

NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Research Grant Applications

Notice Number: NOT-OD-18-228

Key Dates

Release Date: September 14, 2018

Related Announcements

[NOT-OD-18-116](#)

[NOT-OD-16-011](#)

[NOT-OD-16-012](#)

[NOT-OD-18-227](#)

[NOT-OD-18-229](#)

Issued by

National Institutes of Health ([NIH](#))

Agency for Healthcare Research and Quality ([AHRQ](#))

Purpose

The purpose of this Notice is to inform the biomedical and health services research communities of planned updates to application instructions and review criteria language for research grant applications submitted for due dates on or after January 25, 2019, and for research and development contract proposals submitted in response to solicitations posted on or after January 25, 2019.

The planned updates include changes to the following areas:

- The rigor of the prior research, formerly Scientific Premise (Note: Please refer to [NOT-OD-16-011](#) for a list of activity codes excluded from the Enhancing Reproducibility policy)
- Inclusion reporting
- Protections for human subjects

Background

The upcoming updates clarify the current application instructions and review criteria by replacing the term "scientific premise" with "the rigor of the prior research" and adding instruction and review language so that "the rigor of the prior research" is addressed under Significance and Approach. In addition, the updates include new policy requirements for the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects ([NOT-OD-18-116](#)). The exemption language within the review criteria for the Protections for Human Subjects will be updated in preparation for the implementation of the Revised Common Rule.

Summary of Updates

Revisions to the application guide will be available through the [How to Apply - Application Guide](#) website by November 25, 2018. Significant updates are indicated in the tables below:

Form	Section	Heading	Current language	Revised language
Research Plan	Research Strategy	Significance	Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.	Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
Research Plan	Research Strategy	Approach	Not Applicable	Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.
Human Subjects and Clinical Trials Information	Section 2 – Study Population Characteristics	2.4 Inclusion of Women, Minorities, and Children	2. Inclusion of Children [References to the Inclusion of Children in Clinical Research policy]	2. Inclusion Across the Lifespan [References to Inclusion of Children replaced with Inclusion Across the Lifespan]

Unless stated otherwise in the Funding Opportunity Announcement, reviewers will be asked to consider the revised review questions summarized in the table below. All active Funding Opportunity Announcements with due dates on or after January 25, 2019 will be updated with the revised language or a link to the revised language by November 25, 2018.

Section	Criteria	Current language	Revised language
Scored Review Criteria	Significance	Is there a strong scientific premise for the project?	Is the prior research that serves as the key support for the proposed project rigorous?
Scored Review Criteria	Approach	Not Applicable	Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
Scored Review	Approach	If the project involves	If the project involves

Criteria		human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?	human subjects and/or NIH-defined clinical research, are the plans to address: 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?
Additional Review Criteria	Protections for Human Subjects	For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will...	For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will...
Additional Review Criteria	Inclusion of Women, Minorities, and Individuals Across the Lifespan	When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals	When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to

		and research strategy proposed.	determine if it is justified in terms of the scientific goals and research strategy proposed.
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Note:

- Refer to [NOT-T-O-D-18-227](#) for updates to Career Development Award application instructions and review criteria language.
- Refer to [NOT-OD-18-227](#) for updates to Fellowship Award application instructions and review criteria language.

Resources

- Inclusion Across the Lifespan - [Policy Implementation website](#)
- [NIH Enhancing Reproducibility website](#) (will be updated by November 25, 2018)

Inquiries

Please direct all inquiries to:

For questions about enhancing reproducibility contact: reproducibility@nih.gov

For questions about inclusion across the lifespan contact: inclusion@od.nih.gov

For questions about NIH protections for human subjects in research contact: oepehs@mail.nih.gov

For questions about AHRQ protections for human subjects in research contact: HopeHongzhu.He@ahrq.hhs.gov

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