Including Diverse Populations in NIH-funded Clinical Research

Dawn Corbett, MPH
NIH Inclusion Policy Officer
Division of Human Subjects Research, Office of Extramural Research

NIH Virtual Seminar
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Timeline of NIH Inclusion Policies

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

2015 • NIH changes definition of child to individuals under 18

2016 • 21st Century Cures Act includes new requirements for inclusion

2017 • NIH requires NIH-defined Phase 3 trials report results of analyses in Clinicaltrials.gov

2019 • Inclusion Across the Lifespan Policy becomes effective
Inclusion of Women and Minorities in NIH Research

- Women and members of racial and ethnic minority groups must be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion (NOT-OD-18-014)

- NIH-defined phase 3 clinical trials must be designed to permit analysis by sex/gender, race and ethnicity
  - Applicable NIH-defined phase 3 clinical trials must report results of analyses in Clinicaltrials.gov
Inclusion Across the Lifespan

• Individuals of all ages must be included in NIH human subjects research unless there are scientific or ethical reasons not to do so (NOT-OD-18-116)
  – Effective for applications submitted for due dates on or after January 25, 2019 (and for contract solicitations issued and intramural studies initiated after that date)

• Submission of individual-level data on participant sex/gender, race, ethnicity and age at enrollment in progress reports required
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<td>Years</td>
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Knowledge Check

Cost is an acceptable reason to exclude women from an NIH clinical research study

**FALSE**
What’s Required When Applying for Funding?

• Plans for inclusion of women and minorities
  – Plans for analyses by sex/gender, race, and ethnicity for Phase III trials

• Inclusion enrollment report
  – Data on sex/gender, race, and ethnicity of the sample (planned and/or actual)

• Plans for inclusion of individuals across the lifespan
  – Age limits (if applicable) and justification
See the Application Guide for detailed information

- PHS HS/CT Information Form
- Study Record
  1. Basic information
  2. Study Population Characteristics
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments
Inclusion Enrollment Report

**NEW Inclusion Enrollment Report Title**

Specify whether **Existing Dataset or Resource** will be Used

Include Separate Tables for Domestic/Foreign Populations
## Inclusion Enrollment Reports

### Planned

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### Cumulative (Actual)

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Peer Review of Inclusion

SUMMARY STATEMENT

PROGRAM CONTACT: (Privileged Communication) Release Date: 08/11/2020

Jane Doe
240 111-5555
janesmith@od.nih.gov

Application Number: 1 R01 IC12345-01

Principal Investigator
DOE, JOHN

Applicant Organization: ABC SCHOOL OF MEDICINE

Review Group: ZRG1 ABC-D(50)
Center for Scientific Review Special Emphasis Panel
Program for Collaborative Biomedical Research

Meeting Date: 07/20/2020 RFA/PA: IC 20-006
Council: OCT 2020 PCC: M51B B
Requested Start: 12/01/2020

Project Title: An Excellent Research Project

SRG Action: Impact Score: 24

Human Subjects: 30- Human subjects involved
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Gender: 1A-Both Genders, scientifically acceptable
Minority: 5A-Only foreign subjects, scientifically acceptable
Age: 3U-No children (only adults and older adults), scientifically unacceptable.
Clinical Research - not NIH-defined Phase III Trial
What Makes A Good Inclusion Plan?

Guidelines available at

Complete

Scientifically

Appropriate

Realistic!
Recurrence Themes

- Select **trial outcomes** that reflect participant concerns
- Limit use of unnecessary **inclusion/exclusion criteria**
- Adequately weigh **risks of excluding** groups—like pregnant women and children—with that of their participation
- **Minimize** participant and caregiver **burden**
- Consider the **diversity** of individuals within a given group (e.g. size, comorbidities, diet, cognitive status)
- Regularly **assess recruitment and retention** and make modifications as needed
Inclusion Plans: Other Points to Consider

• Demographics of source population
• Family and community involvement
• Language and participant communication
• Staff expertise
• Budget
A researcher proposes a study to determine the efficacy of a novel treatment for prostate cancer. The study excludes individuals whose sex at birth is female.
Case Study #2

A researcher proposes a study to examine use of a smartphone app to improve glycemic control in diabetic individuals. The study excludes individuals who do not speak English because the consent form is available only in English.
Case Study #3

A researcher proposes a study in individuals 18 to 60. The study indicates children are excluded because the legal age to consent to research is 18 in the state where the research will be conducted. Individuals over 60 will be excluded because of the likelihood of co-morbidities in this group.
– Work with Institute/Center staff to resolve unacceptable inclusion concerns

– Provide inclusion enrollment report(s) if missing or needs updated as a result of peer review and/or programmatic adjustments
After the Award…Now What?

• Provide **actual inclusion enrollment data** in progress reports

• For NIH-defined Phase III Clinical Trials – **report status/results of analyses** by sex/gender, race, and ethnicity
  – For **applicable** NIH-defined Phase III Clinical Trials, report results by sex/gender and/or race/ethnicity in Clinicaltrials.gov within 1 year of primary completion date

• Provide PHS Human Subjects and Clinical Trials Information Form for delayed onset studies
Uploading Participant-Level Data in HSS

Videos, Templates, and Other Resources on HSS Training Site!

If funded, NIH recipients will need to provide data on participant race, ethnicity, sex/gender, and date of birth

FALSE
RESOURCES

WEB
Inclusion of Women and Minorities
https://grants.nih.gov/grants/funding/women_min/women_min.htm
Inclusion Across the Lifespan
https://grants.nih.gov/grants/funding/lifespan/lifespan.htm

EMAIL
inclusion@mail.nih.gov

NIH
National Institutes of Health
Office of Extramural Research