

Rigor and Reproducibility

<http://grants.nih.gov/reproducibility/index.htm>

Instructions and review language focus on four areas deemed important for enhancing rigor and transparency:

1. The scientific premise of the proposed research
 - The **scientific premise** for an application is the research that is used to form the basis for the proposed research question(s). NIH expects applicants to describe the general strengths and weaknesses of the prior research being cited by the applicant as crucial to support the application. It is expected that this consideration of general strengths and weaknesses 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.
2. Rigorous experimental design for robust and unbiased results
 - **Scientific rigor** is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. This includes full transparency in reporting experimental details so that others may reproduce and extend the findings.
3. Consideration of relevant biological variables
 - **Biological variables**, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response.
 - NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex.
4. Authentication of key biological and/or chemical resources
 - **Key biological and/or chemical resources** include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Key biological and/or chemical resources:
 1. may differ from laboratory to laboratory or over time;
 2. may have qualities and/or qualifications that could influence the research data;
 3. are integral to the proposed research; and
 4. are not limited to resources generated with NIH funds.
 - The quality of resources used to conduct research is critical to the ability to reproduce the results. Each investigator will have to determine which resources used in their research fit these criteria and are therefore key to the proposed research.