

**PUBLIC COMMENTS ON BEHALF OF
THE SOCIETY FOR WOMEN’S HEALTH RESEARCH
SUBMITTED BY KATHRYN G. SCHUBERT, PRESIDENT & CEO**

**Prepared for the Task Force on Research Specific to Pregnant and Lactating Women
July 2, 2020**

The Society for Women’s Health Research (SWHR) is pleased to submit these public comments to the Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) following the Task Force’s June 24, 2020 public meeting.¹

For 30 years, SWHR has been the thought leader in promoting research on biological sex differences in disease and improving women’s health through science, policy, and education. Because of SWHR’s advocacy efforts, women are now routinely included in most major medical research studies, and scientists funded by the National Institutes of Health (NIH) are required to consider sex as a biological variable (SABV) in their research.

In line with our foundational mission to ensure women’s participation in biomedical research, SWHR strongly supports the appropriate inclusion of pregnant women and lactating women in clinical therapeutics research. This population’s historical exclusion from clinical trials has led to significant, unacceptable knowledge gaps that hinder clinical decision-making and harms progress in women’s health. Pregnant women and lactating women must be protected through research, not from research.

With these ideas in mind, SWHR applauds the work of the Task Force in advising the Secretary of Health and Human Services (HHS) on best practices to lessen the knowledge gap regarding safe and effective therapies for pregnant and lactating women. SWHR is broadly supportive of all 15 recommendations the Task Force presented in its September 2018 report to HHS and Congress.

Additionally, the importance of the Task Force’s second phase of work cannot be understated. The forthcoming implementation plan will be crucial to ensure thoughtful application of the recommendations from the Task Force’s initial report. We are pleased to hear that PRGLAC is on track to deliver a robust report on implementation strategy to the Secretary this summer. SWHR stands ready to work with federal agencies and lawmakers to ensure the upcoming plan is executed effectively.

In response to the June 24, 2020 public Task Force meeting, we would highlight the importance of the Task Force’s work in light of the current COVID-19 pandemic. Research across a variety of infectious diseases — including the Zika virus, the H1N1 flu virus, and the SARS, MERS, and COVID-19 coronaviruses — suggests pregnancy places women at particular risk for disease-related complications. Within current COVID-19 treatment research, pregnant women and breastfeeding women are actively being excluded from federally-funded studies, including the Adaptive COVID-19 Treatment Trial. One recent paper suggests that across more than 300 trials investigating possible COVID-19 treatments, there is near universal exclusion of pregnant women.²

Incentivizing and/or requiring inclusion of pregnant women and lactating women within pandemic-related trials must be prioritized. Vaccines and treatments should be readily available

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to this population without concern for adverse outcomes for either mother and/or child. SWHR appreciates PRGLAC’s attention to addressing these pressing public health concerns.

Additionally, SWHR applauds the Task Force for addressing the important topic of liability-mitigation within the implementation plan (Recommendation 7). Exploring strategies to reduce risk within this type of research should be a priority when considering implementation strategies. If we hope to create a larger evidence base that allows pregnant women and lactating women to better understand therapeutic options, we must find creative strategies to “de-risk” research such that those conducting clinical trials and research are motivated to pursue appropriately inclusive methodologies.

Increasing our understanding of safety and efficacy in pregnant women and lactating women will require cultural shifts across the field of therapeutics research. We are grateful to the members of the PRGLAC Task Force and to the Task Force’s working groups for their efforts to improve research for this population.

Thank you in advance for consideration of these comments. If you have questions, please contact Sarah Wells Kocsis, Vice President of Public Policy, at swellskocsis@swhr.org.

¹ Federal Register /Vol. 85, No. 107 /Wednesday, June 3, 2020 /Notices.

² Whitehead, CL, Walker, SP (2020). Consider pregnancy in COVID-19 therapeutic drug and vaccine trials. The Lancet, 395(10237), E92. doi: 10.1016/S0140-6736(20)31029-1