biological variables, as appropriate, in the design and analyses of proposed studies.
- Research plans and findings should indicate which biological variables are tested or controlled.
- Justify exclusion of variables that may be relevant but are not considered in the research plan.
- The Women and Minorities and Inclusion of Children sections may be used to expand your discussion on inclusion and provide additional justification

Rigor and Reproducibility

4. Authentication of Key Biological and/or Chemical Resources

Authentication of Key Resources Plan

New Attachment!

- This is a new attachment required on the SF 424 (R&R) Other Project Information Form, in the Other Attachments field.
- Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

*Caution - information in this attachment must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process.

Rigor and Reproducibility

4. Authentication of Key Biological and/or Chemical Resources

Authentication of Key Resources Plan (Continued)

New Attachment!

- 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; and
  3) are integral to the proposed research.
- These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

Vertebrate Animals

Summary of Changes:

- 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.

Vertebrate Animals

What to include:

Description of Procedures

- Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.

Justifications

- Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model

Minimization of Pain and Distress

- Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury

Euthanasia

- State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification

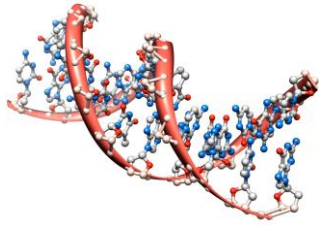
Definition of a Child

The age of a child will now be defined as individuals under 18 years old rather than 21 years old.

Training Grant Applications

There are also significant changes to the training grant application instructions.

If you are aware of a training grant application being submitted, please make sure to review the new application instructions and contact your Proposal Team if you have any questions.



Genomic Data Sharing Policy

- Applications proposing to generate large-scale human and/or non-human genomic data are expected to include a genomic data sharing plan.
- A cover letter should also be attached stating the proposal is expected to generate large-scale genomic data.

- Applicants who want to use the NIH-designated repository for human genomic data to achieve the specific aims of their proposal, in the Research Plan of the application should:
  1. Address plans to request access to the data, and
  2. State their intention to abide by the NIH Genomic Data User Code of Conduct

Resources

- NIH Rigor and Reproducibility website: https://www.nih.gov/research-training/rigor-reproducibility

Training

NIH developed four video modules with accompanying discussion materials that focus on integral components of reproducibility and rigor in the research endeavor, such as bias, blinding, and exclusion criteria. These modules are intended only to stimulate conversation, which may be facilitated by the use of the discussion materials, and are not meant to be comprehensive training modules. They may serve as a foundation upon which to build further education, training, and discussion.

The modules can also be found on the NIGMS Clearinghouse for Training Modules to Enhance Data Reproducibility site, along with other materials once available.

Introduction to the Modules pdf

Module 1: Lack of Transparency
Discussion Material pdf

Module 2: Blinding and Randomization
Discussion Material pdf

Module 3: Biological and Technical Replicates
Discussion Material pdf

Module 4: Sample Size, Outliers, and Exclusion Criteria
Discussion Material pdf

Resources

- NIH Rigor and Reproducibility FAQ's: http://grants.nih.gov/reproducibility/faqs.htm
- Office of Sponsored Programs, NIH updates website: https://osp.msu.edu/PL/Portal/DocumentViewer.aspx?cga=aQBkAD0AMQA3ADIA
- NIH explanation of Phase I and II changes: NOT-OD-16-004
- Notice related to Rigor and Reproducibility: NOT-OD-16-011
- Notice related to Vertebrate Animals Section: NOT-OD-16-006
- Notice related to Training Grant changes: NOT-OD-16-007
- New Application instructions: http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

Communications

Presentations:

- Educational session for faculty
  - 1/7/16, 1:30-2:30 in room 1420 of the BPS Building
- ERA Hot Topics elective - 12/8/2015
- Presented to CORD – 11/19/2015 & 1/7/2016

Email & Website Updates:

- OSP/SPA/CGA Listserv announcement - 12/21/2015
- Email sent to MSU NIH faculty - 12/21/2015 & 1/5/2016
- Included News item on the SPA website – 1/6/2016