

Subject: SERCC Newsletter
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From: Scientific Editing and Research Communication Core
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Scientific Editing and Research Communication Core



Addressing Rigor and Reproducibility in NIH Applications

In 2016, the National Institutes of Health (NIH) implemented its policy on rigor and reproducibility to encourage scientific integrity, public accountability, and social responsibility (for more about the rationale, see [Enhancing Reproducibility Through Rigor and Transparency](#)). In this newsletter, we describe the NIH guidelines and review criteria for rigor and reproducibility in grant applications, and we share our strategies for addressing these points.

Questions peer reviewers are asked to respond to in evaluating NIH applications (see Section 3 of [NIH Enhancing Rigor and Reproducibility Guidelines](#)):

- Is the prior research that serves as the key support for the proposed project rigorous?
- Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- 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?

Where rigor and reproducibility should be addressed:

Different aspects of rigor and reproducibility should be addressed in the **Significance Section** of the Research Strategy Document, the **Approach Section** of the Research Strategy Document, and the **Authentication of Key Biological and/or Chemical Resources Document**, as outlined below.

Significance Section

The [NIH Guidelines](#) specify to describe the strengths and weaknesses in the *rigor of the prior research* (published and unpublished) that serves as the key support for the proposed project.

We recommend that you include the following subsection in the Significance Section (also see [SERCC Templates](#)):

- “Scientific premise and rigor of prior research” (~0.5–0.75 pages)
 - Describe the data (both published and unpublished) that serve as the key support for the proposed approach, citing only the strongest supporting publications.
 - Discuss the strengths and weaknesses in the rigor of these data, evaluating how reliable they are.
 - If rigor is not an issue (it may not be), discuss limitations of the data.
 - End with general statements about how weaknesses of prior research will be overcome (leave details for the Approach section).
 - Organize this subsection either by aim or as relevant to understanding the overall project goal.

We also recommend that you place this subsection between others labeled “Importance of the Research Problem” and “Significance of the Expected Research Contribution.”

Approach Section

The [NIH Guidelines](#) specify to

- describe plans to address weaknesses in the *rigor of the prior research* that serves as the key support for the proposed project,
- emphasize how the *experimental design and methods proposed* will achieve robust and unbiased results, and
- explain how relevant *biological variables*, such as sex, are factored into research designs, analyses, and reporting in vertebrate animal and human studies.

We recommend that you incorporate the following subsections into the Approach Section (also see [SERCC Templates](#)):

- “Addressing weaknesses in rigor of prior research” (~0.25 pages)
 - If weaknesses in the rigor of the prior research that serves as key support for the proposed project are not an issue, discuss how you will overcome limitations of prior studies.
- “Strategies to ensure rigor of the proposed research” (~0.25 pages)
 - Describe how you will ensure that the approach used is rigorous, unbiased, and appropriate for the work proposed. See [examples](#) on the NIH website.
 - Be sure to include a power analysis if appropriate.
- “Consideration of biological variables” (as applicable, ~0.25 pages)
 - For sex, discuss the inclusion of equal numbers of each; the impact on results; separate analysis of results; and the karyotype of cell lines. If you are proposing to study only one sex, even if the rationale seems obvious, provide strong justification from the scientific literature, preliminary data, or other relevant considerations. See [NIH Reviewer Guidance to Evaluate Sex as a Biological Variable \(SABV\)](#).
 - For variables other than sex, discuss weight, age, genetic background/strain, and health status, if applicable.

Authentication of Key Biological and/or Chemical Resources Document

[NIH Guidelines](#) specify to

- briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies,
- state in one page or less how you will identify and validate key biological and/or chemical resources, including the frequency, as needed for your research, and
- not include authentication data in your plan.

We do not have specific recommendations for how to write this document, but examples of types of information to include are available in an [Authentication Plan Example](#) on the NIH website. Also, we urge you to submit this document even if the

only text on this page is “Not Applicable.”

Other notes:

- Do not discuss rigor and reproducibility in parts of the grant other than those designated by the NIH because this will be considered an attempt to bypass page limits. For example, power analyses should not be presented in the Vertebrate Animal Section.
- For research training and career applications, both institutional and individual, be sure to include information about how skills in methods for enhancing reproducibility will be obtained (more information is available near bottom of the NIH web page [Guidance: Rigor and Reproducibility in Grant Applications](#)).
- As always, make the reviewers’ job as easy as possible by ensuring the information relevant to rigor and reproducibility is included in the appropriate sections of your application **and** that it is easy to identify.

Best of luck writing your next NIH proposal!
Chris Blaumueller and the SERCC Team

Announcements:

[Update Your NSF PAPPG Bookmark](#)

The NSF recently announced revisions to its Proposal & Award Policies & Procedures Guide (PAPPG) (NSF 24-1) and published a Summary of Changes. This new guide will be effective for proposals submitted or due on or after May 20, 2024. Contact the NSF Policy Office at policy@nsf.gov if you have questions regarding these changes).

[Plagiarism Detection Software](#)

iThenticate is available from the UI Office of Teaching, Learning & Technology, as described in an article by the Office of the Vice President for Research. Also, tips on how to avoid plagiarism, self-plagiarism, and other questionable writing practices can be found in a guide from the Health and Human Services Office of Research Integrity.

Upcoming Opportunities:

[Have a question about writing grants or research articles?](#)
[Contact us](#) and we will answer it in a future newsletter.

Radiochemistry Seed Grant Opportunity

LOI due April 12 | Full application due June 14

As part of its [Seeding Excellence Initiative](#), the Research Development Office (RDO) within the University of Iowa Office of the Vice the President for Research (OVPR) invite collaborative research proposals to support projects which integrate radiochemistry with other disciplines while promoting advancements in scientific knowledge, technology, and applications. Successful proposals may receive awards up to \$45,000 for 18 months.

[Full RFA](#)

Ask the Editor: SERCC Virtual Office Hours

2nd and 4th Friday of every month starting April 12 | 9:30–10:30 AM | Zoom

The SERCC is hosting virtual office hours twice a month. If you have a question related to writing a grant, manuscript, or other scientific document stop by to talk with a scientific editor. We are also happy to answer any questions you have regarding our services. Open to all faculty, staff, fellows, postdocs, and students.

[More information](#) | [Link to event](#)

STEM Innovator Session

April 16 | 10:00–11:00 AM | Zoom

Dr. Leslie Flynn (Clinical Associate Professor, Management and Entrepreneurship) will provide an overview of the STEM Innovator Program and how it may be incorporated into [NSF Broader Impacts](#) and NSF CAREER proposal education plans. [More information](#) | [Register here](#) by April 4.

Maximizing Pivot to Find Funding and Collaborators

April 16 | 9:30–10:30 AM | Zoom

Do you want to maximize your time spent searching for funding opportunities or potential project collaborators? Learn how Pivot can save you time and effort in identifying the right funding opportunities for your research as well as in identifying collaborators with the relevant expertise.

[More Information](#) | [Register here](#)

CAREER Unlocked: Insights from NSF CAREER Awardees

April 19 | 9:30–10:30 AM | Zoom

The RDO is hosting an NSF CAREER virtual panel session. This will be an opportunity to hear from four accomplished CAREER Award recipients regarding their experience with the application process, need-to-know information, plus much more. Panelists are Thomas Folland (Assistant Professor, Physics and Astronomy), Xuan Song (Associate Professor, Industrial and Systems Engineering), Florence Williams (Assistant Professor, Chemistry); and Kristan Worthington (Associate Professor, Biomedical Engineering).

[More information](#) | [Register here](#) by April 18.

PCORI Addressing Rare Diseases Topical PCORI Funding Announcement (PFA),

Cycle 2 2024

First LOIs accepted May 7 | Deadline for full application Sept 4

The Patient-Centered Outcomes Research Institute (PCORI) intends to issue a Topical PCORI Funding Announcement (PFA) on May 7, 2024, seeking to fund high-quality, patient-centered comparative clinical effectiveness research (CER) projects that focus on rare diseases. This preannouncement provides potential applicants additional time to identify collaborators; obtain patient and stakeholder input on potential studies; and develop responsive, high-quality proposals.

[More information](#)

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