Issues of Inclusion in Clinical Research

James A. Griffin, PhD

Task Force on Research Specific to Pregnant and Lactating Women

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NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Timeline of NIH Inclusion Policies and Participant Data Collection

- **1986**
  - NIH establishes policy encouraging researchers to include women in studies
- **1993**
  - PL103-43 requires inclusion of women and minorities in NIH clinical research
- **1998**
  - **NIH issues policy requiring inclusion of children in NIH clinical research**
- **2002**
  - NIH requires electronic submission of aggregate-level participant data on sex/ gender race and ethnicity
- **2015**
  - **NIH issues notice changing definition of child from individuals under 21 to under 18**
- **2016**
  - **21st Century Cures Act includes requirements for age reporting**

Inclusion of children in NIH research

- **Inclusion of Children**
  - **Children must be included in clinical research studies unless there are scientific or ethical reasons not to do so**
  - **"Children" are currently defined by the NIH as individuals <18 years**
    - **Applies to application due dates January 25, 2016 or later** (see Guide Notice NOT-OD-16-010 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html)

CONGRESS.GOV | Legislation

H.R.34 - 21st Century Cures Act

114th Congress (2015-2016) | Get alerts

SEC. 2038. COLLABORATION AND COORDINATION TO ENHANCE RESEARCH.

Requires NIH to:

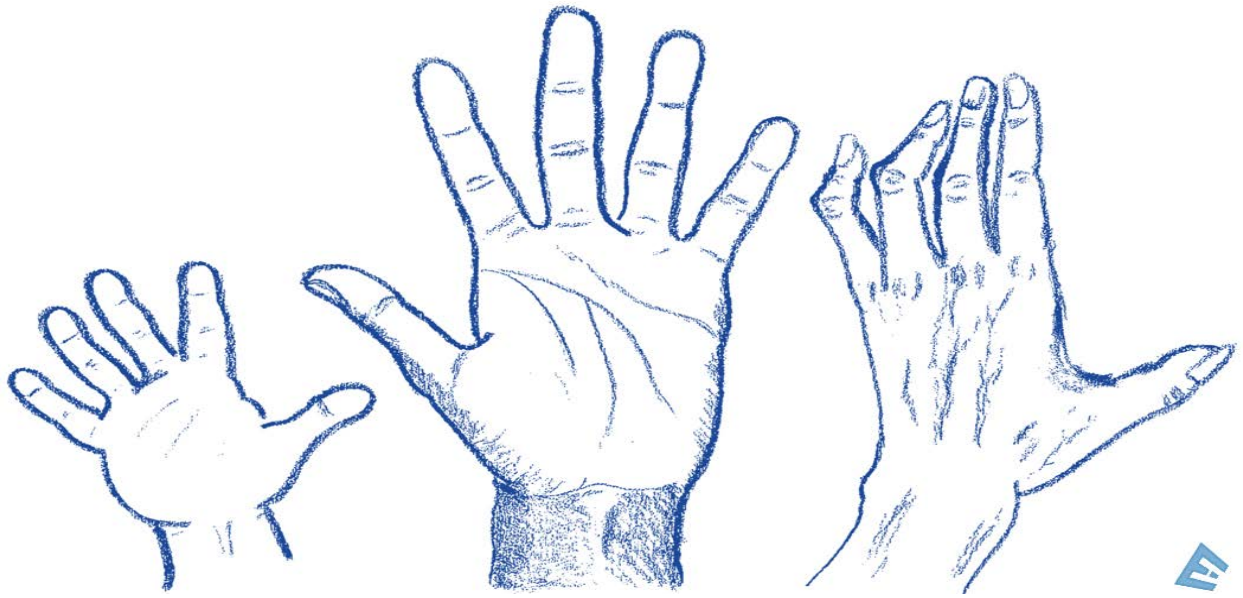
1. Convene a workshop on age groupings and age exclusions in clinical research;
    - Post workshop findings on NIH website
2. Publish guidelines addressing consideration of age in clinical research; and
3. Publish the number of children included in NIH research.

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.

National Institutes of Health
Turning Discovery Into Health

Inclusion Across the Lifespan



https://videocast.nih.gov/launch.asp?23334

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Themes from the Workshop

- In his opening remarks at the workshop, NIH Director Dr. Francis Collins called it "*an opportunity to look at our current approach to inclusion and see what we can do to be as inclusive as possible*."

- Rather than trying to reduce the risk to vulnerable populations from research, the scientific community should consider how these populations might benefit from greater participation in such research, including the generation of efficacy data that are applicable to them.

- A culture shift is needed, whereby *protection from research* is replaced by *protection through research*.

What is relevant to this Task Force?

- Barriers to inclusion discussed at Workshop:
  - Limited number of individuals who can be recruited within the timeframe of traditional study designs.
  - Comorbid and pre-existing conditions that complicate data analysis/interpretation of results.
  - Higher attrition rates may complicate/prolong trials.
  - Insufficient power for subgroup analyses
  - Investigators, peer reviewers, & Institutional Review Board members may be unsure of inclusion policies
  - Consent monitors may be needed to ensure participant interests and autonomy are protected

What is Relevant to this Task Force?

- Workshop participants highlighted the need to include pregnant and lactating women in clinical studies. The frequent exclusion of these women from clinical trials means that doctors have little information to make evidenced-based decisions for the treatment of pregnant and lactating women.

- Challenge of enrolling women who have caregiving responsibilities for children and/or parents and other older adult relatives, which may pose additional barriers for their participation in clinical trials.

Contact info

James Griffin

James.Griffin@nih.gov


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