**Policy on NIH Inclusion Plans**

**This policy applies to all competing grant applications for due dates on or after January 25, 2019**

**Women & Minorities:**

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-supported clinical research studies.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. The research plan/proposal should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

Address the following points with regard to **inclusion of Woman 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 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.
* Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the [Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page](https://grants.nih.gov/grants/funding/women_min/women_min.htm) for more information.

Address the following issues for ensuring valid analyses:

* Inclusive eligibility criteria - in general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups;
* Allocation of study participants of both sexes/genders and from different racial and/or ethnic groups to the intervention and control groups by an unbiased process such as randomization;
* Unbiased evaluation of the outcome(s) of study participants; and
* Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity, particularly if prior evidence strongly suggests that such differences exist.

Plan to Test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups (for NIH-Defined Phase III Clinical Trials only): Applicants also should address whether they plan to test for differences in effect among sex/gender, racial, and/or ethnic groups and why such testing is or is not appropriate.

This plan must include selection and discussion of one of the following analysis plans:

* Plans to conduct analyses to detect significant differences in intervention effect among sex/gender, racial, and/or ethnic subgroups when prior studies strongly support these significant differences among one or more subgroups, or
* Plans to include and analyze sex/gender, racial, and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender, racial, and ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), or
* Plans to conduct valid analyses of the intervention effect in sex/gender, racial, and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

**Inclusion across the Lifespan (all ages including children)**

Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project.  It is the policy of NIH that individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them.  The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

For the purposes of the **Inclusion of Children**, individuals under 18 are defined as a [child](https://grants.nih.gov/grants/glossary.htm#Child); however, exclusion of any specific age or age range group (e.g., [older adults](https://grants.nih.gov/grants/glossary.htm#OlderAdult)) should be justified in this section. In addition, address the following points:

* Children are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether children (as a whole or a subset of individuals under 18) will be included or excluded. If children will be included, include a rationale for selecting a specific age range of children, if relevant. If children will be excluded, provide a rationale for exclusion. See the [NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects](https://grants.nih.gov/grants/guide/notice-files/not98-024.html) for additional information about circumstances that may justify the exclusion of children.
* Include a description of the expertise of the investigative team for working with children of the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
* When children are involved in research, the policies under HHS' [45 CFR 46, Subpart D - Additional Protections for Children Involved as Subjects in Research](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd) apply and must be addressed in the [Protection of Human Subjects](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3) attachment.

Applications/proposals must include a description of plans for including **individuals across the lifespan**, including a rationale for selecting the specific age range justified in the context of the scientific question proposed.  If individuals will be excluded from the research based on age, the recipient/offeror must provide an acceptable justification for the exclusion. Acceptable reasons for excluding individuals based on age may include:

* The disease or condition does not occur in the excluded age group, or the research topic is not relevant to the excluded age group.
	+ *Example:  A study of Alzheimer's disease proposes to exclude children.*
* The knowledge being sought in the research is already available for the excluded age group or will be obtained from another ongoing study, and an additional study will be redundant.
	+ *Example:  A drug studied and approved for use in children will now be studied only in adults.*
* A separate, age-specific study in the excluded age group is warranted and preferable.  While this situation may represent a justification for excluding individuals based on age, consideration should be given to taking age differences into account in the study design, whenever feasible.
	+ *Example:  A clinical trial designed to promote self-monitoring of blood glucose levels in adolescents with Type 1 diabetes proposes to include only adolescents.*
* The study will collect or analyze data on pre-enrolled study participants (e.g., longitudinal follow-up studies that did not include data on children, or analysis of an existing dataset) and data inclusive of individuals across the lifespan are not available to address the scientific question.
	+ *Example:  A study which began prior to implementation of the NIH Policy and Guidelines on the Inclusion of Children proposes follow-up to examine long-term outcomes of individuals with the condition.  The original study excluded children, and similar data are not available from a cohort that includes children.*
* There are laws or regulations barring the inclusion of individuals in a specific age group in research.
	+ Example: Regulations for protection of human subjects allow consenting adults to accept a higher level of risk than are permitted for children.
* The study poses an unacceptable risk to the excluded group, such that their participation would not be considered ethical by the local IRB, peer review and/or NIH staff.
	+ *Example:  Children are excluded from a Phase I study for a treatment that includes significant risk, including death.  Evidence suggests the potential benefits to children do not outweigh the risks.*

Scientific review groups at the NIH will assess each application/proposal as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions.  NIH staff will monitor implementation of this policy during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.