## 2.4 Inclusion of Women and Minorities

***A close up of a sign

Description automatically generated***

***Guidelines***

1. *Required for all studies involving human subjects*
2. ***Format:***
   1. *No page limit*
   2. *Margins min. 0.5”*
   3. *NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype*
3. ***Content:***
   1. *Address all instructions below*
4. *When form is complete:*
   1. *Remove this box*
   2. *Save file as “2.4 Inclusion of Women and Minorities”*

**Instructions:**

**If Recruitment is Planned**

* 1. Describe planned distribution of subjects by sex/gender, race, and ethnicity.
  2. Describe 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. Describe proposed outreach programs for recruiting sex/gender, racial and ethnic group members. *This is particularly important if difficulty recruiting certain groups is anticipated.*
  4. Inclusion of Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, racial, and/or ethnicity. *Cost and geographic location are not acceptable reasons.*

**If Using Existing Datasets or Resources**

1. Include all of the above and,
2. Justify the details as appropriate to the scientific goals of the proposed study

**If study is NIH-Defined Phase III CT:**

1. Include all of the above and,
2. Provide plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial
3. Additional information about valid analysis
4. Plan to test for differences in effect among sex/gender, racial, and/or ethnic groups