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, justify exclusions, and provide an enrollment form (See G.500 Section 2.4 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/gender and race/ethnicity
  - ☐ Provide description of strategies for conducting a valid analysis by sex/gender and race/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 the exclusion of other ages (See the Inclusion Across the Lifespan policy 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 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.