**Inclusion of Women and Minorities**

Instructions: Delete all blue text. For guidance, see [NIH Forms application guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) for additional information.

Format:

Attach this information as a PDF file. See NIH’s Format Attachments page.

Content:

Discuss each of the points listed below and 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.

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](https://grants.nih.gov/policy/inclusion/women-and-minorities.htm)

[Subjects - Policy Implementation Page](https://grants.nih.gov/policy/inclusion/women-and-minorities.htm) for more information.

**Existing Datasets or Resources**. If you will use an existing dataset, 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.

***For Clinical Trials, see the*** [*NIH Forms application guide*](https://grants.nih.gov/grants/how-to-apply-application-guide.html)***for additional requirements.***