

INCLUSION OF PREGNANT AND LACTATING POPULATIONS IN 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 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 populations. **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 and lactating individuals in clinical research.
- Federal guidelines should not place undue barriers around the involvement of pregnant and lactating people in research. For example, dual guardian consent should not be required for these individuals 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 Services (HHS) requirement should be consistent for all agency-regulated studies that include pregnant people.
- 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 and lactating individuals.
- The collection and reporting of clinical information around pregnant and lactating individuals should be made widely available to address information gaps and reduce uncertainty around clinical care decisions for these populations.
- Research sponsors should be required to explain any exclusion of those who are pregnant or lactating 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 those who are pregnant or lactating.
- The government should address industry concerns about liability around inclusion of individuals 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 and lactating people 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 individuals, fetuses, and breastfeeding babies. Consequently, individuals 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 those who are pregnant or lactating. 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 populations.

Pregnant and lactating individuals 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 person needs a preventative or therapeutic, they and their physician are largely blind as to the effect these substances could have on the fetus, the pregnancy, or the breast milk. Because of this, these patients 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, people 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 individual, fetus, or baby. The exclusion of those who are pregnant or lactating 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 and lactating people by including them within crucial therapeutics research. Pregnant and lactating individuals must be protected through research, not from research.

¹Finer and Zolna. Declines in Unintended Pregnancy in the United States, 2008–2011, N Engl J Med. March 3, 2016. DOI: 10.1056/NEJMs1506575.

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

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

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

⁵Amir 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.

⁶Dalton 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

“Sex” refers to the biological classification of living things according to reproductive organs and chromosomes. “Gender” refers to an individual’s self-identification as masculine, feminine, both, or neither, and is intrinsically associated with sociodemographic factors that ultimately affect health. Both sex and gender influence health across the lifespan, and SWHR strives to comprehensively address both sex and gender as they relate to women’s health. When citing research, SWHR uses terminology consistent with what is used in the study. As inclusive language practices continue to evolve in the scientific and medical communities, we will reassess our language as necessary.