

AMA Code of Medical Ethics

Opinion 7.4.3.1 Research Involving Pregnant and Lactating Individuals

Research involving pregnant and lactating individuals, including but not limited to, research regarding interventions intended to benefit pregnant or lactating individuals and/or their fetuses or nursing infants, must balance the health and safety of individuals who participate and the well-being of their fetuses or nursing infant against the desire to develop new and innovative therapies. Although it is important to carefully consider potential fetal risks involved when pregnant and lactating individuals participate in research, it is critical to realize that large scale exclusion from participation by these individuals has also precluded potential benefits and in some cases resulted in harm for this group. The paucity of data on safe and effective medical treatment during pregnancy and breastfeeding has resulted in physicians and patients choosing between pursuing medical interventions with uncertain risks to themselves and their fetuses or nursing infants, or foregoing the interventions altogether, which might itself cause harm due to undertreatment of medical conditions.

Understanding both the potential risks of participation and of non-participation, physicians conducting research must obtain the informed, voluntary consent of pregnant or lactating individuals, and adhere to general principles for ethical conduct of research as in all human participant's research. In addition, physicians conducting research should:

- (a) Include pregnant and lactating individuals in research for which they would otherwise be eligible in order to establish a greater knowledge base, produce relevant data, and promote respect for individuals.
- (b) Consider excluding pregnant and lactating individuals only when a study poses a substantial risk of significant harm to them or their fetuses or nursing infants, and:
 - (i) specify why the research excludes pregnant and lactating individuals;
 - (ii) seek alternative research methodologies to rectify gaps in knowledge.
- (c) Where scientifically appropriate and available, base studies that include pregnant and lactating individuals on well-designed, ethically sound, existing research with nonhuman animals or nongravid human participants to better assess potential risks.
- (d) Minimize risks to the fetus or nursing infant to the greatest extent possible, especially when the research is not conducted primarily to investigate potential benefit for fetuses or nursing infants, but rather for the development of important biomedical knowledge that cannot be obtained by any other means.

AMA Principles of Medical Ethics: I,III,V