

Ethics of research during pregnancy

Recent evidence suggests that pregnant women are at a higher risk of morbidity and mortality from COVID-19, compared with age-matched women who are not pregnant. Yet the historical and systematic exclusion of pregnant women from research continues in the context of the COVID-19 pandemic, resulting in a lack of evidence for this population. How can pregnant women be ethically and safely included in research and what part should researchers play in this? What role is there for community engagement to reconcile cultural norms and beliefs with the ethical and clinical rationale for research during pregnancy? And how do current governance mechanisms and regulation help or hinder the inclusion of pregnant women in research?

The 2016 [Global Forum on Bioethics in Research](#) (GFBR) meeting focused on the ethics of research in pregnancy. The full GFBR meeting report is available [at this link](#). The proceedings and case studies are also available in [Reproductive Health](#). This [PHEPREN](#) and GFBR seminar will reflect on the GFBR meeting conclusions and discuss if – and how – pregnant women are being included or excluded from COVID-19 research. See below for further background reading and recent literature on the topic.

Chair: Maggie Little, Georgetown University, USA

Panel: Marian Knight, Nuffield Department of Population Health, University of Oxford, UK
Loulou Kobeissi, Scientist, Universal Health Coverage – Life Course Division (UHC/LC)/ SRH Integration in Health Systems (SHS); Department of Sexual and Reproductive Health and Research (SRH), World Health Organization (WHO)
Sonali Kochhar, Global Healthcare Consulting, India; Department of Global Health, University of Washington, Seattle, USA

The following questions will form the basis of the seminar's panel discussion. Seminar attendees are invited to submit questions in advance of the seminar when they [register](#) or by [email](#), or during the live discussion.

1. To what extent are pregnant women being included in current COVID-19 research? What are the ethical arguments for inclusion and what are the barriers?

2. How can researchers balance the need to investigate interventions for pregnant women's health in preventing and treating COVID-19 and avoiding risk to them and their foetus?

3. How can research be facilitated in a context in which there are many socio-cultural norms about pregnancy that may impact on research efforts (e.g. where a partner or other family member may have socially assumed rights with regard to a pregnant woman's decision-making, or where there are cultural views on pregnant women giving blood or receiving an intervention)?

4. What is the role of engagement to explain the ethical and clinical rationale for inclusion, and who should be engaged?

5. How do current governance mechanisms and regulation help or hinder research during pregnancy and how should regulatory authorities prepare for the inclusion of pregnant women in trials in advance of public health emergencies?

Background reading

Knight, M., Morris, R.K., & Chappell, L.C. (2020) Include pregnant women in research—particularly covid-19 research. *BMJ* <https://doi.org/10.1136/bmj.m3305>

Costantine, M.M., Landon, M.B., & Saade, G.R. (2020) Protection by Exclusion: Another Missed Opportunity to Include Pregnant Women in Research During the Coronavirus Disease 2019 (COVID-19) Pandemic. *Obstetrics and Gynecology*, <https://doi.org/10.1097/AOG.0000000000003924>

Farrell, R., Michie, M., & Pope, R. (2020) Pregnant Women in Trials of COVID-19: A Critical Time to Consider Ethical Frameworks of Inclusion in Clinical Trials. *Ethics & Human Research* <https://doi.org/10.1002/eahr.500060>

Krubiner, C., Faden, R., & Karron, R. (2020) In the race for coronavirus vaccines, don't leave pregnant women behind. *STAT News*. <https://www.statnews.com/2020/02/25/coronavirus-vaccine-covid-19-pregnant-women/>

Luthra, S. (2020) Some researchers and politicians call for pregnant women to be included in coronavirus vaccine testing. *The Washington Post*. <https://www.washingtonpost.com/health/2020/07/15/some-researchers-politicians-call-pregnant-women-be-included-coronavirus-vaccine-testing/>

The PREVENT Working Group. (2019) Pregnant Women & Vaccines Against Emerging Epidemic Threats: Ethics Guidance for Preparedness, Research, and Response. Johns Hopkins Berman Institute of Bioethics. <https://static1.squarespace.com/static/574503059f72665be88193e9/t/5c082429c2241ba2553ee1f5/1544037418944/PREVENT-Web.pdf>

Smith D.D., Phippen J.L., Adesomo A.A., Rood K.M., Landon M.B., Costantine M.M. (2020) Exclusion of Pregnant Women from Clinical Trials during the Coronavirus Disease 2019 Pandemic: A Review of International Registries. *Am J Perinatol*. <https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0040-1712103>