



Inclusion of Pregnant and Lactating Women in Medical Research

An Official Position Statement of the Society for Women's Health Research

Position

In line with our mission to ensure women's participation in biomedical research, SWHR strongly supports appropriate inclusion of pregnant women and lactating women in clinical research.

Additionally, SWHR supports the implementation of all 15 recommendations developed by the federal Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) aimed at improving the development of safe and effective therapies for these women. SWHR emphasizes the following areas of importance:

- Federal agencies conducting and regulating research should consider novel approaches and best practices to overcome challenges to the recruitment and retention of pregnant women and lactating women in clinical research.
- Federal guidelines should not place undue barriers around the involvement of pregnant women and lactating women in research. For example, dual guardian consent should not be required for pregnant women to participate in research. In pediatric studies with potential direct benefit for the child, only one parent is required to give consent. This Department of Health and Human Service (HHS) requirement should be consistent for all agency-regulated studies in pregnant women.
- Federal agencies should also consider all possible study designs — in addition to the use of complementary approaches like pregnancy registries and real-world evidence sources — to determine the best approach for answering research questions of interest in regards to pregnant women and lactating women.
- The collection and reporting of clinical information around pregnant women and lactating women should be made widely available to address information gaps and reduce uncertainty around clinical care decisions for these women.
- Research sponsors should be required to explain any exclusion of pregnant women and lactating women in clinical trials moving forward. Additionally, incentives should be put in place to encourage drug makers to examine off-label use of medications that are already being taken by women who are pregnant or lactating.
- The government should address industry concerns about liability around inclusion of women who are pregnant or lactating by implementing a system such as the Vaccine Injury Compensation program.



Background

Each year in the United States, 6 million women become pregnant,¹ nearly 4 million women give birth,² and more than 83% of women will breastfeed after delivery.³ Unfortunately, pregnant women and lactating women are excluded from the majority of behavioral and biomedical research. As a result, little data exists on how medical and behavioral interventions may affect pregnant women, fetuses, and breastfeeding babies. Consequently, women who are pregnant or breastfeeding and their health care providers do not have access to the information they need to make confident decisions about their health care.

In considering the use of medications, nearly 94% of women take at least one medicine during pregnancy.⁴ More than 50% of postpartum women (breastfeeding or not) will take at least one medication.⁵ Despite these profound statistics, there is a paucity of human data on drug and vaccine safety and efficacy in pregnant women and lactating women. Limited animal studies of drug interactions in pregnancy are often all the information health care providers have prior to prescribing a Food and Drug Administration-approved medication for these women.

Pregnant women and lactating women take medications for a wide range of pregnancy and nonpregnancy-related conditions, including hypertension, postpartum depression, nausea and vomiting, seizure disorders, type 1 and type 2 diabetes, endocrine disorders, and more. When a pregnant or lactating woman needs a preventative or therapeutic, she and her physician are largely blind as to the effect these substances could have on the fetus, the pregnancy, or the breast milk. Because of this, women and their health care providers may be reluctant to prevent or treat certain diseases, resulting in suboptimal care for pregnant or breastfeeding patients. This is especially troubling given the increasing global prevalence of chronic disease and the growing number of women entering pregnancy with pre-diagnosed morbidities associated with medication usage.⁶

Without reliable information, women who are pregnant or breastfeeding may decide to avoid taking medications, avoid vaccinations, or stop breastfeeding, even though this may not be the best health option for the woman, fetus, or baby. The exclusion of pregnant women and lactating women in research has led to significant, unacceptable knowledge gaps that hinder clinical decision-making and may harm women's health. Federally funded research must do a better job to prioritize the needs of pregnant women and lactating women by including them within crucial therapeutics research. Pregnant women and lactating women must be protected through research, not from research.

SWHR uses the word “woman” (and the pronouns “she” and “her”) to refer to individuals who are assigned female sex at birth. As gender-neutral language continues to evolve in the scientific and medical communities, we will reassess this usage as necessary.

¹ Finer and Zolna. Declines in Unintended Pregnancy in the United States, 2008–2011, N Engl J Med. March 3, 2016. DOI: 10.1056/NEJMsa1506575.

² Martin et al. National Vital Statistics Report. November 27, 2019. https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf

³ CDC 2018 Breastfeeding Report Card. <https://www.cdc.gov/breastfeeding/data/reportcard.htm>

⁴ Mitchell et al. Am J Obstet Gynecol. 2011 Jul. doi: 10.1016/j.ajog.2011.02.029.

⁵ Amir et al. Postpartum women's use of medicines and breastfeeding practices: a systematic review. Int Breastfeed J. 2015; 10: 28. doi: 10.1186/s13006-015-0053-6.

⁶ Dalton et. al. Disparities in Chronic Conditions Among Women Hospitalized for Delivery in the United States, 2005–2014. *Obstetrics & Gynecology*: December 2017. doi: 10.1097/AOG.0000000000002357