

# Inclusion Across the Lifespan

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# Objectives of Presentation

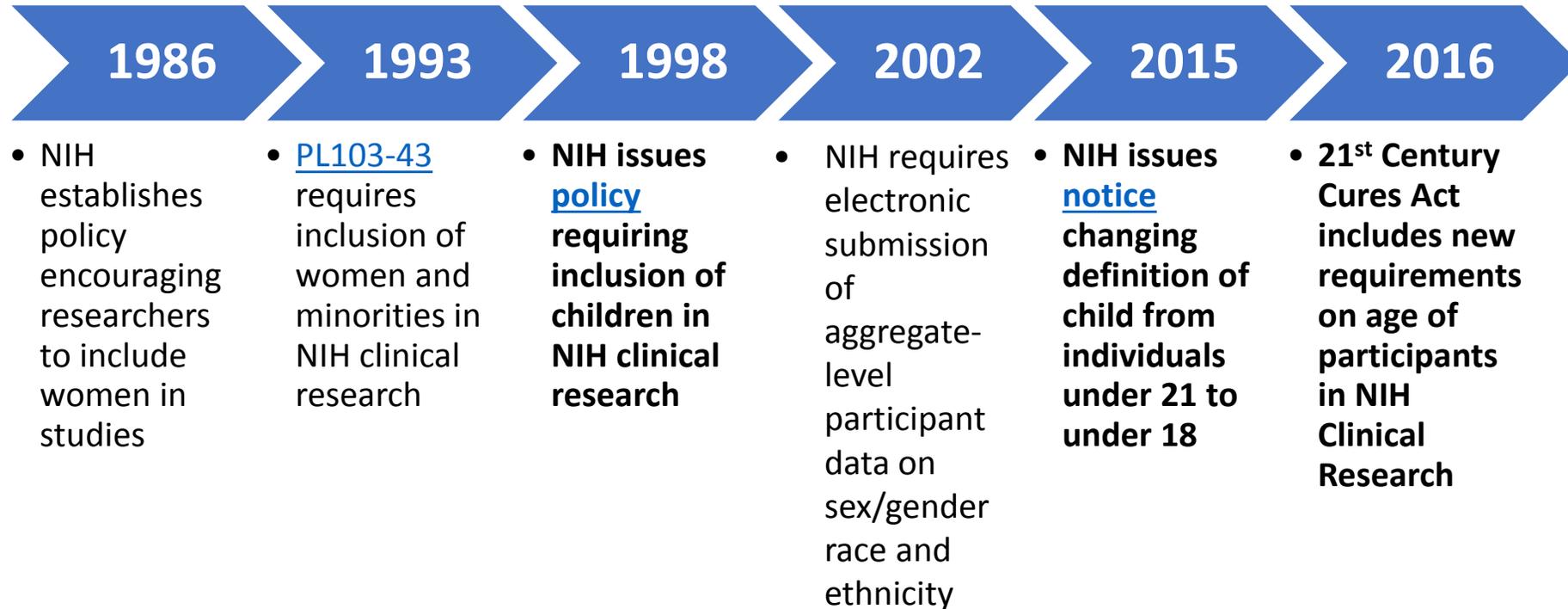
- Review steps taken to implement requirements of 21<sup>st</sup> Century Cures regarding age of participants in clinical research
- Present proposed changes to policy and procedures



# Background



# Timeline of NIH Inclusion Policies and Participant Data Collection



## H.R.34 - 21st Century Cures Act

114th Congress (2015-2016) | [Get alerts](#)

### **SEC. 2038. COLLABORATION AND COORDINATION TO ENHANCE RESEARCH.**

#### **Requires NIH to:**

1. Convene a workshop on age groupings and age exclusions in clinical research within 180 days of enactment
  - Post workshop findings on NIH website
2. Publish data on age of participants in NIH clinical research, including pediatric subgroups
3. NIH Director must determine whether the inclusion guidelines on age need revision within 180 days of the workshop



# Actions Taken



# Inclusion Across the Lifespan Workshop

## June 1-2, 2017 Bethesda, MD

**Purpose:** To discuss the challenges and barriers to including children and older adults in clinical trials and to identify strategies that would produce more age-inclusive clinical trials.



# Inclusion Across the Lifespan Working Groups

- Four working groups discussed the following topics:
  - Study Populations
  - Ethical Issues
  - Study Design
  - Data Collection and Reporting
- Workshop identified a number of themes applicable to NIH, government research entities, and the scientific community as a whole.
- Videocast available at <https://videocast.nih.gov/launch.asp?23334>



# Inclusion Across the Lifespan RFI

## Request for Information (RFI): Invitation to Comment on Inclusion in Clinical Research Across the Lifespan

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Notice Number: NOT-OD-17-059

### Key Dates

**Release Date:** April 26, 2017

**Response Date:** June 30, 2017

### Related Announcements

None

### Issued by

National Institutes of Health (NIH)

### Purpose

In response to scientific need and a congressional mandate in the 21st Century Cures Act (P.L. 114-255), the National Institutes of Health (NIH) is convening a workshop of experts on the appropriate inclusion of pediatric and older populations in research studies involving human subjects. A workshop will be held on June 1-2, 2017, to bring together experts in clinical research to discuss augmenting participation of these populations in NIH-funded clinical studies. In addition, the NIH is publishing this Notice to solicit input from the wider scientific community and welcomes comments from the public concerning inclusion in research.

### Background

The 21st Century Cures Act states in part:

*Appropriate Age Groupings in Clinical Research*

1) Input from Experts – Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall convene a workshop of experts on pediatric and older populations to provide input on –



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

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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.



# Proposed Policy Changes



# Proposed Revisions to Inclusion of Children Policy

- Proposed revisions represent immediate actionable steps considering collective stakeholder input:
  1. Policy will apply to individuals of all ages
    - Age range must be justified scientifically and/or ethically
  2. Clinical research studies will submit individual-level data on sex/gender, race, ethnicity, and age at enrollment



# Next Steps

- Publication of Inclusion Across the Lifespan Workshop Summary Report on NIH website
- Publication of Inclusion Across the Lifespan Policy in NIH Guide

