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

**INSTRUCTIONS:**

*Instructions are taken directly from the* [*NIH SF424 Application Guide*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf)*. For internal use only, do not distribute. Please delete prior to submission.*

**Format:** No page maximum, 11pt font or larger (suggest fonts - Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana), at least 0.5” margins, single column formats are highly encouraged. Attach this information as a PDF file.

**Content:** Organize your attachment into two sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – “Inclusion of Women and Minorities” and “Inclusion of Children.” Also include any additional information requested in the FOA. You will also have to complete an Inclusion Enrollment Report (IER). Note that you may need to include multiple IERs for each study. Refer to the instructions for the IER below for more information.

1. Inclusion of Women and Minorities Address 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.
* 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 for more information.

Existing Datasets or Resources. If you will use an [existing datase](https://grants.nih.gov/grants/glossary.htm#Existingdataset)t, resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study. For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources.

2. Inclusion of Children For the purposes of the Inclusion of Children, individuals under 18 are defined as a child; however, exclusion of any specific age or age range group (e.g., older adults) 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, R - 101 Research Instructions for NIH and Other PHS Agencies - Forms Version E Series R.500 - PHS Human Subjects and Clinical Trials Information 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 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 apply and must be addressed in the Protection of Human Subjects attachment.

[More information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf)