Pregnant women as research participants: why is additional protection required?

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❖Clarification may be required with respect to
(1) the ethical grounds of providing additional protection to pregnant women and
(2) what constitutes additional protection to them.

❖Arguments regarding pregnant women may pertain to women of childbearing potential and lactating women, even if they are not currently pregnant, depending on the reasons for additional protection.

Background

Today, blanket exclusion of pregnant women from research participation is not endorsed; however, a tendency still remains to exclude pregnant women from participating in research. This exclusion results in insufficient data to guide clinical practice for pregnant women, and hence adds risks to pregnant women and fetuses (Lyerly et al. 2007, 2008, 2009; Baylis 2010; Goldkind et al. 2010).

The United States (US) Federal Regulations classify pregnant women together with fetuses and neonates as populations requiring additional protection (45 CFR 46 Subpart B).

The Council for International Organizations and Medical Sciences (CIOMS) Guidelines do not classify pregnant women as a vulnerable population; however, the CIOMS Guideline 17 provides certain conditions for their research participation.

Are there any problems with the autonomy of pregnant women?

An autonomous person must have decisional capacity and his/her voluntariness must be secured.

The Belmont Report stipulates that those with "diminished autonomy are entitled to protection". This may apply to children (45 CFR 46 Subpart D) due to their inadequate capacity and to prisoners (45 CFR 46 Subpart C) due to their plausible lack of voluntariness. Physically or mentally disabled persons, and economically or educationally disadvantaged persons (46.107, 47.111) are also referred to as vulnerable populations in the US Common Rule. Coleman points out that it is not clear why certain populations, such as pregnant women, are deemed deficient in decisional capacity or voluntariness (2009).

Specifically regarding pregnant women's decisional capacity, the Committee on the Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies (US) has clarified that pregnant women are capable of making their own decisions (Mastroianni et al. 1994). A similar view is expressed by the American College of Obstetricians and Gynecologists (2007).

Beneficence regarding the fetus

Fetuses require special protection as they are not autonomous agents. It may be the responsibility not only of pregnant women, but also of healthcare professionals and society to protect the fetus' well-being. For the ethical design and conduct of research involving pregnant women, McCullough et al. argue that a fetus should be recognized as a patient, and that maternal and fetal interests must be balanced against each other (2005, 2008). However, the view of the fetus as a (fully distinct) patient remains controversial.

In relation to the fetus, pregnant women face a wide variety of challenges in making autonomous decisions (Kukla et al. 2009). The CIOMS Guidelines express some concern about the informed consent process of women who live in societies where a woman is (1) expected not to express herself, and (2) is considered less important than her fetus (Guidelines 16 and 17). In addition to physiological changes and anxiety due to pregnancy, familial and societal values may undermine a pregnant woman's voluntariness in relation to her fetus. The degree of such influences may differ across cultures and communities.