Society for Maternal•Fetal Medicine
High-risk pregnancy experts

Improving Maternal & Infant Health: Including Pregnant and Lactating Participants in Clinical Trials
FAQ for Institutional Review Board Members & Professional Staff

Clinical research in pregnant and lactating people is essential for developing evidence-based medical care, minimizing risk, and ensuring that this population benefits from safe and effective treatments while contributing to broader medical knowledge.[1]

Unfortunately, these populations are rarely included in clinical research due to real and perceived barriers to their participation, including those related to the federal and institutional policies governing the protection of research participants.

This FAQ document is to help Institutional Review Board (IRB) members and professional staff understand the rationale for the full inclusion of pregnant and lactating people in research and to review the current best practices regarding their inclusion.

Why is clinical research in pregnant and lactating people important?

- The inclusion of pregnant and lactating people in research is crucial for the generation of evidence-based medical care. However, more than 90% of medications approved by the US Food and Drug Administration (FDA) between 1980 and 2011 lacked sufficient data to determine both the efficacy of use during pregnancy and the risk of use for both the pregnancy person and fetus.[2,3]
- When pregnant people are excluded from clinical research, the risk of medication use does not disappear. Rather, that risk shifts from the regulated trial setting to the clinical and individual setting. In that setting, pregnant and lactating individuals are afforded no formal protection from the monitoring of risks, nor are they able to contribute to broader knowledge.
- Conditions that arise due to pregnancy, such as preeclampsia, gestational diabetes, preterm birth, and postpartum hemorrhage, require tailored treatments that can only be developed through research involving pregnant individuals.[4]
- Further, conditions that arise during pregnancy but are not exclusive to pregnant individuals, such as sepsis, require evidence-based treatment. However, lack of research on these conditions during pregnancy may affect the health of pregnant people.
- Pregnancy is not an isolated life event. When individuals with chronic medical illnesses become pregnant, little knowledge is available regarding the safety of continuation of their

[1] Society for Maternal-Fetal Medicine (SMFM), Spong, C.Y., Hackney, D.N., Hughes, B.L., Gyamfi-Bannerman, C., Yee, L.M. and SMFM Health Policy and Advocacy Committee (2025), Society for Maternal-Fetal Medicine Position Statement: Prioritizing and investing in pregnancy research. Pregnancy, 1: e70028. https://doi.org/10.1002/pmf2.70028.
[2] Adam M.P., Polifka J.E., Friedman JM. Evolving knowledge of the teratogenicity of medications in human pregnancy. Am J Med Genet C Semin Med Genet 2011;157c:175-82.
[3] Blehar M.C., Spong C.Y., Grady C., Goldkind S.F., Sahin L., Clayton J.A.. Enrolling pregnant women: issues in clinical research. Womens Health Issues 2013;23:e39-45.
[4] Saenz C., Cheah P.Y., Van Der Graaf R., Henry L.M., Mastroianni A.C. Ethics, regulation, and beyond: the landscape of research with pregnant women. Reprod Health 2017;14:173.

medications or the impact of their chronic medical illness on pregnancy. Lack of research on pregnancy and lactation limits evidence-based care in the context of a lifetime of potential complications. Improving health during pregnancy can have positive long-term effects for both the mother and child, potentially reducing future health issues.[5]
- Pregnant, lactating, and pregnancy-capable people represent a large portion of the US population, and 90% of US women will give birth during their lifetime.[6] Their exclusion hinders scientific advancement.

Why is it important to include an individual with obstetric expertise on an IRB?
- Obstetric experts can provide crucial insights into the unique physiological, psychosocial, and ethical considerations involved in research with pregnant and lactating individuals.
- Individuals with obstetric expertise are needed because they bring specialized knowledge about pregnancy and maternal health, ensuring that research protocols are appropriate and ethical while balancing the risks and benefits to the pregnant or lactating person.
- Obstetric expertise ensures that potential risks and benefits are appropriately evaluated, leading to more balanced and ethical review processes.

What should be the default approach to pregnant or lactating people in regard to clinical research?
- More than 30 years ago, the Institute of Medicine (now National Academy of Medicine) recommended that pregnant individuals should be presumed to be eligible for participation in clinical studies.[7] The nation's leading obstetrics and gynecology professional societies, the Society for Maternal-Fetal Medicine and the American College of Obstetricians and Gynecologists, also support this recommendation.[8,9] The federal Task Force on Research Specific to Pregnant Women and Lactating Women underscored the importance of this recommendation in its 2018 and 2024 reports to the Secretary of Health and Human Services and the United States Congress.[10]
- Best practice is thus for pregnant and lactating people to default to study inclusion with appropriate scientific justification provided for exclusion, rather than to default to exclusion with justification provided for inclusion.

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[5] Saade G.R. Pregnancy as a window to future health. Obstet Gynecol 2009;114:958-60

[6] Livingston, G. They're Waiting Longer, but U.S. Women Today More Likely to Have Children Than a Decade Ago. Pew Research Center. January 18, 2018. https://www.pewresearch.org/social-trends/2018/01/18/theyre-waiting-longer-but-u-s-women-today-more-likely-to-have-children-than-a-decade-ago/

[7] Mastroianni, A.C., Faden, R.R., Federman, D.D., editors. (1994). "Women and health research: Ethical and legal issues of including women in clinical studies." Institute of Medicine; Washington D.C.

[8] Society for Maternal-Fetal Medicine (SMFM), Spong, C.Y., Hackney, D.N., Hughes, B.L., Gyamfi-Bannerman, C., Yee, L.M. and SMFM Health Policy and Advocacy Committee (2025), Society for Maternal-Fetal Medicine Position Statement: Prioritizing and investing in pregnancy research. Pregnancy, 1: e70028. https://doi.org/10.1002/pmf2.70028.

[9] ACOG Committee Statement No. 9: Ethical Considerations for Increasing Inclusivity in Research Participants. Obstetrics & Gynecology 143(6):p e155-e163, June 2024. | DOI: 10.1097/AOG.0000000000005579

[10] Task Force on Research Specific to Pregnant Women and Lactating Women. (2018). "Report to Secretary, Health and Human Services, Congress." Accessed from: https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf

Why should pregnant and lactating clinical research participants not be assigned a "vulnerable" designation?

- Modern best practice is for regulatory bodies to designate pregnant and lactating individuals as "scientifically complex" rather than "vulnerable."[11] Vulnerable individuals are historically those that may not be able to independently consent or could be subject to coercion, such as incarcerated individuals or children. Pregnant and lactating individuals are fully autonomous.
- The federal government acknowledged this in 2017 by removing pregnant patients from the list of vulnerable populations in federal regulations governing human subjects research, known as the Common Rule.[12]

What are the best practices for an IRB to support research involving pregnant and lactating people?

- Identify if your IRB includes an individual with expertise in obstetrics. If not, then one should be appointed.
- Locate and review your IRB's policies regarding pregnant and lactating participants.
- Ensure that your policies default to inclusion of pregnant and lactating individuals, designating them as scientifically complex rather than vulnerable.
    - If your IRB includes an obstetric member, defaults to inclusion, and designates pregnancy as "scientifically complex", then the primary three goals are met.

[11] Ibid.

[12] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html