



## Office of Research and Sponsored Programs

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### NIH Inclusion of Women, Minorities, and Children Guidance

December 2017

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The "Inclusion of Women, Minorities and Children" document is required for all human subjects research. Additional requested documentation for phase III clinical trials is outlined on page two below.

#### Format:

Attach this information as a PDF file. See NIH's [Format Attachments](#) page.

#### 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 -

\*\*\*NIH-Defined Phase III Clinical Trials. If the proposed research includes an [NIH-Defined Phase III Clinical Trial](#) at the "Inclusion of Women, Minorities, and Children" attachment MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial. See the instructions for "Valid Analysis" and "Plans to test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups" below. Additional information about valid analysis is available on the [NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research](#) page.

[Valid Analysis](#) (for NIH-Defined Phase III Clinical Trials only):

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 00000000 T.bu(co)-1(al a)12cnst3(iased) or DimTrlyste in, o)