

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 013
(A-24)

Introduced by: American College of Obstetricians and Gynecologists

Subject: Ethical Impetus for Research in Pregnant and Lactating Individuals

Referred to: Reference Committee on Amendments to Constitution and Bylaws

- 1 Whereas, each year 3.6 million¹ individuals give birth in the United States and 3 million people
2 are lactating; and
3
4 Whereas, 70% of pregnant and lactating people² take some kind of medication when they are
5 pregnant or lactating; and
6
7 Whereas, pregnant and lactating people are generally excluded in clinical research³, there is a
8 dearth of data about the appropriate safety, dosage, and efficacy of most medical interventions
9 in pregnant and lactating individuals; and
10
11 Whereas, the lack of data results in patients and clinicians choosing to (a) forego an intervention
12 which may result in harm from an un(der) treated condition or (b) use an intervention which may
13 carry an uncertain risk of harm for an unknown potential benefit; and
14
15 Whereas, lack of access to research exacerbates health inequities in pregnant and lactating
16 individuals⁴; and
17
18 Whereas, the harm from excluding pregnant individuals from clinical research was very
19 apparent during the COVID-19 pandemic and contributed to vaccine hesitancy and resulted in
20 unnecessary and avoidable maternal and infant mortality and morbidity^{5,6,7}; and
21
22 Whereas, recent initiatives from the White House⁸, National Institutes of Health⁹, and the
23 National Academies of Science, Engineering, and Medicine¹⁰ have emphasized the need for
24 further research in pregnant and lactating individuals; and
25
26 Whereas, the American College of Obstetricians and Gynecologists¹¹, National Academies of
27 Science, Engineering, and Medicine¹⁰, and the U.S. Department of Health and Human Services
28 have moved from an overly protectionist ethic that prioritizes minimization of fetal risk to one
29 that recognizes the scientific, legal, and ethical complexities of research including the risks to
30 the pregnant/lactating individual, fetus, and/or neonate of NOT doing research; and
31
32 Whereas, the HHS Task Force on Research Specific to Pregnant Women and Lactating Women
33 released detailed recommendations, along with an implementation plan, to protect pregnant and
34 lactating individuals through research, rather than from research^{12,13}; and
35
36 Whereas, as this national policy discussion unfolds, the ethical guidance of our profession must
37 undergird this discussion; and

1 Whereas, the existing Code of Medical Ethics Opinion 7.3.4 Maternal-Fetal Research extracts
2 content from both the Code modernization process of 2016 with foundational original material
3 stemming from the “Medical applications of fetal tissue transplantation” opinion passed in 1989;
4 and

5
6 Whereas, much in women’s health, research infrastructure, ethical frameworks, and liability
7 landscape has changed since 1989 and the ethics of research in lactation is not discussed in
8 the Code; therefore be it

9
10 RESOLVED, that our American Medical Association Council on Ethical and Judicial Affairs
11 update its ethical guidance on research in pregnant and lactating individuals. (Directive to Take
12 Action)
13

Fiscal Note: Modest - between \$1,000 - \$5,000

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RELEVANT AMA POLICY

7.3.4 Maternal-Fetal Research

Maternal-fetal research, i.e., research intended to benefit pregnant women and/or their fetuses, must balance the health and safety of the woman who participates and the well-being of the fetus with the desire to develop new and innovative therapies. One challenge in such research is that pregnant women may face external pressure or expectations to enroll from partners, family members, or others that may compromise their ability to make a fully voluntary decision about whether to participate.

Physicians engaged in maternal-fetal research should demonstrate the same care and concern for the pregnant woman and fetus that they would in providing clinical care.

In addition to adhering to general guidelines for the ethical conduct of research and applicable law, physicians who are involved in maternal-fetal research should:

- (a) Base studies on scientifically sound clinical research with animals and nongravid human participants that has been carried out prior to conducting maternal-fetal research whenever possible.
- (b) Enroll a pregnant woman in maternal-fetal research only when there is no simpler, safer intervention available to promote the well-being of the woman or fetus.
- (c) Obtain the informed, voluntary consent of the pregnant woman.
- (d) Minimize risks to the fetus to the greatest extent possible, especially when the intervention under study is intended primarily to benefit the pregnant woman.

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