NIH Request for Information on NIH-Wide Strategic Plan for Research on the Health of Women (NOT-OD-22-186)

Institution: Society for Women's Health Research
Email: policy@swhr.org

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I. Research opportunities in the NIH Strategic Plan for Women's Health Research FY2019-2023 that should be modified to account for recent scientific advances

SWHR believes that the research opportunities identified in the FY2019-2023 Strategic Plan—including, but not limited to, research into basic biological sex differences between males and females, the influence of sex and gender on disease prevention, presentation, management, and outcomes; and research on female-specific conditions and diseases—remain relevant areas of opportunity moving into the next iteration of the Strategic Plan. There remain ample opportunities to build upon these research areas.

Additionally—and particularly in light of recent public health emergencies, such as the COVID-19 pandemic and the monkeypox outbreak—SWHR would encourage ORWH to consider research opportunities related to the impact of public health emergencies on women as well as support for female scientists in science, technology, engineering, mathematics, and medicine (STEMM) careers.

Specifically, with respect to the COVID-19 pandemic, there are important opportunities to explore the impacts of COVID-19 and long COVID infections on women's health, including sex and gender differences, reproductive health issues, and mental health considerations. At a higher level, SWHR recommends that ORWH consider how it—both on its own and in partnership with other NIH entities—can support pandemic preparedness research and development for women, including identifying whether there are certain infectious diseases that pose a greater threat to women, funding additional epidemiology and surveillance research, and ensuring systematic consideration of biological sex in disease research studies. Finally, given the disproportionate impact of the COVID-19 pandemic on women in the workforce—and namely those in STEMM careers—SWHR encourages ORWH to consider specific provisions in the Strategic Plan that would support female scientists' retention and re-entry in biomedical research careers as well as propose initiatives to increase the recruitment and retention of women and other underrepresented populations.

II. Emerging research needs and opportunities that reflect the changing landscape of the study of the health of women that should be added to the plan

Key for the next iteration of the Strategic Plan will be defining the population for whom it is intended to serve. SWHR appreciated that in the FY2019-2023 Plan, NIH noted that it critically assessed how "women's health" is defined and pointed to the biomedical community's recognition that women's health "encompasses all the diseases and conditions that affect women." Yet, this definition does not account for the external factors that may disproportionately impact women and their health, such as serving in the role of caregiver or accessing and receiving high-quality health care.

SWHR encourages ORWH to consider those whose health might not historically be included in the current definition of "women's health," like those assigned female at birth and those who identify on the spectrum of gender to ensure optimal research and health outcomes for those whom the research is intended to serve. Further, SWHR urges the NIH to avoid narrowing the classification of a "woman" to only body parts or functions (e.g., individuals with a uterus, birthing person). In the absence of these definitions, we leave populations vulnerable and research potentially less effective. A methodology for properly defining women's health that removes variability in current definitions would provide greater insight and understanding into the current state of women's health research and how we can build on this work.

Additionally, SWHR recommends that the Strategic Plan prioritize the need for greater inclusion of pregnant and lactating populations in research. Due to historical underrepresentation in clinical research, this high-risk population has been left vulnerable, with them and their health care providers left to make decisions with limited data. SWHR supports expanding and refining research methodologies to improve the recruitment and retention of women to include pregnant and lactating people and including specific sections within the plan that emphasize increased inclusion of these populations.

III. **Cross-cutting scientific themes (for example, multidisciplinary research, and/or utilizing data science, natural language processing, and artificial intelligence) or research-related themes that should be common to all future strategic goals and objectives (such as considerations of sex, gender, and age on health and disease, and health disparities)**

Biological sex has a significant impact on health, from pathology to treatment response. Therefore, it is vital that biological sex be considered in research studies. As part of the next Strategic Plan, SWHR encourages NIH and the ORWH to consider how it might build upon the current NIH Policy on Sex as a Biological Variable

(SABV). SWHR encourages NIH to determine to what extent the NIH policy is being adhered to and identify ways to promote greater adherence to the policy.

Additionally, SWHR suggests more explicitly noting throughout the Strategic Plan's goals the importance of women's health research reflecting a life course perspective. It is not enough to conduct research on diseases and conditions that women experience or on other factors that may influence a woman's health in isolation; exploring how these factors interact and contribute to a women's short- and long-term health is also essential.

Finally, SWHR would recommend that the next version of the Strategic Plan carry over and build upon NIH's work to identify, address, and eliminate disparities for marginalized and underserved populations of women. This includes prioritizing research that examines health disparities, exploring policies within implementation science to eliminate disparities in health care investment and access, and exploring and updating policies to address disparities within the scientific workforce.

1025 Connecticut Ave NW, Suite 1104
Washington, DC 20036
T 202.223.8224
F 202.833.3472
W swhr.org