Frequently Asked Questions

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

I. General NIH Inclusion Policy Questions

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.

Full details on the policy are available here. There are additional requirements for studies meeting the NIH definition for a Phase III clinical trial. These are addressed under FAQ #9 in Section I.

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. A text version of this decision tree can be found here.

Because of how human subjects' research is defined, there may be studies using information from humans that is 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:

What does the term “patient-oriented” encompass? Patient-oriented research includes inpatient and outpatient settings as well as healthy volunteers.

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).

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 policies for addressing inclusion of women, minorities and children do 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 NIH inclusion policy applies.

Does the NIH inclusion policy apply to research using existing datasets or other types of existing resources involving human subjects?

If the study is considered human subjects’ research and meets the NIH definition of clinical research, then it is subject to the NIH inclusion policy. For more details about working with existing datasets or resources involving human subjects see the specific FAQ on existing datasets and resources in inclusion (or Section II in the overall inclusion FAQ).

For the purposes of inclusion policy, what is an existing dataset/resource?

An existing dataset may be constructed of different types of data including but not limited to survey data, demographic information, health information, genomic information, etc. Also included would be data to be derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the NIH definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated.

Does the NIH inclusion policy apply to studies conducted outside of the US that are supported by the NIH?

Yes, the NIH inclusion policy applies to NIH-supported studies conducted outside of the United States. Working with non-US participants can present a unique challenge to reporting racial and ethnic information to the NIH. However, investigators are expected to report information on the sex/gender, race, and ethnicity of participants. See below for additional guidance on collection and reporting of this information.

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 and should be reported to the NIH?

An individual is considered to be a participant once he or she is enrolled or entered into the study. This would include subjects that are eligible for contributing data to the scientific aims and consented for participation, including individuals who subsequently dropout. Subjects who are screened for participation but are not eligible or who do not consent would not be considered as participants. This definition is limited to studies that fall under 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.”

Are there additional inclusion policy requirements for NIH-defined Phase III clinical trials?

For an NIH-defined Phase III clinical trial (defined here), in addition to addressing inclusion as for any NIH-defined clinical research study, investigators must also address requirements for valid analysis in their competing application and address progress in their non-competing (progress report) application. Additional details on applying NIH inclusion policy to NIH-defined Phase III clinical trials can be found here. Competing and non-competing instructions can be found here.

II. Questions on Inclusion Information When Submitting NIH Applications/Proposals

What inclusion-related information do I need to submit in my competing application/proposal if conducting NIH-defined clinical research?

When submitting a new or competing renewal application/proposal to the NIH that includes NIH-defined clinical research studies, investigators should address plans for inclusion on the basis of sex/gender, race, and ethnicity as well as complete the Planned Enrollment Report. At a minimum, the inclusion plan should describe the proposed sample distributions by sex/gender, race, and ethnicity. You should justify the proposed sample in the context of the scientific goals of the proposed study. In addition to Planned Enrollment Reports, investigators submitting a competing renewal application should also complete a Cumulative Inclusion Enrollment Report(s) to describe progress on inclusion from the previous funding period. More detailed instructions are available in the application instruction guides available here.

How do I address inclusion if I do not have definite plans to conduct human subjects research, such as in the case of delayed onset studies?

The federal Protection of Human Subjects regulations, 45 CFR 46, recognize that certain research applications may be submitted to a sponsoring agency with the knowledge that human subjects will be involved during the period of support, but definite plans for this involvement cannot be described in the application (45 CRF 46.118). As noted in the NIH Grants Policy Statement (GPS) 4.1.15, after award and prior to the involvement of human subjects, the grantee must submit to the NIH awarding Institute/Center (IC) for approval, a detailed human subjects section that follows the NIH competing application instructions. Additional guidance on the submission of this information is described here.

What form(s) do I use to submit inclusion enrollment information in my competing application/proposal?

When submitting a new or competing renewal application to the NIH that includes NIH-defined clinical research studies, you should address plans for inclusion on the basis of sex/gender, race, and ethnicity as well as complete the Planned Enrollment Report. In addition to Planned Enrollment Reports, if you are submitting a competing renewal application you should also complete a Cumulative Inclusion Enrollment Report(s) to describe progress on inclusion from the previous funding period. If you are conducting a new research study using an existing dataset, use the Cumulative Inclusion Enrollment Report rather than the Planned Enrollment Report. Additional instructions are available in the application packages available here, in particular see the Supplemental Instructions.

Can I design a clinical research study that limits inclusion to a specific sex/gender, racial, and/or ethnic group?

Yes. When proposing any study meeting the NIH definition of clinical research you should address plans for inclusion in the context of the study population, considering such factors as who is at risk for the disease or condition under study. If you propose to further limit your sample within a given study population, additional justification should be provided in the context of the scientific goals of the study and why this is an appropriate sample.

Is it acceptable to use existing datasets or resources that are limited to specific sex/gender, racial, and/or ethnic groups?

Yes. You can propose a study or analyses of an existing dataset where the cohort is limited in sex/gender, racial, and/or ethnic participation. However, you should justify why this dataset is useful in the proposed scientific context, particularly if the dataset does not reflect the population of the disease or condition under study. Some factors that can be considered as part of the justification include the nature of the scientific question, a requirement for data provided by the cohort, or addressing a gap in knowledge.

If I am using an existing dataset or resource, what form(s) do I use when submitting my application/proposal?

The NIH provides forms with the different application packages for completing information on sex/gender, race, and ethnicity. We are transitioning to a modified layout of the forms starting with competing applications. For additional details see this Guide Notice. As noted above, if you are conducting research with an existing cohort or dataset, you would use the Cumulative Inclusion Enrollment Report rather than the Planned Enrollment Report.

What do I do if my study sample is from a geographic area with a limited population?

When proposing any study meeting the NIH definition of clinical research you should address plans for inclusion in the context of the study population, considering such factors as who is at risk for the disease or condition under study. If you are in a geographic area with a limited population, additional justification should be provided in the context of the scientific goals of the study and why this is still an appropriate sample. Cost to recruit certain groups is not an acceptable justification for limiting the inclusion of those groups. If you are aware of similar research completed or underway employing populations complementary to those available proposed in your study, you can present this as a rationale for limited representation. Alternatively, if the appropriate sample cannot be achieved in your geographic area, you should also address the feasibility of making collaborative or other arrangements to include the appropriate populations in your sample, e.g., seeking collaborators in other geographic areas where there is access to the other populations.

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).

In studies or trials involving multiple sites, is each study site required to address inclusion separately?

No. When multi-site clinical research studies (or trials) are proposed, the appropriate distribution by sex/gender, race, and ethnicity should consider the recruitment across the different sites. The funding Institute or Center (IC) at NIH and/or the PI/research team may decide that it is useful to provide inclusion data individually by site or by overall study, but it should not be provided both ways.

In multi-component applications, does each component (or subproject) have to address inclusion separately?

It depends. Inclusion plans and the distribution of a planned sample by sex/gender, race, and ethnicity should be considered for each clinical research study or trial. If a given study spans multiple components, only one Planned Enrollment Report (for that given study) needs to be provided; however, depending on the structure of the multi-component application, the inclusion plans may need to be referenced in more than one component. See the application guide instructions and the specific Funding Opportunity Announcement (FOA) for additional guidance.

Since I’m working with non-US participants, how do I collect and report information on sex/gender, race, and ethnicity?

When feasible, self-report of sex/gender, race, and ethnicity is the preferred method. However, working with non-US participants can present a unique challenge to the collection and reporting of racial and ethnic information. The racial and ethnic standards used for reporting to the NIH are set by the Office of Management and Budget (OMB) and are defined for the US population. It is not expected that investigators would use the OMB categories for race and ethnicity in data collection instruments designed for use in other countries. Investigators should design culturally appropriate data collection instruments that allow a participant to self-identify with their racial and ethnic affiliation in a way that is meaningful in the cultural and scientific contexts of the study. However, investigators will need to use the OMB-defined categories for reporting sex/gender, race, and ethnicity to the NIH. Since the OMB categories reference world-based geographic origin, this should facilitate the “translation” of the information for reporting purposes to NIH.

For more information on the categories and their definitions, information can be found here. In addition to the OMB description, information about the race and ethnicity categories and use of the NIH forms is available in the SF242 R&R and other NIH application forms available at http://grants.nih.gov/grants/forms.htm.

What if I’m conducting a study with sites within the US and outside the US?

It is important for reporting purposes to NIH that US and non-US participants be distinguishable. At a minimum, investigators must provide separate planned and cumulative inclusion enrollment reports for US and non-US participants even if part of the same study. Further breakout of enrollment reports by site, country, etc. is permissible. Additional instructions are available in the application packages here.

III. How Inclusion Is Considered in the NIH Peer Review Process and Funding Decisions for Applicants

How is inclusion by sex/gender, race, and ethnicity in clinical research considered in peer review?

Peer reviewers will be asked to evaluate the plans for the inclusion by sex/gender, race, and ethnicity in the application; specifically they will evaluate it as acceptable or unacceptable. Reviewers are instructed that their assessment of the applicant’s plan should be factored into the score for scientific and technical merit. Specific reviewer guidance can be found here.

Does the peer review consider additional factors about sex/gender, race, and ethnicity when the application includes an NIH-defined Phase III clinical trial(s)?

Yes. In addition to reviewing plans for inclusion by sex/gender, race, and ethnicity when an NIH-defined Phase III clinical trial is proposed, the reviewers will evaluate the study design and plans addressing valid analysis. The peer reviewer guidelines also address this and can be found here.

How will the peer review of inclusion affect the scoring of my application?

Reviewers are instructed that their assessment of the applicant’s plan should be factored into the score for scientific and technical merit. Specific reviewer guidance can be found here.

What happens if my application gets an unacceptable rating for inclusion at peer review?

The Scientific Review Groups (SRGs) will evaluate the plans for inclusion in a manner consistent with the evaluation of all other factors that contribute to the overall priority score. Acceptable or unacceptable codes are assigned to each application for sex/gender and race/ethnicity. Any application given an unacceptable code “U,” results in a bar-to-­funding and must be resolved before the application/proposal is funded.

If I’m a peer reviewer, where can I find additional guidance on the peer review of inclusion?

Additional peer review guidance for inclusion can be found here.

IV. How to Collect and Report Sex/Gender, Race, and Ethnicity in Awarded NIH Projects

A. Overview of Racial and Ethnic Standards

Who sets the race and ethnicity standards for the categories used in reporting participants to NIH?

The racial and ethnic standards are set by the Office of Management and Budget (OMB). The racial and ethnic categories are defined in terms of geographic origins. For more information on the categories and their definitions, information can be found here.

Where are the race and ethnicity standards and categories described?

In addition to the link above to the OMB description, information about the race and ethnicity categories and use of the NIH forms is available in the SF424 R&R and other NIH application forms available at http://grants.nih.gov/grants/forms.htm.

B. Collection of Race and Ethnicity Information from Research Participants

Who decides what race and ethnicity a research participant is?

Typically, the research participant should be provided the opportunity to self-select and report the racial and ethnic categories that they identify with. Also, data collection must allow for participants to not provide these data, in which case they will be reported to the NIH as “unknown/not reported.”

There may be situations where self-report of race and ethnicity is not feasible because the participant is incapable of providing the information. In these situations, investigators should determine what is the most reasonable approach such as obtaining the information from other sources (e.g., medical records, family members, etc.) or whether it is more appropriate to indicate "unknown/not reported."

How is racial and ethnic information collected from a research participant?

Investigators should design culturally appropriate demographic data collection approaches that allow individuals to self-select the racial and ethnic standards they identify with. Generally, investigators should ask race and ethnicity as two separate questions. The first question should ask an individual’s ethnicity, followed by a question that provides the option of selecting one or more racial categories. As discussed above, individuals have the right not to select any category(s), in which case they will be reported to the NIH as “unknown/not reported.”

How do individuals who are more than one race identify?

In structuring an appropriate demographic data collection, participants should be offered the choice to select as many racial categories that they deem appropriate. When the investigator reports to the NIH, these individuals will be aggregated under the “more than one race” category.

What if my study involves analyzing an existing dataset in which the race and ethnicity categories do not comply with the 1997 OMB standards?

If an investigator is using previously collected data sets that do not conform to the current (1997) OMB standards and does not plan to collect any new/additional data from the subjects, this should be noted in the inclusion section of the competing or non-competing application and/or in the comments section of the Planned Enrollment Report. When preparing to report on actual cumulative inclusion enrollment to the NIH, investigators should report the information they have and use the unknown/not reported category, when necessary. Investigators should not assume what racial or ethnic category an individual would have identified with.

Can the NIH forms be used to collect data from research participants?

The NIH forms should not be used for collecting data from research participants. These forms are only to be used for reporting the enrollment of individuals by sex/gender, race, and ethnicity to the NIH for a given study(s).

Investigators should develop an instrument for collecting this information that is culturally appropriate for the research setting and that meets the scientific needs of the study. Also, investigators should think carefully about the way the information is asked of participants to ensure they obtain the information needed for their study and for reporting on the forms. For example, at times, an individual's self-identity (e.g., sex/gender, race, and/or ethnicity) may differ from their genetic, chromosomal, ancestral lineage etc. Investigators may want to frame the demographic questions differently depending on the scientific goals of the study and what information is needed for that purpose.

Can more detailed questions than indicated by the OMB guidelines be asked about ethnicity and race?

The scientific question being addressed in the study should guide investigators’ decisions regarding collection of any additional information on ethnicity or race. Researchers are encouraged to consider collecting additional information on race and ethnicity that will provide insights into the relationships between race and ethnicity and health. The 1997 OMB guidelines provide minimum standards for data collection and should be used when reporting race and ethnicity to the NIH. However, discussion of more detailed information on race and/or ethnicity may be provided in the competing application and/or non-competing progress reports submitted to the NIH.

Since I’m working with non-US participants, how do I collect and report information on sex/gender, race, and ethnicity?

When feasible, self-report of sex/gender, race, and ethnicity is the preferred method. However, working with non-US participants can present a unique challenge to the collection and reporting of racial and ethnic information. The racial and ethnic standards used for reporting to the NIH are set by the Office of Management and Budget (OMB) and are defined for the US population. It is not expected that investigators would use the OMB categories for race and ethnicity in data collection instruments designed for use in other countries. Investigators should design culturally appropriate data collection instruments that allow a participant to self-identify with their racial and ethnic affiliation in a way that is meaningful in the cultural and scientific contexts of the study. However, investigators will need to use the OMB-defined categories for reporting sex/gender, race, and ethnicity to the NIH. Since the OMB categories are based on world-based geographic origin, this should facilitate the “translation” of the information for reporting purposes to NIH.

For more information on the categories and their definitions, information can be found here. In addition to the OMB description, information about the race and ethnicity categories and use of the NIH forms is available in the SF242 R&R and other NIH application forms available at http://grants.nih.gov/grants/forms.htm.

C. How to Report Race and Ethnicity Information to the NIH

When is information on race and ethnicity reported to the NIH?

In general, when conducting NIH-defined clinical research, investigators are expected to include women and minorities unless inappropriate with respect to the health or the scientific goals of the study. See here for more details on the policy.

Submitting a competing application: When submitting a new or competing renewal application to the NIH, investigators should address plans for inclusion on the basis of sex/gender, race, and ethnicity in their research studies as well as complete the Planned Enrollment Report. In addition to Planned Enrollment Reports, investigators submitting a competing renewal application should also complete a Cumulative Inclusion Enrollment Report(s) to describe progress on inclusion from the previous funding period. Additional instructions are available in the application packages available here.

Submitting a non-competing application (progress report): Investigators should complete an Inclusion Enrollment Report for each study to describe progress in enrolling individuals by sex/gender, race, and ethnicity. Additional instructions are available in the application packages available here.

What report format is used to report sex/gender, race, and ethnicity?

The NIH provides forms with the different application packages for completing information on sex/gender, race, and ethnicity. We transitioned to a new layout of the forms in 2013 (competing applications) and 2014 (non-competing applications). For additional details see this website for relevant Guide Notices and other information.

What does the report format transition mean and when does it start?

Starting with September 2013 receipt dates, investigators preparing new or renewal competing applications will use the modified reporting format available in competing application packages. Note: SBIR/STTR applications will begin using the modified layout after the September 7, 2013 receipt date. Non-competing applications (i.e., progress reports) starting with FY2015 (October 1, 2014).

What changed on the report formats?

The data collection is the same as are the racial and ethnic standards. The changes are to add the “more than one race” category to the Planned Enrollment Report and to simplify the layout of the forms to emphasize that race and ethnicity are distinct concepts for Federal data collection and reporting efforts.

Why did the layout for the forms change?

The layout of the forms changed to reduce confusion about how to complete the enrollment information and to ensure that everyone understands that, for each participant, information about race and information about ethnicity are collected separately, resulting in two separate pieces of data.

How should race and ethnicity data be reported for research participants who identify with more than one race?

In structuring an appropriate demographic data collection, participants should be offered the choice to select all racial categories that they deem appropriate. When the investigator reports to the NIH, individuals who selected multiple racial categories should be aggregated under the “more than one race” category.

What do I do if there are subjects that did not identify their sex/gender, race, and/or ethnicity?

Participants always have the right to not identify with any category, in which case they will be reported to the NIH as “unknown/not reported.”

Since I’m working with non-US participants, how do I collect and report information on sex/gender, race, and ethnicity?

When feasible, self-report of sex/gender, race, and ethnicity is the preferred method. However, working with non-US participants can present a unique challenge to the collection and reporting of racial and ethnic information. The racial and ethnic standards used for reporting to the NIH are set by the Office of Management and Budget (OMB) and are defined for the US population. It is not expected that investigators would use the OMB categories for race and ethnicity in data collection instruments designed for use in other countries. Investigators should design culturally appropriate data collection instruments that allow a participant to self-identify with their racial and ethnic affiliation in a way that is meaningful in the cultural and scientific contexts of the study. However, investigators will need to use the OMB-defined categories for reporting sex/gender, race, and ethnicity to the NIH. Since the OMB categories are based on world-based geographic origin, this should facilitate the “translation” of the information for reporting purposes to NIH.

For more information on the categories and their definitions, information can be found here. In addition to the OMB description, information about the race and ethnicity categories and use of the NIH forms is available in the SF242 R&R and other NIH application forms available at http://grants.nih.gov/grants/forms.htm.

D. How to Collect and Report Sex/Gender Information to the NIH

I’m planning to recruit or am recruiting individuals whose sex at birth does not align with their gender identity. How do I address this on the Planned Enrollment and/or Cumulative Inclusion Enrollment Report forms?

When collecting and reporting information about sex/gender, it’s important to consider what is most relevant to the scientific question under study (e.g., sex at birth, current gender identity, etc.). The NIH encourages information reported on the Cumulative Inclusion Enrollment Report to be based on self-report of the participants whenever feasible. Therefore, how the question is asked of the participants is important. The information obtained from the participants should then be used to complete the table. Participants always have the option not to identify, in which case they would be reported under “Unknown/Not Reported” category on the Cumulative Inclusion Enrollment Report.

V. Additional Information

Where do I go to get more information on the NIH inclusion policy for sex/gender, race, and ethnicity?

Grants and Cooperative Agreements: Additional information about grants and cooperative agreements may be obtained from NIH staff identified in Request for Applications (RFAs), Program Announcements (PAs), or on awards. The following staff from the NIH Institutes and Centers may be contacted for further information about the policy and relevant Institute/Center programs. A list of NIH contacts is available here.

Contracts: For information about contract policy, the contracting officer for the specific contract or the Division of Acquisition Policy and Evaluation, Office of Acquisition Management and Policy (301-496-6014), may be contacted.