The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION SUMMARY

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(Replaces Committee Opinion No. 307, December 2004 and Committee Opinion No. 377, September 2007)

For a comprehensive overview of these recommendations, the full-text version of this Committee Opinion is available at http://dx.doi.org/10.1097/AOG.0000000000001150.

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Committee on Ethics

The American Academy of Pediatrics, American Society for Reproductive Medicine, and Society for Maternal–Fetal Medicine endorse this document. This Committee Opinion was developed by the Committee on Ethics of the American College of Obstetricians and Gynecologists as a service to its members and other practicing clinicians. While this document reflects the current viewpoint of the College, it is not intended to dictate an exclusive course of action in all cases. This Committee Opinion was approved by the Committee on Ethics and the Executive Board of the American College of Obstetricians and Gynecologists.

Ethical Considerations for Including Women as Research Participants

ABSTRACT: Inclusion of women in research studies is necessary for valid inferences about health and disease in women. The generalization of results from trials conducted in men may yield erroneous conclusions that fail to account for the biologic differences between men and women. Although significant changes in research design and practice have led to an increase in the proportion of women included in research trials, knowledge gaps remain because of a continued lack of inclusion of women, especially those who are pregnant, in premarketing research trials. This document provides a historical overview of issues surrounding women as participants in research trials, followed by an ethical framework and discussion of the issues of informed consent, contraception requirements, intimate partner consent, and the appropriate inclusion of pregnant women in research studies.

Attitudes concerning inclusion of women in research trials have changed dramatically over the past several decades. Although changes have been made to encourage and recruit more women into research studies, a gap still exists in the available data on health and disease in women, including those who are pregnant. In addition, concerns about the potential for pregnancy in research trial participants have led to practices involving overly burdensome contraception requirements. This document provides a historical overview of issues surrounding women as participants in research trials, followed by an ethical framework and discussion of the issues of informed consent, contraception requirements, intimate partner consent, and the appropriate inclusion of pregnant women in research studies.

On the basis of the principles outlined in this Committee Opinion, the American College of Obstetricians and Gynecologists offers the following recommendations and conclusions:

- Although significant changes in research design and practice have led to an increase in the proportion of women included in research trials, knowledge gaps remain because of a continued lack of inclusion of women, especially those who are pregnant, in premarketing research trials. Continued emphasis on recruitment of women into research must be encouraged. The potential for pregnancy should not automatically exclude a woman from participating in a clinical study, although the use of contraception may be required for participation in specific circumstances.
- In order to aid in the recruitment of women, researchers should specifically address obstacles to

participation that may be experienced disproportionately by women, such as the lack of adequate child care during time spent as a research participant.

- Further efforts are needed to ensure that research is designed to include representation of all potentially affected individuals, including those in diverse and underserved populations who often are not fully represented in current study designs.
- Pregnant women in research trials should be defined as a "scientifically complex" rather than a "vulnerable" population.
- Contraception requirements for research participants of reproductive capacity often are out of proportion to the actual risks of study drugs or interventions. Instead, the requirement for contraception in a given research trial should be tailored to the individual study design and should be determined based on the actual risks to the pregnancy of an individual research participant.
- In the absence of a few specific scenarios, requiring participation consent from a woman's intimate partner is neither warranted nor ethically justified.
- Maternal and fetal risks are deeply interconnected, and consideration of enrolling pregnant women in research requires balancing the risk of fetal harm with the potential for benefit and the importance of the information to be gained on the health of women and fetuses.

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