INCLUSION PLAN FOR WOMEN, MINORITIES, AND CHILDREN IN CLINICAL RESEARCH

GUIDE, TEMPLATE & ENROLLMENT TABLE for NCATS PRIOR APPROVAL

**OVERVIEW OF REGULATION**

Federal law requires that women and minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed.

NIH policy also states that children (currently defined as persons under the age of 19) be included in human subjects research supported by NIH unless an acceptable justification for their exclusion is provided.

**Note:** It is not expected that every study will include both sexes/genders, all racial and ethnic groups and subgroups, and children. Inclusion on the basis of sex/gender, race, and ethnicity, as well as the inclusion of children should be guided by the scientific aims of the study. Applicants should describe and justify fully the distribution of individuals that will be included in the research.

For more information, please see the NIH website [Frequently Asked Questions – Inclusion on the Basis of Sex/Gender, Race, and Ethnicity](https://grants.nih.gov/grants/funding/women_min/women_min_qa.htm)

Please see following pages for INCLUSION PLAN TEMPLATE and TARGETED ENROLLMENT TABLE

INCLUSION PLAN

**DESCRIPTION AND RATIONALE OF SUBJECT SELECTION**

*Describe the subject selection criteria and rationale for selection considering the population at risk for the disease/condition under study and the scientific objectives and proposed study design.*

**RATIONALE FOR EXCLUSION**

*If the proposed sample is not representative of those at risk for the disease/condition under study, provide an adequate justification, which must include the following:*

1. *the literature on the existence of (or lack of) differences on the basis of sex/gender, race, and ethnicity*
2. *the proposed sample size*
3. *the need to fill a particular research gap*
4. *the feasibility of establishing collaborative arrangements (cost is not an acceptable justification)*
5. *the purpose of the research constrains applicant selection (e.g., unique stored specimens, rare surgical specimens etc.)*

**DESCRIPTION OF OUTREACH PROGRAMS FOR RECRUITMENT**

*Describe recruitment and outreach plans or other methods for enrolling the individuals proposed as part of the sample.*

**DESCRIPTION AND RATIONALE FOR INCLUSION/EXCLUSION OF CHILDREN**

*Describe plans for the inclusion/exclusion of children (individuals under the age of 19), which must include the following:*

1. *description and give rationale of the age ranges of individuals expected to be recruited*
2. *description and give justification of the exclusion of children altogether or of a subset of children*

TARGETED ENROLLMENT TABLE FOR INCLUSION PLAN

|  |  |
| --- | --- |
| **Racial Categories** | **Ethnic Categories** |
| **Not Hispanic or Latino** | **Hispanic or Latino** | **Total** |
| **Females** | **Males** | **Females** | **Males** |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| **Total** |  |  |  |  |  |