**R.500.2.4. Inclusion of Women, Minorities, & Children**

*Please address each of 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*
* *Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting and/or geographical location alone are not acceptable reasons for the exclusion of particular groups.*