



# **Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies, Volume 1**

*Anna C. Mastroianni, Ruth Faden, Daniel Federman*

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In the nineteenth century some scientists argued that women should not be educated because thinking would use energy needed by the uterus for reproduction. The proof? Educated women had a lower birth rate. Today's researchers can only shake their heads at such reasoning. Yet professional journals and the popular press are increasingly criticizing medical research for ignoring women's health issues.

**Women and Health Research** examines the facts behind the public's perceptions about women participating as subjects in medical research. With the goal of increasing researchers' awareness of this important topic, the book explores issues related to maintaining justice (in its ethical sense) in clinical studies.

Leading experts present general principles for the ethical conduct of research on women--principles that are especially important in the light of recent changes in federal policy on the inclusion of women in clinical research.

**Women and Health Research** documents the historical shift from a paternalistic approach by researchers toward women and a disproportionate reliance on certain groups for research to one that emphasizes proper access for women as subjects in clinical studies in order to ensure that women receive the benefits of research.

The book addresses present-day challenges to equity in four areas:

- Scientific--Do practical aspects of scientific research work at cross-purposes to gender equity? Focusing on drug trials, the authors identify rationales for excluding people from research based on demographics.
- Social and Ethical--The authors offer compelling discussions on subjectivity in science, the evidence for male bias, and issues related to race and ethnicity, as well as the recruitment, retention, and protection of research participants.
- Legal--**Women and Health Research** reviews federal research policies that affect the inclusion of women and evaluates the basis for researchers' fears about liability, citing court cases.
- Risk--The authors focus on risks to reproduction and offspring in clinical drug trials, exploring how risks can be identified for study participants, who should make the assessment of risk and benefit for participation in a clinical study, and how legal implications could be addressed.

This landmark study will be of immediate use to the research community, policymakers, women's health advocates, attorneys, and individuals.

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