**2.4 Inclusion of Women, Minorities, and Children**

*Attach as a PDF file. Include Sections 1 and 2 as described below. See samples on the following pages.*

1. **Inclusion of Women and Minorities**
* 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 appropriate demographic distribution depends on
* The scientific question(s) being addressed
* The prevalence of the disease, disorder, or condition among women, men, and/or racial/ethnic groups
* Potential gaps in scientific knowledge
* Other factors, but NOT proportional representation based on census data
* Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
* Justify the exclusion or limited inclusion of any group by sex/gender, race, and/or ethnicity. Acceptable reasons for designing a study that is not representative of the affected population could be:
* Literature on the existence of (or lack of) differences on the basis of sex/gender, race, and ethnicity
* The proposed sample size a.
* The need to fill a particular research gap
* The feasibility of establishing collaborative arrangements (cost is NOT an acceptable justification)
* The purpose of the research constrains applicant selection (e.g., unique stored specimens, rare surgical specimens, etc.)
* If the proposed research includes an [NIH-Defined Phase III Clinical Trial](https://grants.nih.gov/grants/glossary.htm#NIHDefinedPhaseIIIClinicalTrial), this attachment MUST address plans for considering sex/gender, race, and ethnicity in the design and valid analysis of the trial.
1. **Inclusion of Children**
* NIH policy requires that applicants and grantees include children when conducting clinical research, unless there is a strong justification for their exclusion
* Justify exclusion of any specific age or age range. A child is any individual under 18 years old.
* If children will be included
* Describe and justify the age range(s) of individuals expected to be recruited
* Describe the team’s expertise in working with children of the included ages
* Describe facilities to accommodate children
* Indicate whether a sufficient number of children are included for a meaningful analysis relative to the purpose of the study
* If children will be excluded
* Describe and justify the age range(s) of individuals expected to be recruited
* Describe and justify the exclusion of children under 18 or of a subset of children
	+ The research topic is irrelevant to children
	+ Laws or regulations prohibit inclusion of children
	+ The knowledge being sought is already available for children or is addressed by an ongoing study (provide references)
	+ A separate, age-specific study is warranted and preferable
	+ Insufficient data are available to assess potential risk in children

**SAMPLE 1: CLINICAL TRIAL RECRUITING SPECIAL POPULATIONS**

**2.4 Inclusion of Women, Minorities, and Children**

1. **Inclusion of Women and Minorities**

SLE affects all races, all genders, and all ages, but is more prevalent in women in their childbearing years who are of African, Asian or Native American ancestry. This study will recruit patients with active, but not organ-threatening SLE, with no restrictions for race or gender. We therefore expect the study population to reflect the general demographics for SLE. Our trialists are versed in the nuances of minority population enrollment to facilitate equity in clinical trial participation. Based on this and our geographic location, many of our study participants come from groups that have been long under-represented in clinical studies, particularly rural and underserved minority populations (e.g. American Indian, African American, and Hispanic populations). Therefore, we anticipate having sufficient numbers of female and minority participants in this study.

Additional resources are available to further increase recruitment of minority participants if needed. The Oklahoma Shared Clinical and Translational Resources has a Special Populations Unit (SPU) which helps investigators obtain IRB approval from various tribal clinics or health systems to allow advertisement of projects at their facilities. This includes the Oklahoma City Indian Clinic, tribal health systems (Cherokee, Chickasaw and Choctaw), the Indian Health Service, and the Southern Plains Tribal Health Board representing the 39 federally recognized tribes in Oklahoma. Through the NIH-funded Oklahoma Pediatric Clinical Trials Network, the Oklahoma Clinical and Translational Science Institute has a relationship with the Latino Community Development Agency and African-American church groups. While this trial network is pediatric focused, these relationships also allow for us to outreach to adult populations. We can also advertise through local historically black newspapers and tribal communications departments.

The study drug is well known to be teratogenic and pregnancy is strictly contraindicated while women are taking this drug. Safety of use during lactation is unknown. Therefore, women who are pregnant, planning pregnancy, or breastfeeding will not be eligible for this study.

1. **Inclusion of Children**

This will be a trial of individuals between the ages of 18 and 60 years. Children younger than 18 are not included since this is unlikely to be a safe protocol for them. However, individuals between the ages of 18 and 21 will be eligible for this study. Individuals older than 60 years of age will be excluded from participation because of concerns about the safety of this drug combination in older people who are likely to suffer from age-related diminution in glomelular filtration, hepatic reserve, and arterial wall elasticity, for whom potential adverse events from medications may pose an unacceptable risk. We do not believe that this will greatly reduce our pool of eligible participants given that SLE flares are often milder in older individuals and they will be less likely to meet the disease activity criteria. From our extensive experience, most SLE patients presenting with this level of disease activity but without major internal organ involvement are between 20 and 55 years of age.

**SAMPLE 2: MECHANISTIC STUDY USING NEW AND EXISTING SAMPLES FROM AN ESTABLISHED COHORT**

**2.4 Inclusion of Women, Minorities, and Children**

1. **Inclusion of Women and Minorities**

This study will analyze existing samples from 200 SLE patients in our Oklahoma Cohort for Rheumatic Diseases, and these subjects will be included without regard for sex, gender, race, or ethnicity. Therefore, we anticipate this group will reflect the demographics of the Oklahoma Cohort for Rheumatic Diseases (85% female, 57% European American, 17% American Indian, 14% African American, and 6% Hispanic).

In addition, we will procure new samples from 30 of the 200 SLE patients described above as well as 10 unaffected controls from our Oklahoma Immune Cohort, who have provided consent for re-contact. Because the analyses using newly procured samples will not be powered for subset analyses, the newly procured samples will come from only female subjects (see Research Strategy).

The Oklahoma Cohort for Rheumatic Diseases serially follows 1,568 patients with rheumatic diseases. Over 135,000 samples are available from >9,000 subject visits, with >15 years of follow-up for some patients. This cohort enrolled over 1,000 individuals who reported no symptoms consistent with a systemic autoimmune disease (see Enrollment Report). Connective tissue disease screening questionnaires, demographics, and clinical information were collected from each individual, along with DNA, RNA, serum, plasma, and PBMCs.

1. **Inclusion of Children**

Children under the age of 18 years are not included in the prospective enrollment of individuals to the study. Due to the amount of blood required, this study is restricted to individuals who are at least 18 years of age and up to 75 years of age. However, individuals between the ages of 18 and 21 years will be eligible to participate in the study.

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