ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

SEPTEMBER 19, 2017

PATRICIA VALDEZ, Ph.D.

NIH EXTRAMURAL RESEARCH INTEGRITY OFFICER



RPG Application and Review

Element of Rigor	Section of Application	Criterion Score	Additional Review Consideration	Contribute to Overall Impact?
Scientific Premise		Significance	NA	Yes
Scientific Rigor	Research	Approach	NA	Yes
Consideration of Relevant Biological Variables Such as Sex	Strategy	Approach	NA	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	NA	Adequate or Inadequate	No





Policy Applies to:

Research

- Career Development
- Centers
- People-based
- Program Projects
- Small Business
- Resource-Related

Does Not Apply to:

- Administrative supplements
- Conferences
- Construction
- Instrumentation
- Publication support

Training (coming soon - see NOT-OD-16-034)

- Individual Fellowships
- Institutional Training
- Institutional Career Dev





Impressions So Far

- Confusion about Scientific Premise
- Uneven attention to Biological Variables
 Such As Sex
- Questions about which resources to Authenticate



Scientific Premise

- The strength of the prior research used to support the proposed research question or project
- Prior research can include:
 - observations,
 - preliminary data, or
 - published literature
- Describe general strengths and weaknesses of the supporting research





Scientific Premise is Not

- The hypothesis of the project
- The perceived importance of the project
- The rationale of the project
- The feasibility of the project



Consideration of Relevant Biological Variables, Such As Sex

- May not need to power initial study to detect sex differences
- Provide justification if proposing to study one sex
 - sex-specific condition of phenomenon (e.g., ovarian or prostate cancer),
 - acutely scarce resources, or
 - sex-specific hypotheses possible due to known differences between males and females.
- Cost and absence of known sex differences are inadequate justifications for not addressing sex.



Reminder: Authentication Of Key Biological and/or Chemical Resources (NOT-OD-17-068)

- Definition of key biological and/or chemical resources
- Examples (cell lines, chemicals, genetically modified animals or cells)
- Do not include:
 - Plans for authentication of data sets, databases, machinery, or electronics
 - Plans for the development and authentication of new key biological and/or chemical resources
 - Plans for authentication of standard laboratory reagents that are not expected to vary
 - Authentication or other data





Research Performance Progress Reports (RPPR)

B.2 What was accomplished under these goals?

Goals are equivalent to specific aims. In the response, *emphasize the approaches taken to ensure robust and unbiased results.* Include the significance of the findings to the scientific field.

B.6 What do you plan to do for the next reporting period to accomplish the goals?

Include any important modifications to the original plans, *including* efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased. Provide a scientific justification for any changes involving research with human subjects or vertebrate animals. A detailed description of such changes must be provided under Section F. Changes.

① https://www.nigms.nih.gov/training/pages/clearinghouse-for-training-modules-to-enhance-data-reproducibility.aspx









Site Map	Staff Search	My Order
		Search

NIGMS Home

Research Funding

Research Training

News & Meetings

Science Education

About NIGMS

NIGMS Home > Training, Workforce Development, & Diversity > Clearinghouse for Training Modules to Enhance Data Reproducibility

Clearinghouse for Training Modules to Enhance Data Reproducibility

In January 2014, NIH launched a series of initiatives to enhance rigor and reproducibility in research. As a part of this initiative, NIGMS, along with nine other NIH institutes and centers, issued the funding opportunity announcement RFA-GM-15-006 to develop, pilot and disseminate training modules to enhance data reproducibility. Graduate students, postdoctoral fellows and early stage investigators are the primary audiences for these training modules.

For the benefit of the scientific community, we will be posting the products of these grants on this Web site as they become available.

In addition, we are sharing here a series of four training modules developed by NIH. These modules focus on integral aspects of rigor and reproducibility in the research endeavor, such as bias, blinding and exclusion criteria. The modules are not meant to be comprehensive, but rather are intended as a foundation to build on and a way to stimulate conversations, which may be facilitated by the use of the accompanying discussion materials. Currently, the modules are being integrated into NIH intramural training activities.

NIH Rigor and Reproducibility Training Modules

Introduction to the Modules [PDF, 110KB]



Module 1: Lack of Transparency Lack of Transparency Discussion Material [PDF, 97.2KB]

Module 2: Blinding and Randomization
Blinding and Randomization Discussion Material [PDF, 104KB]

Module 3: Biological and Technical Replicates
Biological and Technical Replicates Discussion Material [PDF, 98.7KB]

Module 4: Sample Size, Outliers, and Exclusion Criteria
Sample Size, Outliers, and Exclusion Criteria Discussion Material [PDF, 107KB]

Related Information

Administrative Supplements to NIGMS Predoctoral Training Grants

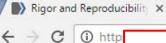
NIH Web Portal on Rigor and Reproducibility

NIH Grants & Funding Web Site on Rigor and Reproducibility in Grant Applications

NIH Reproducibility Workshops Cell Biology

Videocast [Day 1 | Day 2]

Structural Biology Genome Technology Cell Culture Studies



https://grants.nih.gov/reproducibility/









Grants & Funding NIH's Central Resource for Grants and Funding Information

Entire Site

Search this Site

eRA | Glossary & Acronyms | FAQs | Help

HOME

ABOUT GRANTS

FUNDING

POLICY & COMPLIANCE

NEWS & EVENTS

ABOUT OER

Home » Policy & Compliance » Rigor and Reproducibility

NIH Grants Policy Statement

Notices of Policy Changes

Compliance & Oversight

Select Policy Topics

Rigor and Reproducibility

Scientific rigor and transparency in conducting biomedical research is key to the successful application of knowledge toward improving health outcomes. The information provided on this website is designed to assist the extramural community in addressing rigor and transparency in NIH grant applications and progress reports.

On This Page:

- Goals
- Guidance: Rigor and Reproducibility in Grant Applications
- Resources
- News
- References

Goals

The NIH strives to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science. Updates to grant applications instructions and review language are intended to:

- · clarify long-standing expectations to ensure that NIH is funding the best and most rigorous science,
- · highlight the need for applicants to describe details that may have been previously overlooked.
- · highlight the need for reviewers to consider such details in their reviews through updated review language, and
- minimize additional burden.

Related Resources

FAQs

ORWH Studying Sex to Strengthen Science (S4) @

NIH Rigor and Reproducibility @

NIGMS Training

Modules @

Intranet Resources on

Rigor and

Transparency

reproducibility@nih.gov

(NIH Staff Only)

Contact:

THANK YOU!

QUESTIONS?

reproducibility@nih.gov

