

Notice of Intent to Revise the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects

Notice Number: NOT-OD-18-008

Key Dates

Release Date: December 1, 2017

Related Announcements

[NOT-OD-16-010](#)

[NOT-98-024](#)

Issued by

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

Purpose

The purpose of this Notice is to inform the research community that NIH intends to revise the NIH Policy and Guidelines on the Inclusion of Children. On November 9, in consultation with NIH Institute and Center Directors and in follow-up to the June 1-2, 2017 NIH workshop on Inclusion Across the Lifespan, the NIH Director determined that NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects will be revised. A discussion of this issue is scheduled as a formal agenda item for the upcoming December 14-15 meeting of the Advisory Committee to the NIH Director.

Background

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, includes new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify the criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. Furthermore, the Act requires NIH to convene a workshop of experts on pediatric and older populations to provide input on these issues, and taking account input received through the workshop, the NIH Director is charged with deciding whether any changes to NIH inclusion policies are needed.

On June 1-2, 2017 NIH held a workshop on Inclusion Across the Lifespan to discuss barriers and opportunities for participation of children and older adults in clinical research studies. A videocast of the proceedings of the workshop is available at <https://videocast.nih.gov/launch.asp?23334>. In addition, on April 26, 2017 NIH issued a Request for Information (RFI): Invitation to Comment on Inclusion in Clinical Research Across the Lifespan ([NOT-OD-17-059](#)) to solicit input from the wider scientific community and general public regarding the appropriate inclusion of pediatric and older populations in research studies involving human subjects.

Resources

Further information regarding the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects children is available at the following website:

<https://grants.nih.gov/grants/funding/children/children.htm>.

Inquiries

Please direct all inquiries to:

NIH Inclusion Policy Officer
Office of Extramural Research (OER)
Telephone: 301-435-0921
Email: inclusion@od.nih.gov