

ALERT: New NIH Requirements for Research Grant Applications

What is this? NIH has begun a new initiative designed to improve the rigor of experimental design in research, and to increase the reproducibility of scientific experiments. Investigators will be required to explicitly discuss and address three areas in the Research Plan and add an attachment addressing “Authentication of Key Biological and/or Chemical Resources”. **These changes will be explicitly included in the new Study Section proposal review and scoring criteria.**

Who is affected? Virtually all grant applications and annual progress reports, including R01, R03, R21, and all K (career development awards) will need to comply.

When will this start? Required for all grants and progress reports due on or after January 25, 2016.

What do I need to do? You need to explicitly include new information in the grant. We recommend using specific language to highlight compliance and make it easy for reviewers to find:

Significance section:

- Explicitly state the scientific premise for the proposed project. We recommend starting the Significance section of your grant application with a paragraph or subsection entitled “Scientific Premise and Hypothesis”. This separates the premise from the hypothesis your grant is trying to address; the premise leads to the hypothesis.
 - **Premise:** a condition on which a logical argument is based.
 - **Hypothesis:** a plausible conjecture to be proved or disproved by experimentation.
- Explicitly discuss the strengths and weaknesses of published research or preliminary data crucial to the support of your application. Consider a separate section in the Significance entitled “Strengths and Weakness of Supporting Data” or, alternatively, a 1-3 sentence appraisal of the data at the end of each section where it is presented.

Approach section:

- Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
- NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.
- Explain how relevant biological variables are factored into research designs and analyses for studies in vertebrate animals and humans. (e.g. strong justification from the literature or preliminary data must be provided for studying only female mice.)

Authentication of Key Biological and/or Chemical Resources (NEW Attachment):

- Briefly describe methods to ensure the identity and validity of key biological and chemical reagents used in the proposed studies. These include cell lines, specialty chemicals, antibodies and other biologics. Do not include standard reagents (e.g. buffers, solvents).
- Information in this section must focus only on authentication/validation of key resources used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. **Applications identified as non-compliant with this limitation will be withdrawn from the review process.**

Where can I get more information? NIH has published notices outlining updates to instructions for applications: Overview ([NOT-OD-16-004](#)), details on Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications ([NOT-OD-16-011](#)) and Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications ([NOT-OD-16-012](#)).