Society for Women's Health Research

January 29, 2015

Office of Clinical Research and Bioethics Policy
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750, Bethesda, MD 20892

Re: Draft NIH Policy on the Use of Single Institutional Review Board for Multi-site Research (Notice OD-15-026)

The Society for Women's Health Research (SWHR®) appreciates the opportunity to submit comments in response to the National Institutes of Health (NIH) Office of the Director's Draft NIH Policy on the Use of Single Institutional Review Board (IRBs) for Multi-site Research (Notice OD-15-026).

SWHR is dedicated to transforming women's health through research, advocacy and education. We are a national non-profit organization based in Washington, D.C. and are widely recognized as the thought leader in promoting research on sex differences in all stages of medical research. For the past 25 years, we have actively advocated for inclusion of women and minorities in all phases of clinical trials and medical research. Due to SWHR's advocacy efforts, women are now routinely included in most major medical research studies and scientists are considering sex and gender as a variable in their research.

SWHR recognizes that NIH wishes to utilize single IRBs to speed the initiation of clinical trial research. We recommend that a single IRB review process take into account inclusion of both sexes in dual-sex clinical trials and that other demographic subgroups (such as race, age, ethnicity) are adequately represented and included where appropriate. We believe this will optimize clinical research to achieve greater efficiency in the initiation of studies across NIH's entire research portfolio.

Recently, NIH established policy changes regarding the inclusion of both sexes in preclinical research. Ensuring that both sexes are included in dual-sex clinical studies during the review by single IRB would provide appropriate framework for translation of preclinical research into clinical research, thereby facilitating efficiency of clinical trials. We further encourage that the clinical protocols provide detail in how subgroup populations will be appropriately analyzed to ensure that the clinical trials are well designed before their initiation.

Exception to the policy: If exceptions to the use of a single IRBs is made and the use of a local IRB review is necessary to meet the needs of specific populations, SWHR recommends that NIH have appropriate policies and guidelines in place that would ensure appropriate subgroups inclusion and analysis is done.

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Further, local IRBs should adhere to the same review standards and requirements as the single IRB. **SWHR believes that it is critical that IRBs, multi-center or single, have a critical role to play in ensuring that there is a consistent standardization in collecting and analyzing demographic subgroup data.**

We appreciate the opportunity to provide comments on this important policy change. Please feel free to contact us should you need additional information or have questions. We can be reached at 202-223-8224 or by email at monica@swhr.org.

Sincerely,

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