Rigor and Transparency

Changes focus on four areas deemed important for enhancing rigor and transparency:

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, and
4) authentication of key biological and/or chemical resources

The basic principles of rigor and transparency and the four areas of focus apply to the full spectrum of research, from basic to clinical. Investigators will need to consider how all four areas apply to their proposed research. Likewise, reviewers will assess whether these areas have been appropriately addressed by the applicant through revised language defining the peer review criteria.

I. Significance and Approach Additional Requirements

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. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

If your study involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on Inclusion of Women and Minorities and Inclusion of Children may be used to expand upon and justify the proposed proportions.

II. New Authentication of Key Biological and/or Chemical Resources Attachment

For projects involving key biological and/or chemical resources, grant applications must include a new PDF attachment related to the 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; and
3. are integral to the proposed research.

These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award. Information in this section 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.

III. Application Review Information

Unless stated otherwise in the Funding Opportunity Announcement (FOA), reviewers will be asked to consider additional review questions in order to assess rigor and transparency in research grant applications.

**Scored Review Criteria**

**Significance**
Is there a strong scientific premise for the project

**Approach**
Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?

- Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

**Additional Review Considerations**

**Authentication of Key Biological and/or Chemical Resources**
For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

IV. Research Performance Progress Reports

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. The RPPR instructions will be updated by January 25, 2016. Reporting on rigor in RPPR will help NIH implement and evaluate the policy for both current and new awards, as well as prepare non-competing renewals for the next competitive renewal.