**INCLUSION OF WOMEN AND MINORITIES TEMPLATE**

SF424 (R&R) – Version F

Last revised 6/10/20

**Content Instructions**

* Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
* Describe the 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.
* Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
* Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the [Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page](https://grants.nih.gov/policy/inclusion/women-and-minorities.htm) for more information.
* Existing Datasets or Resources. If you will use an [existing dataset](https://grants.nih.gov/grants/glossary.htm#Existingdataset), resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study. For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH [FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources](https://grants.nih.gov/faqs#/inclusion-basic-on-sex-gender-and-race-ethnicity.htm).
* NIH-Defined Phase III Clinical Trials. If the proposed research includes an [NIH-Defined Phase III Clinical Trial](https://grants.nih.gov/grants/glossary.htm#NIHDefinedPhaseIIIClinicalTrial), the "Inclusion of Women and Minorities" attachment MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and [valid analysis](https://grants.nih.gov/grants/glossary.htm#ValidAnalysis) of the trial. See the instructions for "Valid Analysis" and "Plans to test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups" below. Additional information about valid analysis is available on the [NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research page](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm).
  + ***Valid Analysis*** (for NIH-Defined Phase III Clinical Trials only). Address the following issues for ensuring valid analyses:
    - Inclusive eligibility criteria - in general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups;
    - Allocation of study participants of both sexes/genders and from different racial and/or 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 by sex/gender, race, and/or ethnicity, particularly if prior evidence strongly suggests that such differences exist.
  + ***Plan to Test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups*** (for NIH-Defined Phase III Clinical Trials only). Applicants also should address whether they plan to test for differences in effect among sex/gender, racial, and/or ethnic groups and why such testing is or is not appropriate. This plan must include selection and discussion of one of the following analysis plans:
    - Plans to conduct 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 one or more 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.

**Review Criteria and/or Questions to Consider**

* Are women and minorities included in the proposed clinical studies? If not, is the explanation for their exclusion sufficient?
* If use of an existing data set is proposed, is its use justified in the proposed scientific context despite limited sex/gender, racial, and/or ethnic participation?
* For phase III clinical trials, is a sufficient valid analysis included? Has the PI adequately described how potential group differences will be evaluated?

**Suggested outline**

We have provided a suggested outline on the third page of this document. If you would like, you can enter your text directly below each subsection header. This document is already formatted appropriately (0.5 inch margins, Arial font, 11 point text). Just delete the first two pages and you are on your way to a complete draft!

**INCLUSION OF WOMEN AND MINORITIES**

***Planned Distribution and Rationale for Inclusion / Exclusion:***

***Sex/gender:***

***Race:***

***Ethnicity:***

***Planned Outreach Programs For Recruitment:***

***Phase III Clinical Trials (if applicable)***

***Valid Analysis:***

***Plan to Test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups:***