This template is based on the NIH instructions here https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.4

Discuss each of the points listed below.

When document is complete, delete this box and save as PI Last Name_2.4 Inclusion of Women and Minorities_DDMONYEAR (example-01JAN2022)

NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype, 11 pt or larger, margins .05 or larger https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

For more information:

- NIH's Policy Implementation Page on the Inclusion of Women and Minorities
- HHS' 45 CFR 46 Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
- NIH Grants Policy Statement, Section 4.1.15.8: Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation

2.4 INCLUSION OF WOMEN AND MINORITIES

Address the following points:

- 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 for more information.

Existing Datasets or Resources. If you will use an existing dataset, 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.

NIH-Defined Phase III Clinical Trials.

If the proposed research includes an NIH-Defined Phase III Clinical Trial, 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 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" here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.4