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November 10, 2017

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Janine Austin Clayton, MD  
Director  
Office of Research on Women's Health  
National Institutes of Health  
6707 Democracy Boulevard  
Bethesda, MD 20817

Dear Dr. Clayton:

The Society for Women's Health Research (SWHR<sup>®</sup>) commends the National Institutes of Health (NIH) Office of Research on Women's Health (ORWH) for updating its Trans-NIH Strategic Plan for Research on Women's Health. We greatly appreciate the opportunity to provide input on topics under consideration to stimulate new research areas, priorities, and approaches to help put science to work for the health of women, as outlined in the September 12, 2017 Request for Information (RFI) Notice (NOT-OD-17-108).

SWHR is a nonprofit organization based in Washington, DC that is widely recognized as a national thought leader in promoting research on biological differences in disease. We are dedicated to improving women's health through science, advocacy, and education. Because of SWHR's advocacy efforts, women are now routinely included in most major medical research studies, and scientists are required to consider sex and gender as variables in their research. Biological sex is defined as the classification of living things as female or male based on the complement of sex chromosomes and the presence of reproductive organs.<sup>1</sup> Gender refers to a complex psychosocial construct that takes into account not only biology but also the influences of society and environment.<sup>2</sup>

SWHR is pleased to offer the following suggestions on the three cross-cutting themes, and the proposed goals to support them.

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<sup>1</sup> Exploring the Biological Considerations to Human Health: Does Sex Matter? In: Witzmann TM, editor; Pardue ML, editor, Washington, DC: The National Academies Press, 2001.

<sup>2</sup> Ibid.

## Cross-Cutting Theme 1: Expand the Exploration of Sex as a Biological Variable (SABV) in NIH Research

SWHR strongly endorses expanding the exploration of sex as a biological variable (SABV) in NIH research activities. Research demonstrates that being female or male can greatly influence susceptibility, prevalence, and age of onset of disease and conditions. SWHR has consistently worked to make sure all of the Institutes at the NIH are aware of the impact of biological sex and gender differences in the research work they support. It is our great hope that by emphasizing and promoting the inclusion of sex and gender differences as crucial biological variables in all of its research portfolios, the exploration of SABV among NIH researchers will not only be expanded but also expedited.

The implementation of the NIH Policy on Consideration of Sex as a Biological Variable in NIH-funded Research (NOT-OD-15-102) has been a positive catalyst for advancing SAVB in NIH research. However, because the policy only requires that investigators *consider* the role of SAVB in research designs, analyses, and reporting—and stops short of *requiring* it—there is variability in the testing and reporting of sex-difference findings in NIH research. SWHR believes that testing for sex differences should become standard practice except when prior evidence suggests no differences exist, and also that there needs to be greater transparency and consistency in reporting of sex-difference research findings.

In support of these aims, SWHR strongly endorses increased training of researchers on SABV study design in pre-clinical and clinical research. Scientists must be informed that sex differences exist in all levels (cellular, molecular, and systems), including sex differences in the use of stem cells. SWHR also encourages further study of the identification of biomarkers and other mechanisms, which may be dependent on the understanding of sex, gender, race, and ethnic differences.

To help foster the dissemination of research findings to key stakeholders, NIH research study sections must be well informed of sex-difference research and opportunities for data sharing. Researchers should seek to publish sex-difference research findings in an array of scientific journals, such as *Biology of Sex Differences*, *Cell*, *Science*, and *Nature*, among others. NIH must serve as a champion in promoting published findings, and can do so through leveraging its news briefs and other communication channels that have broad reach.

## Cross-Cutting Theme 2: A Multi-Dimensional Approach to the Science of Women's Health

Novel cross disciplinary approaches are necessary to capture the interplay of influences on women's health. SWHR has recognized the need to have researchers and clinicians across various disciplines with diverse perspectives, conceptual frameworks, and methods come together to discover new ideas in a particular field. As an example, the SWHR Interdisciplinary Network on Sleep is a collaborative model that brings together researchers and clinicians across sleep-related fields, including epidemiology, obstetrics/gynecology, neurology, pain, physiology, psychiatry, pulmonology, and sleep medicine. In applying a multi-dimensional approach to the science of sleep, the Network has identified and examined sex and gender differences in sleep and circadian rhythms, and their impact on health and well-being across the lifespan.

SWHR is a strong proponent of convening cross-disciplinary experts to identify and discuss strategies for examining factors that contribute to the understanding of the health of women. We encourage ORWH to use and promote multi-dimensional approaches that foster collaboration, cooperation, and resources.

### Cross-Cutting Theme 3: Quality of Life and Disease Burden over the Life Course

Research on women's health must reflect a life-course perspective. We applaud ORWH for recognizing the impact that biological functions and life experiences at various stages of life have on both women's and men's health.

As an example, research has shown that there are important biological and hormonal differences across the lifespan that influence symptoms and consequences of sleep and circadian rhythm sleep-wake disorders in women.<sup>3,4</sup> Women and men with sleep apnea often present with different symptoms, yet available screening tools may bias diagnosis towards symptoms seen more commonly in men, thus failing to identify females with the condition. Improving sleep health requires consideration of these differences for proper patient identification and treatment.

We commend ORWH for prioritizing quality of life and disease burden over the life course as one of three core topics in its strategic plan for women's health research.

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Thank you for providing this opportunity to comment on the Trans-NIH Strategic Plan for Research on Women's Health RFI Notice. We hope you will take our comments into consideration as you finalize your plan for the next several years, and we look forward to assisting ORWH in any plan implementation.

If you have questions, please contact Sarah Wells Kocsis, Vice President of Public Policy, at 202.496.5003 or [swellskocsis@swhr.org](mailto:swellskocsis@swhr.org).

Sincerely,



Amy M. Miller, PhD  
President and Chief Executive Officer  
Society for Women's Health Research

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<sup>3</sup> Krishnan V, Collop NA. Gender differences in sleep disorders. *Current Opinion in Pulmonary Medicine*. 2006; 12 (6): 383-389.

<sup>4</sup> Mong JA, Cusmano DM. Sex differences in sleep: impact of biological sex and sex steroids. *Philosophical Transactions of the Royal Society of London Series B, Biological Sciences*. 2016; 371 (1688): 20150110.