



National Institutes of Health
Office of Research on Women's Health

Putting science to work for the health of women

NIH Clinical Trial Inclusion Checklist for PIs

- Describe plans for the inclusion of women and individuals from racial and ethnic minority groups, justify exclusions, and provide an enrollment form. See [G.500 Section 2.4](#) and [Section 2.9](#) of the General Application Guide for NIH and Other PHS Agencies.
- For Phase III clinical trials ONLY:
 - Explain whether the intervention is expected to produce clinically relevant differences based on sex or gender, race, and ethnicity.
 - Provide description of strategies for conducting a valid analysis by sex or gender, race, and ethnicity (See [G.500 Section 2.4.1 of the General Application Guide Under "NIH-Defined Phase III Clinical Trials"](#).)
- Justify the proposed age range of the participants and any age-based exclusions (See the [Inclusion Across the Lifespan policy website](#) and [§2038\(H\) of the 21st Century Cures Act](#).)
- If pregnant women are included in the clinical trial, ensure protections and requirements are fulfilled as prescribed in [45 CFR 46, Subpart B](#).
- Update annual progress report with enrollment progress.

For more information, including HIPAA and OMB Standards, please see the NIH ORWH Inclusion Toolkit at <https://orwh.od.nih.gov/toolkit>.