4.2 Inclusion of Women and Minorities

Create a section heading entitled "Inclusion of Women and Minorities" and place it immediately following the “Protection of Human Subjects" section. Although no specific page limitation applies to this section of the application, be succinct. The NIH Policy on the Inclusion of Women and Minorities in Clinical Research is described and referenced in Section 5.6.

Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the inclusion of women and minorities in NIH-defined clinical research.

In this section of the Research Plan, address, at a minimum, the following four points:

1. The planned distribution of subjects by sex/gender, race, and ethnicity for each proposed study using the format in the Planned Enrollment Report. (Instructions for completing this table are provided below in 4.3.) If using existing specimens and/or data without access to information on the distribution by sex/gender, race, and/or ethnicity, so state and explain the impact on the goals of the research as part of the rationale that inclusion cannot be described (item 3 below). Alternatively, describe the sex/gender, racial, and ethnic composition of the population base from whom the specimens and/or data will be obtained. Include the Planned Enrollment Reports in this section.
2. A description of the subject selection criteria and rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3. A compelling rationale for proposed exclusion of any sex/gender, racial, or ethnic group (see examples below).
4. A description of proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects.

Below are examples of acceptable justifications for the exclusion of:

A. ***One sex/gender:***

1. One sex/gender is excluded from the study because:
   - inclusion of these individuals would be inappropriate with respect to their health;
   - the research question addressed is relevant to only one sex/gender;
   - evidence from prior research strongly demonstrates no difference between sexes/genders; or
   - sufficient data already exist with regard to the outcome of comparable studies in the excluded sex/gender, and duplication is not needed in this study.
2. One sex/gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by sex/gender (e.g., uniquely valuable stored specimens or existing datasets are single sex/gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
3. Sex/gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete sex/gender documentation are used), and this does not compromise the scientific objectives of the research.

B. ***Racial and/or ethnic groups or subgroups:***

1. Some racial and/or ethnic groups or subgroups are excluded from the study because:
   - inclusion of these individuals would be inappropriate with respect to their health;
   - the research question addressed is relevant to only specific racial or ethnic groups;

- evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- a specific racial or ethnic group(s) study is proposed to fill a research gap; or
- sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.

2. Some racial or ethnic groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
   - the size of the study;
   - the relevant characteristics of the disease, disorder or condition; or
   - the feasibility of making a collaboration or consortium or other arrangements to include representation. In general, cost is not an acceptable justification for exclusion.
3. Some racial or ethnic groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity (e.g., uniquely valuable cohorts, stored specimens or existing datasets are of limited racial and/or ethnic representation, very small numbers of subjects are involved, or overriding factors dictate selection of subjects, such as matching of transplant recipients or availability of rare surgical specimens).
4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial and/or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

4.2.1 Additional Instructions and Requirements When NIH-Defined Phase III Clinical Trials Are Proposed

If the proposed research includes an NIH-Defined Phase III Clinical Trial, the section on Inclusion of Women and Minorities also must address whether clinically important sex/gender, racial, and/or ethnic differences are expected from the intervention effect. The discussion may include supporting evidence and/or data derived from animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies as well as observational, natural history, epidemiology and/or other relevant studies. The discussion of expected sex/gender, racial, and ethnic differences in intervention effect must include selection and discussion of one of the following analysis plans:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender, racial, and/or ethnic subgroups when prior studies strongly support these significant differences among subgroups, or
- Plans to include and analyze sex/gender, racial, and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender, racial, and ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), or
- Plans to conduct valid analyses of the intervention effect in sex/gender, racial, and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

4.3 Instructions for Completing the Planned Enrollment Report(s) for Race and Ethnicity Data for Subjects in Clinical Research

The NIH Policy on the Inclusion of Women and Minorities in Clinical Research is described in Part II, Section 5.6. The NIH Policy on Reporting Race and Ethnicity Data for Subjects in Clinical Research is described and referenced in Section 5.8. For paper PHS398 applications, if your application involves subprojects, attach the

Planned Enrollment Reports to the relevant subproject descriptions. For electronic SF424 (R&R) applications, if your application includes Planned Enrollment Reports, these will be entered into a structured data form(s).

A. ***New Applications***

All new NIH-defined clinical research studies should collect data in such a manner as to be able to report information on participants with respect to two categories of ethnicity and five categories of race which are based on the Office of Management and Budget (OMB) reporting standards for data on race and ethnicity. Investigators should review the instructions and Frequently Asked Questions about using the Enrollment Table format at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Instructions for Completing Planned Enrollment Reports

(http://grants.nih.gov/grants/funding/phs398/phs398.html for paper applications)

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by sex/gender, racial, and ethnic categories using the Planned Enrollment Report(s).

If the application includes more than one study, provide separate Planned Enrollment Reports for each. At a minimum, any foreign studies (or studies including foreign subjects) must be reported separately from domestic studies (or studies including domestic subjects). See below for additional guidance under "Research Conducted at Foreign Sites."

If the application includes a study recruiting subjects at more than one site/location, investigators may create a single Planned Enrollment Report or separate Planned Enrollment Reports (per site), depending on the scientific goals of the study and whether reporting of inclusion enrollment data separately or combined would most accurately demonstrate compliance with the NIH Policy on Inclusion of Women and Minorities in Clinical Research. For applications that involve subprojects, provide Planned Enrollment Reports for each study in a given subproject.

Completing each Planned Enrollment Report:

Provide a unique study title that will facilitate identification of each Planned Enrollment Report.

Select whether the study involves domestic or foreign subjects.

Provide the information as numbers of subjects, not percentages.

The Total Field on the Planned Enrollment Report (bottom right) means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov (http://clinicaltrials.gov/ct2/about-studies/glossary#C).

Provide the numeric distribution of individuals on the basis of their sex/gender, ethnicity, and race. Note that Hispanic is an ethnic category, not a racial category. Subjects are permitted to select more than one race when self-identifying. If the sample is likely to include individuals who identify with more than one race, they should be accounted for in the "More than one race" category on the Planned Enrollment Report(s). If including individuals identifying as more than one race is not expected, enter zeroes in that category.

List any proposed racial or ethnic subpopulations in the comment field.

Research Conducted at Foreign Sites:

If proposed studies involve a foreign site(s), investigators are encouraged to design culturally sensitive and appropriate data collection instruments that allow research participants to self-identify their racial and/or ethnic affiliation. However, these items should be designed in a way that they can be aggregated by the investigator into the OMB-required categories which are defined in Section 5.8, when reporting these data to NIH. Also, the investigator can report on any racial or ethnic subpopulations or culturally relevant descriptors by listing this information in the comments section of the Planned Enrollment Report(s). This may be particularly useful when distinctive subpopulations are relevant to the scientific hypotheses being studied.

Delayed-Onset Human Subjects Research:

If the proposed research includes studies that meet the definition for delayed-onset human subjects research described in Section 2, Scenario D in the Human Subjects section of the instructions, then enter a comment on the Planned Enrollment Report(s) indicating this is a delayed-onset study. For study title, you may enter the Project Title along with the words "Delayed Onset Study."

Additional Guidance: For additional guidance and FAQs related to inclusion and inclusion data forms, please see: http://grants.nih.gov/grants/funding/women_min/women_min.htm.

B. ***Renewal and Revision Applications***

(http://grants.nih.gov/grants/funding/phs398/phs398.html for paper applications)

For Renewal applications, investigators should provide information on cumulative enrollment from the previous funding period(s). The Inclusion Enrollment Report must be used for reporting actual accrual data to the NIH. Where possible, include the Study Title that is associated with inclusion data from the previous funding period. If inclusion enrollment from the previous funding period was reported on separate inclusion enrollment reports, provide them in the same way.

For Revision applications, any proposed additions to the Planned Enrollment Report(s) should be provided.

Instructions for reporting annual total enrollment in funded awards are provided in the PHS 2590 Instructions (http://grants.nih.gov/grants/funding/2590/2590.htm).

In addition, if a given study will continue with additional enrollment or if new studies are proposed, provide a Planned Enrollment Report for each.