Issues of Inclusion in Clinical Research

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Task Force on Research Specific to Pregnant and Lactating Women
November 7, 2017
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)
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.
Inclusion Across the Lifespan


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.
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