

Gender and the Inclusion of Minorities and Children in NIH Funded Research

This information is designed to assist applicants with incorporating the NIH guidelines related to gender and the inclusion of women, minorities and children in research applications submitted to NIH for funding.

What is the NIH policy on the inclusion of women and minorities in clinical research?

Mandated by Congress, 1993 PL 103-43 stipulates:

- Women and minorities must be included in all clinical research studies, unless there is an acceptable scientific justification for exclusion
- Women and minorities must be included in Phase III clinical trials in numbers adequate for valid analysis
- Cost is not an allowable reason for exclusion of these populations

NIH Policy On Inclusion Amended October 2001:

http://grants.nih.gov/grants/funding/women_min/women_min.htm

NIH Definitions of Research

What is clinical research?

The NIH definition of clinical research is as follows:

(1) Patient-oriented research

Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. **Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.** Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies;

(2) Epidemiologic and behavioral studies;

(3) Outcomes research and health services research

How does NIH define Clinical Trials?

See <http://grants.nih.gov/grants/guide/notice-files/not98-084.html> for definitions of Phase I, II, and III clinical trials.

Phase III Clinical trials are defined as “a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. The definition includes pharmacologic, nonpharmacologic, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

What constitutes an acceptable minority inclusion plan?

Reviewers use one or more of the following to judge applications:

- Minority individuals are included in scientifically appropriate numbers
- Some or all minority groups or subgroups are excluded due to:
 - Inclusion of these individuals would be inappropriate with respect to their health;
 - The research required by the statement of work is relevant to only racial or ethnic group;
 - Evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- A single minority group study is proposed to fill a research gap:
- Significant data already exists with regard to the outcome of comparable studies in the exclude racial or ethnic groups and duplication is not needed in this study.
- Some minority groups or subgroups are excluded or poorly represented because the geographical location where the work is to be performed has only limited numbers of these minority groups who would be eligible for the study, AND the offerer has satisfactorily addressed this issue in terms of:
 - The size of the study;
 - The relevant characteristics of the disease, disorder, or condition;
 - The feasibility of making collaboration or consortium or other arrangements to include representation.
 - Racial and ethnic origins of specimens or existing datasets cannot be accurately determined (e.g., pooled samples)

What additional information is needed regarding the inclusion of minorities?

- Population characteristics
- National and local demography
- Knowledge of the racial/ethnic/cultural characteristics
- Prior experience and collaborations in recruitment and retention with target population
- Subpopulations to be included
- Letters of commitment from relevant community groups and organizations

How are racial and ethnic populations defined?

Ethnic categories:

Hispanic or Latino; A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish Origin” can be used in addition to “Hispanic or Latino”.

Not Hispanic or Latino

Racial categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, central, or South America, and who maintains tribal affiliations of community attachment.

Asian: A person having origins in any of the original peoples of Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American: A person having origins in any of the black racial groups of Africa.

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa

What constitutes an acceptable gender inclusion plan?

The research plan must include a description of plans to conduct analyses to detect significant differences in the intervention effect. “A **significant difference**” is a difference that is of clinical or public health importance, based on substantial scientific data.

- When strong evidence suggests that there is no significant difference or public health importance between males and females in relation to the study variables, representation of both genders is not required. Representation of both genders is not required; however inclusion of both genders is encouraged.
- The research plan must include a description of plans to conduct the valid analyses of the intervention effect. **Valid analysis** means an unbiased assessment.
- One gender is excluded due to:
 - Inclusion of these individuals would be inappropriate with respect to their health; or
 - Inclusion of these individuals would be inappropriate with respect to the purposes of the research (e.g. study of prostate cancer would only include men)

What is the NIH policy on the inclusion of children in NIH funded research?

NIH requires that children (i.e., under the age of 21) must be included in all human subjects research conducted by the NIH, unless there are compelling reasons not to include them.

How does the NIH define children?

A child is defined as an individual under the age of 21.

When is acceptable not to include children?

- The research topic is not relevant for children
- There are laws and regulations barring the inclusion of children
- The knowledge being sought would be redundant
- A separate, age-specific study in children is warranted and preferable
- Insufficient data are available in adults to judge potential risk in children
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children)
- Other special cases justified by the investigator and found acceptable to the review group and the Institute Director

Policies on inclusion of children are found at this site:

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

How are applications evaluated for the inclusion of women, minorities, and children?

When evaluating for inclusion of these populations, reviewers assign an overall code to indicate if the inclusion is acceptable (A) or unacceptable (U). Acceptable or A = representation is scientifically and recruitment/retention has been realistically addressed, or an acceptable justification for exclusion has been provided.

U or Unacceptable = representation is unacceptable. Applications fail to confirm to NIH policy guidelines in relation to the purpose of the study or fail to provide sufficient information; or does not adequately justify exclusion of minority consideration in subjects or does not realistically address recruitment or retention

Reviewers also assign gender (G) minority (M) and children (C) codes
Thus each application will be assigned a code

GENDER CODE G

1=Both gender
2=Only women
3=Only men
4=Gender unknown

Minority CODE M

1=Minority and nonminority
2= Only minority
3=Only nonminority
4=Minority representation unknown

Children CODE C

1=Children and adult
2=Only children
3=No children
4=Representation of children unknown

For example:

G1A = both genders scientifically acceptable
M4U = Minority representation unknown and unacceptable
C2A = Only children acceptable

If an application receives an unacceptable coding, the applicant may be notified by NIH staff to address the unsatisfactory coding. Applications are barred from funding until such issues are corrected satisfactorily. Applicants are encouraged to carefully review the forms and instructions outlined in the PHS 398 for guidance in meeting this important requirement. Once an applicant satisfactorily addresses the concern, the unacceptable code(s) is removed and if fundable, the funding process will be continued.

Related references:

Taylor Harden, J. & McFarland, G. (2000). Avoiding Gender and Minority Barriers to NIH Funding. Journal of Nursing Scholarship,32(1), 83-86.

The PHS 398 application kit is located at: <http://grants.nih.gov/funding/phs398/phs/>. Details related to gender and inclusion of women, minorities, and children are found in the application kit.