“Clinical Research Involving Pregnant Women”
Francoise Baylis and Angela Ballantyne, editors, 2016, 301 pages, Springer, $179
Review by Norman M. Goldfarb

“Clinical Research Involving Pregnant Women” addresses a knotty question: How can pregnant women (and their fetuses) get the best treatments that medical science can offer without risking their health in the clinical studies needed to verify the safety and effectiveness of those treatments?

Everyone agrees that pregnant women need safe medications, but how to verify the safety of a treatment is a real head-scratcher. The precautionary principle — better safe than sorry — can preclude almost any testing in pregnant women except perhaps for conditions specific to pregnancy. The absence of testing, of course, creates its own risks, which might far outweigh those of clinical research, since it means that physicians are trying out those same treatments on pregnant women without the benefit of the safety precautions of, and the knowledge gained from, clinical research.

One of the contributors to this book, Chris Kaposy, questions the assumption that pregnant women should be excluded from participating in clinical studies unless there is good reason to include them. He argues, instead, that pregnant women should be included unless there is good reason to exclude them. He proposes the following rules for excluding pregnant women from a clinical study:

- The decision to exclude pregnant women from clinical research should be trial specific.
- The assessment of whether to exclude pregnant women should take the nature and severity of the disease into consideration.
- The availability and results of previous nonclinical data and pregnant and nonpregnant animals and results from clinical data should factor into the assessment of risk versus potential benefit.
- The availability of an intervention that is standard of care, and the knowledge about the associated risks of such standard of care, are relevant for determining whether pregnant women should be excluded.
- The risk versus potential benefit assessment should take into account the stage of pregnancy in relation to overall development of the fetus, especially regarding fetal brain development.
- Exclusion considerations should consider the risks to the pregnant woman, the fetus, or child.
- The pregnant woman’s choice regarding continuing or terminating the pregnancy may be a relevant factor in determining whether they should be excluded.
- It is important to consider the risks to individual pregnant women from not participating in proposed clinical research.
- The likelihood that the drug or intervention in the study will be used or needed by the population of pregnant women even without research evidence should affect deliberations about whether to exclude pregnant women.
While these rules do not put a brick on the scales of inclusion, they do reframe the inclusion vs. exclusion question for serious deliberation.

The book includes 16 chapters by 28 authors:
- Missed Trials, Future Opportunities
- Why Physicians and Women Should Want Pregnant Women Included in Clinical Trials
- Better Safe Than Sorry: Risk, Stigma and Research During Pregnancy
- Presumptive Inclusion and Legitimate Exclusion Criteria
- Fair Inclusion of Pregnant Women in Clinical Research: A Systematic Review of Reported Reasons for Exclusion
- Research Ethics Review of Drug Trials Targeting Medical Conditions of Pregnant Women
- Pregnant Women’s View About Participation in Clinical Research
- Pregnancy, Vulnerability and the Risk of Exploitation in Clinical Research
- When Hypothetical Vulnerability Becomes Actual: Research Participation and the Autonomy of Pregnant Women
- Equipoise, Uncertainty and Inductive Risk in Research Involving Pregnant Women
- Does My Bias Look Big in This?
- Research into Lifestyle Changes in Pregnancy
- Ethics and Research with Pregnant Women: Lessons from HIV/AIDS
- Ethical Issues in a Trial of Maternal Gene Transfer to Improve Foetal Growth
- Clinical Research Involving Pregnant Women Seeking Abortion Services: United States Perspectives
- Research on Uterine Transplantation: Ethical Considerations.

The book is available in bookstores.

**Reviewer**

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