



POLICY GUIDANCE

NIH, CCSG, and University of Arizona HPP Policies FAQs, Definitions, and Summaries

Contents

Inclusion on the Basis of Sex/Gender and Race/Ethnicity	1
Racial and Ethnic Categories and Definitions for NIH Diversity Programs and for Other Reporting Purposes.....	3
OnCore HIPAA Assurance Statement.....	4
For Cancer-Related Trials Only: Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (P30).....	5

Inclusion on the Basis of Sex/Gender and Race/Ethnicity

General NIH Inclusion Policy Questions

Last Revised: May 23, 2018

What is the purpose of the NIH policy on the inclusion of women and racial/ethnic groups as participants in research?

The overarching goal of [this policy](#) is to ensure the appropriate inclusion of women and minorities in all clinical research supported by the NIH. NIH-supported clinical research should address/include the population(s) at risk for the disease or condition under study and ensure that the distribution of study participants by sex/gender, race and ethnicity reflects the population needed to accomplish the scientific goals of the study.

What is subject to the policy?

All research projects supported by the NIH that meet the NIH definition for clinical research are subject to the NIH inclusion policy. This includes studies supported by grants, cooperative agreements, R&D contracts, and NIH intramural programs. [Here](#) is a link to a decision tree to help in determining whether a given study is subject to the policy.

Because of how human subjects research is defined, there may be studies using information from humans that are not considered human subjects research. Although these studies are not subject to the NIH Inclusion Policy, this does not mean that an understanding of the demographics (e.g., sex/gender, race, ethnicity, age, etc.) is not important. The NIH encourages applicants to address this information, as appropriate, for the scientific question(s) under study.

What is the definition of NIH clinical research?

Clinical research is defined as:

- (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; and
- (3) Outcomes research and health services research.

Note: Studies that meet the requirements for Institutional Review Board (IRB) review Exemption 4 are not considered NIH-defined clinical research. More information on Exemption 4 can be found [here](#).

For the purposes of inclusion policy only: Additional clarification of part (1) of the NIH definition of clinical research:

1. **What does the term “patient-oriented” encompass?**

Patient-oriented research includes inpatient and outpatient settings, as well as healthy volunteers.

2. **Who is considered a “colleague?”**

A colleague is considered to be anyone involved in conducting the research; doing any activity related to the research other than just providing specimens/data (also referred to as a provider).

3. **What is considered a “direct interaction?”**

In addition to having a direct interaction by an investigator (or colleague) with the participant, another form of direct interaction is defined as any colleague/investigator with access to PII (personally identifiable information).

How is research that is Exempt from IRB (Institutional Review Board) review considered under the NIH inclusion policy?

Human subjects research that meets the criteria for IRB Exemption 4 is not considered “clinical research” as defined by NIH; therefore, the NIH policy for addressing inclusion of women and minorities does not apply to research that is determined to meet the criteria for Exemption 4. However, research meeting other IRB exemptions may or may not meet the NIH definition for clinical research and should be considered on a case-by-case basis to determine whether the NIH inclusion policy applies.

Is cost an acceptable justification for not including certain groups in clinical research studies or trials?

No. The cost associated with ensuring that the clinical research study population composition is appropriate in regards to sex/gender, racial, and/or ethnic distribution is not an acceptable justification for excluding (a) particular group(s).

What is the “target population” for a given study?

The number of subjects in the trial or study that are expected to be enrolled during the entire period of the study and are needed to evaluate the research question, and the expected distribution by sex/gender, race, and ethnicity based on the prevalence of the disease or outcome of interest in the population and study characteristics.

When is someone considered a “participant” whose enrollment should be reported to the NIH?

Any individual who is considered to be a human subject for a study as [defined by 45 CFR 46](#) is considered a participant whose enrollment should be reported to NIH. An individual is considered to be a [human subject](#) once the individual is enrolled or entered into the study, including situations where data is collected about an individual through a proxy, such as the collection of data about infants from mothers. This definition includes all subjects who are eligible to contribute data to the scientific aims of the study, including individuals who subsequently drop out. Subjects who are screened for participation but are not eligible would not be considered participants. This definition is limited to studies that fall under the definition of [clinical research](#) at NIH.

Are clinical research subjects required to provide information about their sex/gender, race, and ethnicity?

Whenever possible, collection of information on sex/gender, race, and ethnicity should involve self-report by the individual research participant. The data collection instrument should include the option to not identify sex/gender, race, and/or ethnicity, in which case, these participants would be reported to the NIH as “unknown/not reported.”

Racial and Ethnic Categories and Definitions for NIH Diversity Programs and for Other Reporting Purposes

Excerpted from NIH Notice ID [NOT-OD-15-089](#)

Racial and Ethnic Categories

In 1997, the Office of Management and Budget (OMB) issued the [Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity](#). These standards are commonly used for federal data collection purposes, not only in the decennial census, but also in household surveys, on administrative forms (e.g., school registration and mortgage lending applications), and in medical and clinical research. The revised standards contain five minimum categories for race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: "Hispanic or Latino" and "Not Hispanic or Latino."

Definitions for Racial and Ethnic Categories

The Revisions to OMB Directive 15 defines each racial and ethnic category as follows:

1. **American Indian or Alaska Native:** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
2. **Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
3. **Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
4. **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."
5. **Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
6. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

The categories and definitions provide a common language to promote uniformity and comparability of data on race and ethnicity. Moreover, federal agencies have a continuing commitment to monitor the operation of its review and award processes to detect, and deal appropriately with, any instances of real or apparent inequities. All analyses conducted on race and ethnicity report aggregate statistical findings and do not identify individuals.

OnCore HIPAA Assurance Statement

We want to assure you that you won't have any issues placing your research data in the OnCore CTMS. This system is the officially recognized and approved system at the University of Arizona for all clinical research. OnCore is an incredibly sophisticated software product that provides compliant protection and limits access to the trial and associated trial data to appropriate personnel. All administrative and IT staff are already governed under many current certificates of confidentiality regarding all data within the OnCore system. If you have any questions, please contact [John Howard](#) at the UArizona HIPAA Privacy Program (HPP).

Furthermore, the University of Arizona has been awarded a (P-30) CCSG grant that requires us to report on all clinical research related at the University of Arizona. This is the reason we need subjects' race, ethnicity, and age, in addition to the protocol and accrual information.

For Cancer-Related Trials Only: Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (P30)

Except from the Clinical Protocol and Data Management Section

I. Provide an overview of accrual to interventional clinical trials over the project period preceding the renewal application. (Note: This is a summary of data on interventional trials; the definitions, reporting years, and accrual sites used in Data Table 4 apply to the data in this table.) A sample template is below:

ACCRUAL TO INTERVENTIONAL* CLINICAL PROTOCOLS BY REPORTING YEAR (MM/YYYY)* AND SOURCE OF SUPPORT (FOR PRIOR FOUR YEARS OF ACTIVITY)

Reporting Year (specify mm/yyyy)					
National Group					
External Peer Review					
Institutional (investigator initiated)					
Industry					
Total Accrual to Interventional Clinical Protocols					

**Centers may also provide data on accrual to non-interventional clinical studies in a similar format if desired, using Data Table 4 data for observational, ancillary, and correlative studies.*

II. For the Inclusion of Women and Minorities in Clinical Research, include in tables information on:

Demographics: In three sections, provide summary information showing the demographics of the primary geographic catchment area of the Center by ethnic categories and subcategories and by gender, as well as for the cancer patient population treated at the Cancer Center. Centers have the option of also providing data on demographics of cancer patients in the catchment area, if available.

Accrual: Using the official NIH gender and racial/ethnic categories and subcategories, provide summary accrual information from the most recent 12-month period for all clinical research studies conducted at the center in each of the following areas: (a) interventional therapeutic clinical trials, (b) interventional non-therapeutic clinical trials, and (c) non-interventional epidemiologic, observational, and outcome studies. Relate this information to the demographic information provided above.

► Learn More

NCI Data Guidelines: <https://cancercenters.cancer.gov/Documents/edata508.pdf>