

INCLUSION OF WOMEN AND MINORITIES

It is important to provide a detailed plan of who will be included (and/or excluded) and how the distributions of individuals on the basis of sex/gender, race, and ethnicity are justified in the context of the scientific goals of the application. Simply stating that certain individuals will not be excluded or that individuals of either sex/gender or any race/ethnicity are eligible is not sufficient. Details about why the individuals are the appropriate individuals to accomplish the scientific goals of the study should be provided.

In some cases, the racial distribution may need to be based on the percent of patients from different groups who are known to have the condition/disease (e.g. Tay Sachs, sickle cell anemia). This is an example of an occasional exception to using the local demographics as per "details about why the individuals are appropriate".

SAMPLE TEXT:

Only patients with who present with [condition/disease/diagnosis being studied] will be recruited for this study. No patients will be excluded or included based on race or gender. Based on demographic data from previous patient visits to Austin area SHF network hospitals, the racial distribution of patients enrolled in this study would be expected to be: 35% Black, 60% Caucasian, and 5% Other. Efforts will be made to include equal numbers of women in this study.

Women make up approximately [50%] of the population in [Travis County, TX] (U.S. Census Bureau, 2010), will be recruited from the Austin, TX area, and a representative sample of men and women will be recruited into this study (50 men, 50 women). About 34% of Austin area residents are of Hispanic origin, and approximately 66% are Non-Hispanic and 2.0% are Non-Hispanic other ethnic minorities (U.S. Census Bureau, 2010). Based on these estimates, about 37 patients recruited into this study will be ethnic minorities.