Hispanic or Latino • Not Hispanic or Latino • American Indian/Alaskan Native • Asian • Native Hawaiian or Other Pacific Islander • Caucasian • Black or African American • Hispanic or Latino • Not Hispanic or Latino • American Indian/Alaskan Native • Asian • Native Hawaiian or Other Pacific Islander • Caucasian •Black or African American • Hispanic or Latino • Not Hispanic or Latino • American Indian/Alaskan Native • Asian

OUTREACH NOTEBOOK

Frequently Asked Questions

Concerning the NIH Guidelines on the Inclusion of Women and Minorities in Clinical Research

March 2003

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Office of the Director

Preface

The Revitalization Act of 1993, required that the National Institutes of Health (NIH) develop "Guidelines on the Inclusion of Women and Minorities As Subjects in Clinical Research". The guidelines, first published in 1994 (Federal Register, March 28, 1994, 59FR14508-14513; http://grants.nih.gov/grants/guide/notice-files/not94-100.html), have been updated most recently in October 2001 (http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). Research applications and proposals to be supported by NIH must comply with this statute and the policy and guidelines that implement it.

This document contains a series of frequently asked questions with answers to assist in the preparation of research applications, proposals, and progress reports in accordance with the NIH Policy and Guidelines. The questions cover areas listed in a table of contents for ease in finding specific topics of interest. Although this document provides additional clarification and explanation, it is important to read the NIH Guidelines.

If there are further questions about this policy, please contact the NIH representative from the appropriate Institute or Center which are listed at the end of this document. The information contained in this document will be updated should there be any significant changes in the NIH Guidelines.

This document is available electronically on the ORWH website (www4.od.nih.gov) as well as the NIH web page on Inclusion of Women and Minorities Policy Implementation http://grants.nih.gov/grants/funding/women_min/women_min.htm. The NIH web page also includes links to other documents and references related to the NIH policy on Inclusion.

Members of the NIH Tracking and Inclusion Committee are indebted to the diligence and work of the Subcommittee Reviewing Inclusion Issues. Subcommittee members are listed below:

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The committee also wishes to extend its deepest appreciation to the NIH staff and those in the extramural community who contributed to the development of the Frequently Asked Questions.

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FREQUENTLY ASKED QUESTIONS CONCERNING THE 1994 NIH GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

POLICY

1. What is required by the 1993 NIH Revitalization Act?

The 1993 NIH Revitalization Act, mandated that:

- NIH ensure women and minorities and their subpopulations are included in clinical research;
- for clinical trials, women and minorities and their subpopulations are included as subjects. In Phase III clinical trials, they must be included in numbers adequate to allow for valid analyses of differences in intervention effect (See this section; Questions 2 and 3 for further details on analysis plans);
- NIH establish guidelines for circumstances under which such inclusion is inappropriate;
- cost is not allowed as an acceptable reason for excluding these groups; and,
- NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies.

Guidelines developed in response to this law were published in the Federal Register in March 1994, and in the NIH Guide for Grants and Contracts in August 2000 and October 2001. NIH will not fund any grant, cooperative agreement or contract or support any intramural project which does not comply with this policy. Research awards covered by this policy require the grantee /contractor to report annually on cumulative enrollment of women and men, and on the race and ethnicity of research participants.

2. What is the NIH policy on the inclusion of women and minorities as subjects in research?

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant

Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-funded clinical research studies.

NIH-defined Phase III clinical trials (see Definitions) must be designed and carried out to allow for valid analysis of differences between men and women and racial/ethnic groups and this must be communicated to applicants. Peer review groups will determine whether each NIH-defined Phase III clinical trial has an appropriate study design. Summary statements (grants/cooperative agreements) or peer review evaluation reports (contracts) document the quality of the study design and proposed analyses.

Applications/proposals/protocols for NIH-defined Phase III clinical trials require a description of plans to conduct analyses to address differences by sex/gender and racial/ethnic groups, including subgroups if applicable. The final protocol(s) approved by the Institutional Review Board (IRB) must include these plans for analysis. The award will require that for each funded protocol, investigators must report in their annual Progress Report cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences. If final analyses of sex/gender and race/ethnicity are not available at the time of the Final Progress Report or Competing Continuation for the grant, a justification and plan ensuring completion and reporting of the analyses are required. If final analyses are required as part of the contract, these analyses must be included as part of the deliverables. These requirements will be cited in the terms and conditions of all awards for grants, cooperative agreements and contracts supporting NIH-defined Phase III clinical trials.

3. What are the details for inclusion in NIH-defined Phase III clinical trials?

Applications/Proposals for an NIH-defined Phase III clinical trial require a review of evidence to show whether or not clinically important sex/gender and race/ethnicity differences in the intervention effect are to be expected. This evidence may include, but is not limited to, data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies. Based on prior studies, investigators must decide which of the following three situations apply to their proposed clinical trial. (Note: For contracts, this may be determined by the Government and one of these three scenarios may be required by the statement of work in the solicitation.)

- **Prior Studies Support the Existence of Significant Differences**

  If the data from prior studies strongly support the existence of significant differences of clinical or public health importance in intervention effect based on sex/gender, race/ethnic groups, and relevant subpopulation comparisons, the primary question(s) to be addressed and the design of the trial must specifically accommodate this. For example, if men and women are thought to respond differently to an intervention, then the clinical trial must be designed to answer two primary questions, one for men and the other for women, with adequate sample size for each.

  The Research Plan (for grant applications) or Proposals (for contract solicitations) must include a description of plans to conduct analyses to detect significant differences in intervention effect (see DEFINITIONS - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable. The final protocol(s) approved by the Institutional Review Board (IRB) must include these plans for analysis. The award will require that for each funded protocol, investigators must report in their annual Progress Report cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences. If final analyses of sex/gender and race/ethnicity are not available at the time of the Final Progress Report or Competing Continuation for the grant, a justification and plan ensuring completion and reporting of the analyses are required. If final analyses are required as part of the contract, these analyses must be included as part of the deliverables. These requirements will be cited in the terms and conditions of all awards for grants, cooperative agreements and contracts supporting NIH-defined Phase III clinical trials.

  Inclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions. If these analyses reveal no differences, a brief statement to that effect, indicating the groups and/or subgroups analyzed, will suffice.

- **Prior Studies Support No Significant Differences**

  If the data from prior studies strongly support no significant differences of clinical or public health importance in intervention effect based on sex/gender, racial/ethnic and/or relevant subpopulation comparisons, then sex/gender and race/ethnicity will not be required as subject selection criteria. However, the inclusion and analysis of sex/gender and/or racial/ethnic subgroups is still strongly encouraged.

- **Prior Studies Neither Support nor Negate Significant Differences**

  If the data from prior studies neither strongly support nor strongly negate the existence of significant differences of clinical or public health importance in

intervention effect based on sex/gender, racial/ethnic, and relevant subpopulation comparisons, then the NIH-defined Phase III clinical trial will be required to include sufficient and appropriate entry of sex/gender and racial/ethnic participants, so that valid analysis of the intervention effects can be performed. However, the trial will not be required to provide high statistical power for these comparisons.

The Research Plan (for grant applications) or Proposals (for contract solicitations) must include a description of plans to conduct analyses to conduct valid analysis (see DEFINITIONS - Valid Analysis) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable. The final protocol(s) approved by the Institutional Review Board (IRB) must include these plans for analysis. The award will require that for each funded protocol, investigators must report in their annual Progress Report cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences. If final analyses of sex/gender and race/ethnicity are not available at the time of the Final Progress Report or Competing Continuation for the grant, a justification and plan ensuring completion and reporting of the analyses are required. If final analyses are required as part of the contract, these analyses must be included as part of the deliverables. These requirements will be cited in the terms and conditions of all awards for grants, cooperative agreements and contracts supporting NIH-defined Phase III clinical trials.

Inclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions. If these analyses reveal no differences, a brief statement to that effect, indicating the groups and/or subgroups analyzed, will suffice.

For all three situations, cost is not an acceptable reason for exclusion of women and minorities from clinical trials.

4. Who is responsible for implementation of the policy and guidelines?

The entire scientific community has a responsibility for implementing the policy as a partnership between research subjects, principal investigators, institutional review boards, peer review groups, NIH staff, NIH advisory councils, NIH Institute and Center Directors, and the NIH Director.

Principal investigators should assess the theoretical and/or scientific linkages between sex/gender and race/ethnicity, and their topic of study in preparing their applications/proposals and conducting their research. Institutional Review Boards (IRBs) will review NIH protocols in terms of the inclusion policy as part of their review for protection of human subjects. NIH staff in the administrative review of applications, prior to peer review, will check to see that inclusion is addressed. Any grant application proposing clinical research that fails to address inclusion will be returned without review.

Peer review groups will include a scientific and technical merit evaluation of the proposed inclusion plan, assign appropriate scores and consider inclusion as a factor in scoring.

For contract proposals, the review group determines if the description of plans to conduct analyses to address differences by sex/gender, racial/ethnic groups, and relevant subpopulations is adequate. If the offeror has determined that inclusion of women and/or minority populations is not feasible, the rationale and justification for exclusion will be examined to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable, the offeror may or may not be excluded from the competitive range, based on review of the other evaluation criteria. If the offeror is included in the competitive range (for contract proposals) or if the government holds discussion with the selected source (for sole-source acquisitions), they will be given an opportunity to further discuss, clarify, or modify their plan during discussions. If the plans are still considered unacceptable, the proposal may not be considered further for award.

For both grants and contracts, the advisory council/board of each IC shall prepare biennial reports describing the manner in which the IC has complied with the provisions of the statute.

NIH will provide educational opportunities for the extramural and intramural community concerning this policy; monitor its implementation during the development, review, award and conduct of research; and manage the NIH research portfolio to address the policy.

DEFINITIONS

1. **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,
   (3) Outcomes research and health services research.
   http://www.nih.gov/news/crp/97report/execsum.htm

2. **NIH-defined Clinical Trial**

   NIH has developed a special definition for an NIH-defined Phase III clinical trial to be used regarding this policy when referring to a clinical trial. This is to distinguish this type of trial from the other types of clinical research funded by NIH, and from other definitions, e.g. by the Food and Drug Administration (FDA).

   For the purpose of these guidelines, an NIH-defined "clinical trial" is 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. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

   In determining whether a study fits the NIH definition of a Phase III clinical trial, an essential consideration is trial outcome - whether it would contribute to a change in the standard of care or contribute to a change in public health policy, regardless of the number of participants in the study. This NIH definition of a Phase III clinical trial is broad and encompasses the wide range of research funded by NIH. It differs from the FDA definition of Phase III clinical trials, which focuses primarily on a clinical investigation of drugs, vaccines, biologics, and devices. Clinical trials of experimental drugs covered in the FDA definition proceed through four phases (21 CFR Section 312.21, 4-1-94 edition). For additional

information regarding the FDA definitions of the different phases of clinical trials, check the NIH Clinical Trials Website at: http://clinicaltrials.gov.

3. **Valid Analysis**

The term "valid analysis" means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- allocation of study participants of both sexes/genders (males and females) and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- unbiased evaluation of the outcome(s) of study participants, and
- use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

4. **Significant Difference**

For purposes of this policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

5. **Sex/Gender**

The term gender refers to the classification of research subjects into either or both of two categories: Women and men. Sex refers to biological sex, either male or female.

6. Racial and Ethnic Categories

A. Minority Groups

A minority group is a readily identifiable subset of the U.S. population that is distinguished by racial, ethnic, and/or cultural heritage.

The Office of Management and Budget (OMB) Directive No. 15 http://www.whitehouse.gov/omb/fedreg/ombdir15.html defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. The categories in this classification are social-political constructs and should not be interpreted as anthropological in nature.

When an investigator is planning data collection on race and ethnicity, these categories shall be used. The collection of greater detail is encouraged. However, more detailed items should be designed in a way that they can be aggregated into these required categories. Using respondent self-report or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation. Respondents shall be offered the opportunity to select more than one racial designation. When data are collected separately, provision shall be made to report the number of respondents in each racial category who are Hispanic or Latino.

The following definitions apply for 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 also be used in addition to "Hispanic or Latino."

Not Hispanic or Latino

The following definitions apply for 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 or community attachment.

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. (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. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

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

B. Majority Group

White - a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms "minority groups" and "minority subpopulations" are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

C. Subpopulations

Each racial and ethnic group contains subpopulations that are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one race or ethnicity. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study.

7. **Outreach Strategies**

These are outreach efforts by investigators and their staff(s) to appropriately recruit and retain populations of interest into research studies. Such efforts should represent a thoughtful and culturally sensitive plan of outreach and generally include involvement of other individuals and organizations relevant to the populations and communities of interest, e.g., family, religious organizations, community leaders and informal gatekeepers, and public and private institutions and organizations. The objective is to establish appropriate lines of communication and cooperation to build mutual trust and cooperation such that both the study and the participants benefit from such collaboration.

INFORMATION FOR SUBMITTING APPLICATIONS/PROPOSALS

1. **What should you consider in the design of a clinical research study?**

In your clinical research study design for a research grant or proposal in response to a contract solicitation, the appropriate numbers of men, women, and members of racial/ethnic groups should be based on the scientific question under study (research grants and cooperative agreements) or on requirements set forth in the solicitation statement of work (contract). While diversity and broad representation are strongly encouraged, it is not expected that both sexes and members of every racial/ethnic group and subpopulation will be included in every study or contract. Consider how the following questions apply to your study before deciding the composition of your target population:

- Is the scientific question/solicitation statement of work applicable equally to both men and women and to all racial/ethnic groups and their subpopulations?

- Is the condition under study or defined in the statement of work more prevalent or severe in one particular group?

- For research grants and cooperative agreements, have enough studies already been performed in one or more groups, leaving gaps that can be filled by focusing the research on certain population groups?

After answering these questions, determine the target population you need and your study design by considering the answers to the following:

- In order to obtain the appropriate diversity must I have access to participants from additional clinics or facilities? Will over-sampling of certain groups be possible?

- If a single clinic or facility is not adequate, can the needed participants be enrolled by going to hospitals or other clinical facilities in the nearby geographic region?

- If demographic limitations prevent answering scientific questions locally for the appropriate sex and minority groups, is it feasible or necessary to expand the geographic area or to establish satellite centers?

For contracts, the target population may be provided in the statement of work in the solicitation. You may need to address the above questions in preparing your response to the solicitation.

2. **Can you design a clinical research study/respond to a contract solicitation that includes only one sex and/or one racial/ethnic group or subpopulation?**

YES. If you propose a study of only one sex or racial/ethnic group (or subpopulation), you must have a scientific justification for limiting the diversity of your study population, such as high prevalence of the condition, unique disease characteristics, or gaps in knowledge in the selected population. In this case, you must justify why your study has a limited target population and provide in your application information or reference to any published reports about ongoing studies that address the appropriate diversity.

3. **Can you use existing cohorts that are deficient in women or minority participants?**

YES. Applicants/Offerors can propose a study or analyses of an existing data base where the cohort is deficient in sex/gender and/or racial/ethnic participation. However, you must justify why you will use an existing cohort that lacks the diversity required by the inclusion policy. The nature of the scientific question, a requirement for data provided by the cohort, or addressing a gap in knowledge may be used to provide the basis of a justification.

4. **What type of information on the diversity of the target study population should you provide in your application/proposal?**

For all clinical research studies, you must follow grant application instructions (PHS 398) or the instructions contained in the statement of work in the contract solicitation regarding the plans for recruitment and retention of study participants. The research plan/proposal should include a description of the composition of the proposed study population in terms of sex/gender and racial/ethnic membership, and provide a rationale for selection of such subjects as well as proposed outreach programs for their recruitment. At a minimum, you should do the following:

- Describe the population characteristics of the disease or condition under study, including national and local demographics of the population, and demonstrate your knowledge and understanding of the racial/ethnic/cultural characteristics of the population. Provide any data, including references, regarding how the disease or condition may affect women, men, racial/ethnic groups and relevant subpopulations differentially.

- Address the treatment or intervention characteristics of the population indicating whether clinically important sex/gender, racial/ethnic, and relevant subpopulation differences exist in the intervention effect. Describe and provide known data, including references.

- Describe your prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied including plans, arrangements and letters of commitment from relevant community groups and organizations for your planned study.

For all clinical research studies, you must also complete the table found in the PHS 398 application "Targeted/Planned Enrollment Table" (http://grants.nih.gov/grants/funding/phs398/enrollment.pdf). Use this table to indicate the number of participants proposed for your study according to the specific categories.

First describe the target population in terms of ethnicity:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
	Sex/Gender		
Ethnic category	**Females**	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total			

Second, describe the target population in terms of race:

Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of all Subjects *			

List any subpopulations that are proposed to be included in the study as an attachment to the Targeted/Planned Enrollment Table.

For contracts, the "Targeted/Planned Enrollment Table" will be included as an attachment to the solicitation. See NCI RFP Workform at http://rcb.nci.nih.gov/forms/forms.htm

Additional information about completing and using this table can be found in the NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

5. What additional information must you provide in your application/proposal for any NIH-defined Phase III clinical trial?

For an NIH-defined Phase III clinical trial, in addition to the information above, you must also provide evidence to show whether or not clinically important sex/gender, racial/ethnic, and relevant subpopulation differences in the intervention effect are to be expected. (Additional details on applying the *Women and Minorities Inclusion Policy for Phase III Clinical Trials* can be found in the section POLICY, Questions 2 and 3.)

- If prior studies support the existence of significant differences between groups, your research plan/proposal must also include a description of how analyses will be conducted to detect significant differences in the intervention effect. For purposes of this policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large clinical difference of potential importance that is not statistically significant.

- If the data from prior studies strongly support that there is no significant difference of clinical or public health importance in intervention effect between subgroups, then sex/gender and/or race/ethnicity will not be required as subject selection criteria. However, the inclusion and analysis of sex/gender and racial/ethnic subgroups is still strongly encouraged for the proposed trial.

- If data from prior studies neither strongly support nor strongly negate the existence of significant differences of clinical or public health importance in intervention effect based on sex/gender and/or racial/ethnic comparisons , then your research plan/proposal for the NIH-defined Phase III clinical trial must also include a description of plans to conduct a valid analyses of the intervention effects in subgroups. For the purpose of this policy, the term "valid analysis" means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need

to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- allocation of study participants of both sexes/genders (males and females) and from different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- unbiased evaluation of the outcome(s) of study participants, and
- use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and/or racial/ethnic groups.

For all Phase III Clinical Trials, the final protocol(s) approved by the Institutional Review Board (IRB) must include these plans for analyses. For research grants, applicants are strongly encouraged to contact Program Directors for guidance prior to submitting their applications. For contracts, offerors may contact the contracting officer ONLY for guidance prior to submitting their proposals. The following table summarizes the inclusion requirements for clinical research and for NIH-defined Phase III clinical trials.

Type of Study	Include Women and Minorities?	Include Minority Subpopulations?	Design to Measure Differences?
Clinical Research Studies	YES	YES	Recommended but not required
NIH-Defined Phase III Clinical Trials	YES	YES	Required

6. **What should you include in your application/proposal to describe your efforts for outreach to recruit and retain women and minorities in your study?**

You should include in your application/proposal a description of your proposed outreach plan to recruit and retain the women and members of racial/ethnic groups and relevant subpopulations in the target population. Outreach efforts often include the involvement of organizations and persons relevant to the populations and communities of interest, e.g., religious organizations, community leaders, and public and private institutions. You should take precautions to ensure that there is minimal possibility of coercion or undue influence in any incentives offered to prospective participants when recruiting or attempting to retain participants in studies.

NIH staff have prepared a notebook, *NIH Outreach Notebook on the Inclusion of Women and Minorities in Clinical Research*, which addresses recruitment and retention of women and minorities in clinical studies, provides relevant references, and discusses ethical issues. A link to this notebook can be found at: http://grants.nih.gov/grants/funding/women_min/women_min.htm

7. **What should you do if you are located in a geographic area that does not offer a study population with the diversity required by the policy on the inclusion of women and minorities in clinical research studies?**

In your application/proposal, you are required to provide a clear and compelling description and rationale for your proposed study population and its appropriateness for the purpose of your research. When there is limited representation of women or members of racial/ethnic groups you must also provide a satisfactory rationale for lack of any diversity based on the health of the participants and the scientific needs of the research being proposed. If you are aware of similar research completed or underway employing populations complementary to those available in your locale, you can present this as a rationale for limited representation. If the appropriate diversity cannot be achieved in your geographic area, you must address the feasibility of making collaborative or other arrangements to include greater diversity, e.g., seeking collaborators in other geographic areas where there is access to more diverse populations.

8. **Is increased cost an acceptable justification for not including women, minorities and subpopulations in clinical research studies?**

NO. The legislation states that the cost associated with increasing the diversity of a clinical research study population composition to include the appropriate representation of men, women, and members of minority groups and their subpopulations is **not** an acceptable justification for excluding any group.

9. **In multi-center clinical research studies, does each study site have to meet the inclusion requirements separately?**

NO. When multi-center clinical research studies are proposed, the inclusion requirements may be met by combining recruitment from the multiple sites. However, each clinical site must still describe its planned recruitment, retention and outreach plans, which will be evaluated as part of the initial review of the application or proposal. As part of its funding plan, the NIH may select recruitment sites with high minority and/or relevant subpopulation enrollments for inclusion in multi-center studies to achieve inclusion of the most diverse study population.

See **Question 4** under INFORMATION ON THE NIH PEER REVIEW PROCESS for additional discussion of contract projects.

10. **Does the policy on the inclusion of women and minorities apply to foreign projects and contract proposals funded by the NIH?**

YES. The NIH policy on inclusion of women in research conducted outside the U.S. is the same as that for research conducted in the U.S. However, for the population of the foreign country the definition of the minority groups may be different than in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

11. **How do the Guidelines impact on Institutional Review Boards (IRBs)?**

IRBs have long had as part of their responsibilities the examination of ethical issues and the determination of equitable selection of subjects in accordance with the regulations for protection of human subjects (45 CFR 46.111(a)(3)). The inclusion of both men and women and of minorities in research (intramural and extramural) is important, both to ensure that they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. To the extent that participation in research offers direct benefits to the participants, under-representation of men, women, or minorities denies them the opportunity to receive this benefit. Moreover, for the purpose of generalizing research results, investigators must include the widest possible range of population groups.

INFORMATION ON REPORTING RACE AND ETHNICITY IN APPLICATIONS/PROPOSALS AND ACTIVE RESEARCH GRANTS/CONTRACTS

Complete information on the NIH Policy on Reporting Data on Race and Ethnicity: Subjects in Clinical Research can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html. The set of questions and answers below also are included as FAQ's in the NIH Policy on Reporting Data on Race and Ethnicity.

Note: The FAQ's below also apply to offers of research contracts. However, information on the tables for reporting sex/gender and race/ethnicity for research contracts should be used rather than those found in the PHS 398. See http://rcb.nci.nih.gov/forms/forms.htm

1. What if my new application/proposal involves analyzing secondary data in which the race and ethnicity categories do not comply with the new OMB guidelines?

If an investigator is using secondary data sets that do not conform to the new OMB guidelines and does not plan to collect any new/additional data from the subjects, this should be noted in the New Application. In this circumstance, the investigator should complete the "Targeted/Planned Enrollment Table" for a New Application and the "Inclusion Enrollment Report" for Continuation Applications, Competing Supplement Applications, and Annual Grant Progress Reports if the data allow. However, if the existing data do not allow accurate correspondence with the new categories, the investigator should report the information using the prior categories and use the 4/98 Version of the Inclusion Table.

2. There are many ways of tabulating the multiple race and ethnicity responses, particularly since the race and ethnicity categories are not mutually exclusive. Do the numbers reported in the tables have to "add up"?

The numbers in several parts of the two tables must be the same. In both the "Targeted/Planned Enrollment Table" for a New Application and the "Inclusion Enrollment Report " for Continuation Applications, Competing Supplement Applications, and Annual Progress Reports, the sum in "Ethnic Category: Total of All Subjects" must equal the sum in "Racial Categories: Total of All Subjects." In addition, the "Racial Categories: Total Hispanics or Latinos" in Part B of the "Inclusion Enrollment Report Table" must equal the Total Hispanic or Latino number reported in Part A of the "Inclusion Enrollment Report." Footnotes in the tables clearly identify which numbers must be the same.

3. Can the Targeted/Planned Enrollment Table or the Enrollment Inclusion Report be used to collect data from individuals?

Neither the Targeted/Planned Enrollment Tablet nor the Enrollment Inclusion Report should be used for collecting data from individuals. These tables are only to be used for reporting aggregate data.

To collect data from an individual respondent, investigators should use respondent self-report or self-identification and use two separate questions. The first question should be about ethnicity, followed by a question that provides the option of selecting one or more racial designations. An example of a format for collecting information from an individual can be found in the "Ethnic Origin and Race" section of the Personal Data Form Page in the PHS 398 (rev. 5/01) http://grants.nih.gov/grants/funding/phs398/personal.pdf

4. Can more detailed questions about ethnicity and race be asked than these guidelines indicate?

The revised OMB guidelines provide minimal standards for data collection. Indeed, researchers are encouraged to explore collecting additional types of information on race and ethnicity that will provide additional insights into the relationships between race and ethnicity and health. For example, after asking the ethnicity and then the race questions, researchers may opt to ask study participants who choose multiple categories to identify the group that they identify with primarily. Further questions identifying membership in subpopulations within the ethnic and racial categories provided by OMB may also be considered. The scientific question being addressed in the study should guide investigators' decisions regarding collection of any additional information on ethnicity or race. Information on subpopulations may be reported by listing the information in an attachment to the required table.

5. What ethnic and racial categories should be used to estimate race and ethnicity, given the new OMB standards?

Investigators should use the categories described in the PHS 398 instructions and listed in the table "Targeted/Planned Enrollment Table" for New Applications. First, the investigator should report the anticipated total number of males and females to be enrolled by Ethnicity (Hispanic or Latino, Not Hispanic or Latino). Then, the investigator should report the anticipated total number of males and females by Racial Categories (American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American, White). The total number of subjects in the Ethnic Category section of the table should equal the total number of subjects in the Racial Categories section. Investigators do not need to estimate the anticipated number of individuals

reporting multiple racial categories (either total number reporting multiple categories or number reporting specific combinations) for New Applications. However, the investigator must follow the OMB guidelines, which include allowing respondents to select multiple race categories, once data collection commences.

6. Data collection began prior to the new standards and the questions do not comply with the new OMB standards. Should questions asked about race and ethnicity be changed in the middle of the study?

If data collection has already begun, we do not expect investigators to change their questions on race and ethnicity prior to the completion of the study. For Annual Progress Reports, in this circumstance, investigators should note that the research project was initiated prior to the implementation of the new reporting guidelines. If the data do not accurately correspond with the new categories, the investigator may continue to use the format in the 4/98 Version of the Inclusion Table.

7. Data collection began prior to the new standards, but race and ethnicity questions do comply with the new standards. Data for previous years has been submitted using the old standards. How should data be reported in this year's progress report?

If you began your data collection prior to the implementation of the new standards but your questions on race and ethnicity comply with the new standards, the choice is left up to the investigator as to how to present the data for Annual Progress Reports. We suggest completion of the new Inclusion Enrollment Report.

8. How should race and ethnicity data be reported when the research involves a foreign population?

Investigators are encouraged to design their data collection instruments in ways that allow respondent self-identification of their racial and ethnic affiliation. However, these items should be designed in a way that they can be aggregated into the required categories. Also, the investigator can report on any racial/ethnic subpopulations by listing this information in an attachment to the required table. This may be particularly useful when distinctive subpopulations are relevant to the scientific hypotheses being studied.

When completing the tables, investigators should asterisk and footnote the table indicating that data includes foreign participants. If the aggregated data only includes foreign participants, the investigator should provide information in one table with an asterisk and footnote. However, if the study includes both domestic and foreign participants, we suggest the investigator complete two separate tables – one for domestic

data and one for foreign data, with an asterisk and footnote accompanying the table with foreign data.

9. How do the 1997 OMB revised standards differ from the previous standards?

OMB issued the previous standards for maintaining, collecting, and presenting data on race and ethnicity in 1977. The minimum acceptable categories were: American Indian or Alaska Native; Asian or Pacific Islander; Black, not of Hispanic origin; Hispanic; White, not of Hispanic origin.

The 1997 OMB revised standards now include two ethnic categories (Hispanic or Latino or Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). When using self-reporting or self-identification to collect data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

10. Where can I find examples of questions for collecting data on ethnicity and race from individuals that I could use in my research?

There are several federal data instruments in the public domain that include questions on ethnicity and race. One is the "Ethnic Origin and Race" section of the Personal Data Form in the PHS 308 (rev. 5/01) <http://grants.nih.gov/grants/funding/phs398/personal.pdf>. This form includes questions that meet the minimum OMB standards by asking the individual first about their ethnicity, followed by a question that provides the option of selecting more than one racial designation.

You also may want to explore collecting additional types of information on race and ethnicity to provide greater insights into the relationships between race, ethnicity, and health. For example, after asking about ethnicity and race, you may want to ask study participants who chose multiple racial categories to identify the group that they identify with primarily, e.g., "If you selected more than one racial group, which one group would you say best represents your race?" In addition, you may want to ask about membership in subpopulations within the ethnic and racial categories provided by OMB. For example, you may want to ask individuals who select American Indian or Alaskan Native to identify the name of the enrolled or principal tribe. Or, you may want to ask about identification with specific subpopulations within specific ethnic or racial categories, such as Puerto Rican, Cuban, Chinese, Japanese, Korean, etc. The scientific question being addressed in your study should guide your decision about collecting any additional information on ethnicity and race.

Examples of federal data instruments that include more detailed questions about ethnicity and race can be found at the US Census Bureau <http://www.census.gov/dmd/www/2000quest.html> and through the National Health and Nutrition Examination Survey (NHANES), as part of the Demographics Information collected in the Sample Person Questionnaire <http://www.cdc.gov/nchs/about/major/nhanes/questexam.htm >.

11. When collecting and reporting population data, does the PI have to follow the OMB guidelines or can other terminology be used?

Population data reported to NIH must comply with the Office of Management and Budget (OMB) Directive 15 for reporting population data on race and ethnicity. However, discretion resides with the PI to design data collection instruments that are culturally sensitive and appropriate. The instruments should allow participants to self-identify his/her ethnicity and/or race; including the option to identify several racial categories. Therefore, the PI must aggregate the data into the OMB minimally required racial and ethnic categories before reporting it to NIH.

For example, a PI may decide to include the term "Chicano" in their data collection instrument. The term "Spanish origin" can also be used in addition to "Hispanic, Latino or Chicano." The investigator should determine the appropriate terms applicable for the target Hispanic population. (For example, the terms Chicano or Latino would be appropriate to use with California Mexican Americans but not Puerto Ricans). Before reporting the data to NIH, the PI must aggregate the data into the ethnic category, "Hispanic/Latino."

In situations where a participant wants to select more than one racial/ethnic category, investigators can ask the participant to "check all race and ethnicity that apply." If more than one response is selected, a statement should be added asking him/her to indicate a Race/Ethnicity that they identify with primarily and report that as their primary race or ethnicity. Asking for identification of the primary race/ethnicity decreases the number of participants that are reported as "Unknown" or "Other." If possible, when these data are collected separately, the PI should report the number of respondents in each racial category. In the case where participants check more than one racial category but does not identify any primary race, then the PI must aggregate the data and report it as "More than one race."

INFORMATION ON THE NIH PEER REVIEW PROCESS

A. GRANTS AND COOPERATIVE AGREEMENTS

1. What will NIH reviewers look for in applications regarding the inclusion of women and minorities in clinical research?

Peer reviewers will be asked to evaluate whether the research plan in the application complies with the policy to include women and minorities in clinical research studies, 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 and they should provide a narrative text to answer each of the following:

- Does the applicant propose a plan for the inclusion of minorities and both sexes for appropriate representation? (The research plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects.)

- Does the applicant propose justification when representation is limited or absent?

- Does the applicant propose exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect for the health of the subjects and/or with respect to the purpose of the **research?**

- Does the applicant propose plans for recruitment/outreach and retention of study participants, and are those plans appropriate and acceptable?

- For ongoing research projects, is the accrual data adequate in relation to target data?

2. Are there additional elements that reviewers will look for when an NIH-defined Phase III clinical trial is proposed?

YES. In addition to the questions listed above, when an NIH-defined Phase III clinical trial is proposed, the reviewers will evaluate the study design and analysis plan:

- Has evidence been adequately evaluated in terms of whether clinically important sex/gender and racial/ethnic differences in the intervention effect are to be expected?

- Has the planned trial been designed to take into account these clinically important sex/gender and/or racial/ethnic differences so that appropriate numbers from each group are planned to be included in the study, including the need to : (a) detect significant differences when available evidence strongly indicates significant sex/gender and/or racial/ethnic differences; or, (b) permit valid analyses when there is no clear-cut scientific evidence to rule out significant differences between sex/gender and/or racial/ethnic groups in intervention effect?

3. Will the criteria for addressing the inclusion of women and minorities in the applicant's plan affect the assigned score for scientific and technical merit?

YES. The Scientific Review Groups (SRGs) will treat the evaluation of the representation of women and minorities and their subpopulations in a manner consistent with the evaluation of all other factors that contribute to the overall priority score. Below are the codes assigned to each application for both sex/gender and minority groups. Any application given an unacceptable code "U", results in a bar-to-funding and must be resolved before the study is funded.

SEX/GENDER	
G1A	Includes both genders, scientifically acceptable
G2A	Includes only women, scientifically acceptable
G3A	Includes only men, scientifically acceptable
G4A	Gender representation unknown, scientifically acceptable
G1U	Includes both genders, scientifically unacceptable
G2U	Includes only women, scientifically unacceptable
G3U	Includes only men, scientifically unacceptable
G4U	Gender representation unknown, scientifically unacceptable

MINORITY	
M1A	Includes minorities and non-minorities, scientifically acceptable
M2A	Includes only minorities, scientifically acceptable
M3A	Includes only non-minorities, scientifically acceptable
M4A	Minority representation unknown, scientifically acceptable

M5A	Includes only foreign subjects, scientifically acceptable
M1U	Includes minorities and non-minorities, scientifically unacceptable
M2U	Includes only minorities, scientifically unacceptable
M3U	Includes only non-minorities, scientifically unacceptable
M4U	Minority representation unknown, scientifically unacceptable
M5U	Includes only foreign subjects, scientifically unacceptable

B. RESEARCH CONTRACTS

1. How does the inclusion policy for women and minorities in clinical research studies apply to the review of research contract proposals and projects?

This inclusion policy applies to NIH research and development contract projects as well as grant and cooperative agreement projects. However there are several differences in procedures for contract projects. The description of the planned contract project is provided in the Request for Proposals (RFP), which includes the statement of work and the evaluation criteria. When planning and preparing the RFP, the NIH project officer must address many issues, including determining whether the project is a clinical research study and whether it is an NIH-defined Phase III clinical trial. In most cases, the study design, sample size issues, and the inclusion requirements for both sexes and members of racial/ethnic groups are also determined by the NIH project officer. Outreach plans need to be addressed and appropriate justifications provided when the requirement is for limited representation. The required review criterion should also be included as part of the evaluation criteria published in the RFP.

As an investigator responding to the RFP, you must address the inclusion policy as reflected in the RFP requirements and evaluation criteria. Peer reviewers will evaluate proposals, looking at plans for recruitment, retention and outreach for study participants, using the published review criteria. In the case of NIH-defined Phase III clinical trials, they also will assess the plan for valid analyses of sex/gender and racial/ethnic differences.

FUNDING INFORMATION

1. How will conformance to the policy for inclusion of women and minorities in clinical research affect funding of grants and cooperative agreements?

Regardless of the priority score, percentile ranking or program relevance of the proposed research, the NIH funding components will not fund/award grants or contracts that do not comply with this policy. The PI of any application selected for funding that was considered by the Initial Review Group to have Unacceptable Gender or Minority Inclusion will need provide a corrective plan to address the deficiencies prior to award.

2. How will conformance to the policy for inclusion of women and minorities in clinical research affect funding of contracts?

Regardless of the other merits of a proposal received in response to a solicitation, the NIH will not award contracts that do not comply with this policy. All issues regarding unacceptable gender or minority inclusion must be resolved prior to award in the case of contracts.

3. What reports need to be prepared using the data on inclusion of women and minorities?

For all clinical research studies, applicants/offerors need to provide information in applications, proposals and progress reports using the following summary table format for planned enrollment of women and minorities. For ongoing studies, awardees need to report annually on the cumulative enrollment of the approved project/protocol(s). Using the same format, the number of subjects enrolled in each study needs to be provided. If more than one study/contract is being reported, the awardee must provide a separate table for each study. Actual accrual will be compared to the targets for inclusion that are found in the original application/proposal.

The Inclusion Enrollment Report consists of two sections, Part A is the Total Enrollment Report indicating the number of subjects enrolled to date (cumulative):
By Ethnicity:

	SEX/GENDER			
Ethnic Category	**Females**	**Males**	**Unknown/Not Reported**	**Total**
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of all Subjects				

Then by Race:

Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than One race			
Unknown or Not Reported			
Racial Categories: Total of All Subjects			*

* These Totals must agree
** These totals must agree

The second section of the report, Part B, is the Hispanic Enrollment Report indicating the number of Hispanics or Latinos enrolled to date:

Part B.: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than One Race				
Unknown or Not reported				
Racial Categories: Total of Hispanics or Latinos *				**

* These Totals must agree
** These totals must agree

Inclusion Enrollment Report Format Page

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For additional information about using and obtaining these tables, please refer to the NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

4. **The policy requires inclusion and subpopulation data in the progress report for each NIH-defined Phase III clinical trial grant or contract. Does that mean that analyses need to be done every year?**

NO. The progress report needs to report cumulative accrual data annually and explain progress in conducting analyses for sex/gender and/or racial/ethnic differences. If analyses of sex/gender and/or racial/ethnic differences are not available at the time of the progress report, then a justification and/or interim data analyses must be reported. Analyses should be

conducted when permitted by the study design and as described in the analysis plan. For contracts, the schedule of deliverables will dictate when reports and analyses are required.

5. **Where can I obtain additional information?**

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.

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 senior extramural staff from the NIH Institutes and Centers may be contacted for further information about the policy and relevant Institute/Center programs:

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6116 Executive Boulevard, Suite 8001
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Dr. Lore Anne McNicol
National Eye Institute
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Ms. Sharry Palagi
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Dr. Miriam Kelty
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Dr. Eleanor Hanna
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