

# NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Fellowship Award Applications

**Notice Number:** NOT-OD-18-227

## Key Dates

**Release Date:** September 14, 2018

## Related Announcements

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

[NOT-OD-18-228](#)

[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 fellowship grant applications submitted for due dates on or after January 25, 2019.

The planned updates focus on the following areas:

- Inclusion reporting
- Protections for human subjects

## Background

The upcoming updates clarify the current application instructions and update the review criteria according to the 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
Human Subjects and Clinical Trials	Section 2 – Study Population Characteristics	2.4 Inclusion of Women, Minorities, and Children	2. Inclusion of Children [References to the	2. Inclusion Across the Lifespan [References to

Information			Inclusion of Children in Clinical Research policy]	Inclusion of Children replaced with Inclusion Across the Lifespan]
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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
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 and research strategy proposed.	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 determine if it is justified in terms of the scientific goals and research strategy proposed.

Note:

- Refer to [NOT-OD-18-229](#) for updates to Career Development Award application instructions and review criteria language.
- Refer to [NOT-OD-18-228](#) for updates to Research Project Grant application instructions and review criteria language.

## Resources

[Inclusion Across the Lifespan - Policy Implementation website](#)

## Inquiries

Please direct all inquiries to:

For questions about inclusion across the lifespan contact: [inclusion@od.nih.gov](mailto:inclusion@od.nih.gov)

For questions about protection of human subjects in research contact: [oepehs@mail.nih.gov](mailto:oepehs@mail.nih.gov)

For questions about AHRQ protections for AHRQ human subjects in research contact: [HopeHongzhu.He@ahrq.hhs.gov](mailto:HopeHongzhu.He@ahrq.hhs.gov)

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