

Rigor and Transparency in Research

To support the **highest quality science, public accountability, and social responsibility in the conduct of science**, NIH's Rigor and Transparency efforts are intended to clarify expectations and highlight attention to four areas that may need more explicit attention by applicants and reviewers:

- Scientific premise
- Scientific rigor
- Consideration of relevant biological variables, such as sex
- Authentication of key biological and/or chemical resources

Role of reviewers: Assess the scientific merit of each application according to the review criteria, which include consideration of scientific premise, rigor, and consideration of relevant biological variables, and the adequacy of the authentication of key biological and/or chemical resources as an administrative issue. Evaluations should be based on current best practices in the field.

Reviewing Rigor and Transparency of Research: **RPG Applications**

	Applies to which applications?	Where will I find it in the application?	Where do I include it in my critique?	Addition to review criteria	Affect overall impact score?
Scientific Premise	All	Research Strategy (Significance)	Significance	Is there a strong scientific premise for the project?	Yes
Scientific Rigor	All	Research Strategy (Approach)	Approach	Are there strategies to ensure a robust and unbiased approach?	Yes
Consideration of Relevant Biological Variables, Such as Sex	Projects with vertebrate animals and/or human subjects	Research Strategy (Approach)	Approach	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?	Yes
Authentication of Key Biological and/or Chemical Resources	Project involving key biological and/or chemical resources	New Attachment	Additional review considerations	Comment on plans for identifying and ensuring validity of resources.	No

Reviewing Rigor and Transparency of Research: Mentored Career Development Applications

	Applies to which applications?	Where will I find it in the application?	Where do I include it in my critique?	What should I consider?	Affect overall impact score?
Scientific Premise	All	Research Strategy	Research Plan	Is there a strong scientific premise for the project?	Yes
Scientific Rigor	All	Research Strategy	Research Plan	Are there strategies to ensure a robust and unbiased approach?	Yes
Consideration of Relevant Biological Variables, Such as Sex	Projects with vertebrate animals and/or human subjects	Research Strategy	Research Plan	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?	Yes
Authentication of Key Biological and/or Chemical Resources	Projects involving key biological and/or chemical resources	New Attachment	Additional review considerations	Comment on plans for identifying and ensuring validity of resources.	No

Scientific Premise: Guidance for Reviewers

GOAL: Ensure that the underlying **scientific foundation** of the project—concepts, previous work, and data (when relevant)—is sound.

- Pertains to the **underlying evidence/data** for the project
- Address under Significance (R applications) or Research plan (Ks)
- Addition to the review criteria: “Is there a strong scientific premise?”
- Specifically, has the applicant:
 - Provided sufficient justification for the proposed work?
 - Cited appropriate work and/or preliminary data?
 - Appropriately identified strengths and weaknesses in prior work in the field?
 - Proposed to fill a significant gap in the field?
 - OR has the applicant explained why this is not possible?

Scientific Rigor: Guidance for Reviewers

GOAL: Ensure a strict application of scientific method that supports robust and unbiased design, analysis, interpretation, and reporting of results, and sufficient information for the study to be assessed and reproduced. Give careful consideration to the methods and issues that matter in your field.

- Pertains to the **proposed research**
- Address under **Approach** (R applications) or **Research Plan** (Ks)
- Addition to review criteria: Are there “strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”
- Possible considerations, if appropriate for the scientific field and research question, include plans for:
 - determining group sizes
 - analyzing anticipated results
 - reducing bias
 - ensuring independent and blinded measurements
 - improving precision and reducing variability
 - including or excluding research subjects
 - managing missing data

Relevant Biological Variables: Guidance for Reviewers

GOAL: Ensure that the research accounts for sex and other relevant biological variables in developing research questions and study designs. The ways in which sex and other biological variables need to be accounted for will differ across research questions and fields of study.

- Pertains to the **proposed research**
- Applies to studies in vertebrate animals and/or human subjects
- Address in **Approach** (R applications) or **Research Plan** (Ks)
- Addition to review criteria: Are there “adequate plans to address relevant biological variables for studies in vertebrate animals or human subjects?”
- Consideration of sex is required in all studies involving human subjects or vertebrate animals (see next slide).
- Specific considerations to assess include:
 - Applies broadly to all biological variables relevant to the research such as sex, age, source, weight, or genetic strain.)
 - Has the applicant considered biological variables, such as sex, that are relevant to the experimental design?
 - Will relevant biological variables be controlled or factored into the study design appropriately?

Sex as a Biological Variable: Guidance for Reviewers

[Consideration of sex](#), included under the umbrella of “Relevant Biological Variables”, is required in all studies involving human subjects or vertebrate animals.

NIH expectations for applicants:

- If little is known about sex differences, the application should include both sexes.
 - Sufficient numbers should be provided to inform the presence or absence of sex differences. Statistically powered comparisons between sexes may not be warranted.
 - Specific hypotheses about sex differences may not be possible.
 - Findings should be reported separately by sex in progress reports and publications.
- If sex differences are known not to exist, a strong justification should be provided if the application proposes to study one sex.
- If sex differences are known, experiments should be designed with appropriate group sizes to detect sex differences.

NIH expectations for reviewers:

- As part of the Consideration of Relevant Biological Variables, assess whether the plans to address sex as a biological variable are adequate (for studies in vertebrate animals or human subjects).
- If the study involves only one sex, is this justified scientifically?
- Assess within the context of the research question and current scientific knowledge.

Plan for Resource Authentication: Guidance for Reviewers

GOAL: Ensure processes are in place to identify and regularly validate key resources used in their research and avoid unreliable research as a result of misidentified or contaminated resources.

- Researchers are expected to authenticate key biological and/or chemical resources used in their research, to ensure that the resources are genuine.
- New Additional Review Consideration
 - 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.
- Rate as acceptable/unacceptable (provide brief explanation if unacceptable)
- Does not affect criterion scores or overall impact score

Related review issues:

- Different research fields may have different best practices for and reach different conclusions about scientific premise and rigor. Assess based on best practices in the field.
- Page limits have not changed. Be alert for page limit violations (e.g. inappropriate use of appendices or other application sections). Alert the SRO if you see a potential issue.
- Page limits, cost and time are not valid reasons to disregard attention to these issues.
- Investigators address rigor and transparency differently (e.g. in labeled sections vs. throughout the research plan). Focus your evaluation on the likely outcome, not grant writing preferences.
- Rigor and transparency considerations apply to R03 (small grant) and R21 (exploratory/developmental) applications. However, preliminary data are not required and the extent to which approach details can be provided may differ. Reviewers should evaluate the scientific merit of these applications, including rigor and transparency, in light of the goals and reviewer guidelines for these activities.

Additional resources

- Rigor and Reproducibility in grant applications (OER site):
<http://grants.nih.gov/reproducibility/index.htm>
- NIH presentation of background and goals of Rigor and Transparency (video)
https://grants.nih.gov/reproducibility/module_1/presentation.html
- Reviewer Guidance on Rigor and Transparency:
[http://grants.nih.gov/grants/peer/guidelines_general/Reviewer Guidance on Rigor and Transparency.pdf](http://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf)
- Consideration of Sex as a Biological Variable in NIH-funded Research
http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf
- Rigor and transparency do not apply to all applications. See List of Eligible Activity Codes:
<https://nih-extramural-intranet.od.nih.gov/d/sites/default/files/RigorActivityCodes-20151006.pdf>. Also, certain Funding Opportunity Announcements are exempt from Rigor and Transparency, by request from the ICs.
- Questions about the NIH policy should be directed to reproducibility@nih.gov

Additional resources

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<http://grants.nih.gov/reproducibility/index.htm>
- NIH presentation of background and goals of Rigor and Transparency (video)
https://grants.nih.gov/reproducibility/module_1/presentation.html
- Reviewer Guidance on Rigor and Transparency:
[http://grants.nih.gov/grants/peer/guidelines_general/Reviewer Guidance on Rigor and Transparency.pdf](http://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf)
- Consideration of Sex as a Biological Variable in NIH-funded Research
http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf
- Rigor and transparency do not apply to all applications. See List of Eligible Activity Codes:
<https://nih-extramural-intranet.od.nih.gov/d/sites/default/files/RigorActivityCodes-20151006.pdf>. Also, certain Funding Opportunity Announcements are exempt from Rigor and Transparency, by request from the ICs.
- Questions about the NIH policy should be directed to reproducibility@nih.gov