RIGOR AND TRANSPARENCY IN NIH & AHRQ GRANT APPLICATIONS

The National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) issued in October 2015 the requirements for rigor and transparency in NOT-OD-16-011 "Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications".

Purpose

The purpose of this notice is to inform the research community of new updates to grant applications and reviews that will enhance the reproducibility of research findings through increased scientific rigor and transparency.

Background

NIH defines scientific rigor as *the strict application of the scientific method to ensure unbiased and well-controlled experimental design, methodology, analysis, interpretation, and reporting of results.*

Scientific rigor also includes transparency in reporting full experimental details so that others may reproduce and extend the findings.

The four areas deemed important for enhancing rigor and transparency and apply to the full spectrum of research, basic to clinical, are

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

Investigators will need to consider how these four areas apply to their proposed research in the grant application. NIH expects the applicants to describe how they will achieve robust and unbiased results when describing the experimental design and proposed methods. Robust results are obtained by using methods designed to avoid bias and can be reproduced under well-controlled and reported experimental conditions.

Grant application reviewers will assess whether these four areas have been appropriately addressed.

What are the updates to the application and review process?

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

Which grant applications do these new requirements apply?

These requirements apply to most research grant applications (including complex research and small business grant applications) submitted for due dates on or after January 25, 2016.

This is not a requirement for grants that support other types of activities. See NOT-OD-16-011 for exclusions.

This will not apply to institutional training grants, institutional career development awards, or individual fellowships until as early as FY2017. See NOT-OD-16-034 for additional details.

What should be included in the Research Strategy of my proposal?

In the *Significance Section*, include

- Consideration of strengths of published work or preliminary data crucial to the support of the application
- Consideration of weaknesses of published work or preliminary data crucial to the support of the application

In the *Approach Section*, include

- Description of experimental design and methods
- Description of how the experimental design and methods 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. Strong justification is required if proposing to study only one sex (See NOT-OD-15-102 for additional details).

What are Key Biologicals and/or Chemical Resources?

These resources may or may not be generated with NIH funds and

1) may differ from laboratory to laboratory over time;
2) may have qualities and 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
- other biologics

Standard laboratory reagents do not need to be included in this plan (e.g. buffers, common biologicals, common chemicals, etc.)

What are the NIH application requirements?

Grant applications covered by this policy must include

- New PDF attachment for authentication of key biological <u>and/or</u> chemical resources used in the proposed studies.

This attachment, your authentication plan, should briefly (in one page or less) describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. This plan should include how you will authenticate key resources and the frequency for which you will do this for the proposed research. Authentication data do not need to be provided.

Information in this attachment must focus <u>only</u> on authentication and/or validation of key resources to be used in the study. All other methods and preliminary data will be within the page limits of the Research Strategy. Failure to comply with this limitation will result in application withdrawal from the review process.

Additional guidance on preparing an authentication plan can be found in the [NIH Office of Extramural Research Nexus Open Mike](#).

What forms do I use in my application and how/where do I upload the document?

APPLICATION DUE DATES	FORM	Document
January 25, 2016 – May 24, 2016	FORMS-C and application guide	Label PDF - "Authentication of Key Resources Plan" Upload in "Other Attachments" section of the "Other Project Information" form
On or after May 25, 2016	FORMS-D and applications guide	Research Plan Form will include a Key Attachment Field "Authentication of Key Biological and/or Chemical Resources"

<u>Note</u>: *For each submission, always download a new grants application package from Grants.gov to ensure that you are using the most recent versions of the forms.*

How will the key biological and/or chemical resources authentication plan be used during the application review process?

For projects involving these resources, the reviewer will comment on the plan proposed for identifying and ensuring the validity of those resources.

Does my Progress Report need to address rigor?

Progress reports for all annual non-competing (Type 5) NIH & AHRQ awards that support research activities (including complex research and small business grant applications) submitted on or after January 25, 2016 will be expected to emphasize the rigorous approaches taken to ensure robust and unbiased results. See NOT-OD-16-031.

The progress report should address

- o What was accomplished under these goals and include the approaches taken to ensure robust and unbiased results
- o What is the plan is for the next reporting period to accomplish these goals and discuss efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased.

What will the Office of Research be reviewing during proposal submission?

During this early phase of implementation, the Office of Research will try to help by taking a look during the grant submission process to see if the *Authentication Plan of Key Biological and/or Chemical Resources* is applicable for the funding mechanism. If applicable but no PDF present, the grant officer will check with the department to ensure that a plan was not required for the research proposed rather than being overlooked by the principal investigator.

If the grant proposal arrives to the Office of Research after the internal submission deadline, no guarantees can be made that time will permit this step.

Additional Resources

Rigor and Reproducibility

Consideration of Sex as a Biological Variable in NIH-funded Research

Enhancing Reproducibility through Rigor and Transparency (Background for these new requirements)

NIH & AHRQ Announce Upcoming Changes to Policies, Instructions, and Forms for 2016 Grant Applications

Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

Additional guidance on authentication at NIH Office of Extramural Research *Extramural Nexus Open Mike*

Advanced Notice of Coming Requirements for Formal Instruction in Rigorous Experimental Design and Transparency to Enhance Reproducibility: NIH and AHRQ Institutional Training Grants Institutional Career Development Awards, and Individual Fellowships

[Updates to NIH & AHRQ Research Performance Progress Reports (RPPR) to Address Rigor and Transparency](#)

[NIH Video: Enhancing Reproducibility through Rigor and Transparency](#)