Guidance for Reviewers: Rigor and Transparency for the Simplified Review Framework

This guidance is ONLY for the review of applications to funding opportunities using the Simplified Review Framework. For funding opportunities ***not*** using the Simplified Review Framework refer to Reviewer Guidance on Rigor and Transparency: Research Project Grant and Mentored Career Development Applications.

Background to Rigor and Transparency: To support the highest quality science, public accountability, and social responsibility in the conduct of science, NIH implemented in 2016 an initiative to enhance reproducibility of research through rigor and transparency. Under this effort, four areas are required to be addressed by applicants and reviewers: (1) Rigor of the prior research, (2) Scientific rigor, (3) Consideration of relevant biological variables, and (4) Authentication of key biological and/or chemical resources

Rigor of Prior Research

Rigor of the prior research concerns the quality and strength of the research being cited by the applicant as crucial to support the application; this is distinct from the hypothesis or justification.

- Applicants should discuss the strengths and weaknesses of the prior research used to support the project and describe how the proposed research will address weaknesses or gaps identified by the applicant. This may include the applicant's own preliminary data, data published by the applicant, or data published by others.
- Reviewers will evaluate the rigor of the prior research as part of Factor 1–Importance of the Research (Significance and Innovation). Overarching considerations: how rigorous is the scientific background and does it justify the proposed study?
- Weaknesses or gaps in the rigor of the prior research that serves as the key support for the proposed project may affect overall impact scores.

Scientific Rigor of the Proposed Research (Design)

Scientific rigor refers to the strict application of scientific methods to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results, and sufficient information for the study to be assessed and reproduced. Whereas rigor of the prior research pertains to key supporting data, scientific rigor pertains to the proposed research.

- Applicants should describe, as appropriate, experimental controls, plans to reduce bias (blinding, randomization, inclusion and exclusion criteria, etc.), power analyses, and statistical methods to achieve robust unbiased results. Applicants should also describe plans to address any weaknesses in the rigor of the prior research serving as the key support for the proposed project.

- Reviewers will evaluate scientific rigor under Factor 2–Rigor and Feasibility (Approach). Overarching consideration: what is the likelihood that compelling, reproducible findings will result from the proposed work?
- As part of Factor 2 reviewers will also evaluate plans to address relevant biological variables for studies in vertebrate animals or human subjects (see below) and, for applications involving human subjects, including clinical trials, the adequacy of Inclusion plans. Guidance for evaluating Inclusion plans is available at Guidelines for the Review of Inclusion.
- Weaknesses or gaps in the scientific rigor of the proposed research may affect overall impact scores.

Consideration of Biological Variables

Biological variables, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease.

- Applicants are expected to factor biological variables into research designs, analyses, and reporting in vertebrate animal and human studies. The way in which sex and other biological variables need to be accounted for will differ across research questions and fields of study.
- A justification is expected if the application proposes to study one sex, for example in the case of a sex-specific condition or phenomenon (e.g., ovarian or prostate cancer), acutely scare resources, or sex-specific hypotheses when there are known differences between males and females. Cost and absence of known sex differences are inadequate justifications for not studying both sexes.
- Reviewers will assess the applicant's plans to address relevant biological variables, such as sex, as part of Factor 2-Rigor and Feasibility (Approach). Additional guidance for reviewing sex as a biological variable in applications can be found at Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV).

Authentication of Key Biological and/or Chemical Resources

Key biological and/or chemical resources are those that 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, not standard laboratory reagents.

- Applicants should provide a brief plan (one page or less) describing methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. The plan should not include authentication data or any other data. The plan may reflect existing guidelines or standards for authentication of a resource when such standards exist.
- Reviewers will discuss the adequacy of the authentication plan as part of Additional Review Considerations which are addressed after final scoring; comments on key resource authentication should not affect scores.

Additional Resources

- NIH Extramural website on Enhancing Reproducibility through Rigor and Transparency
- FAQs on Rigor and Reproducibility