Contraception and Pregnancy in Research

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Pregnant women in medical research
Should pregnant women be allowed to participate in…

Research pertaining directly to pregnancy, labor, and delivery?

Research related to treatments that have already been approved by the FDA for use in nonpregnant women and may be used by pregnant women?

Research involving new medications that have not been approved for use in nonpregnant women?
Pregnant women get sick, and not just with pregnancy-related illnesses
Pregnant women are different from nonpregnant women
Including pregnant women in research studies is an issue of justice.

The Belmont Report

Respect for Persons

Beneficence

Justice
But what about the risk to the fetus?
So let’s just not give any investigational treatments to pregnant women and eliminate the risk!
45 CFR 46 Subpart B lists the rules for including pregnant women in research
True or False?

Studies should be conducted on pregnant animals and nonpregnant women before involving pregnant women in research.

These preclinical and preclinical studies provide data for assessment of risk to the mother and fetus.
True or False?

Research that poses greater than minimal risk to the fetus is never allowed.

Greater than minimal risk studies are allowed if the risk comes from interventions or procedures that hold out the prospect of direct benefit to the woman or fetus.
True or False?

Research that does not hold out the prospect of direct benefit to mother or fetus is never allowed.

False

Studies with no direct benefit are allowed if they hold out no greater than minimal risk to the fetus and the study is intended to develop important biomedical knowledge which cannot be obtained by other means.
True or False?

If the research is expected to benefit the pregnant woman, she can consent to participation without consulting the father.

True

This is also true if the study benefits both the pregnant woman and the fetus.
True or False?

If the research is expected to benefit only the fetus, the mother can consent without consulting the father.

False

The father’s consent need not be obtained if he is unavailable, incompetent, temporarily incapacitated, or if the pregnancy was a result of rape or incest.
Additional required components for research with pregnant women

- Risks must be minimized
- Parent(s) must be informed about impact on fetus
- No inducements may be offered to terminate a pregnancy
- No part in timing, method, or procedures to terminate
- No part in determining viability of a neonate
Contraception as a research requirement
Contraception has costs.
For FDA-approved drugs, follow the labeling instructions
Drugs with evidence that they are not harmful to human fetuses

No mandated contraception
No risk in animals, not tested in humans or harm in animals but no harm in humans

One form of contraception
Proven harm in humans or animals

Manufacturer’s recommendations
OR
Two forms of contraception
Drugs without adequate testing to establish safety or risk

One form of contraception
A pregnancy test may be required for enrollment if there is more than minimal risk to the fetus.
Methods should only be excluded for scientific reasons.
Abstinence should always be an option when contraception is required.
Remember to include men in the plan if appropriate.
What if an unintended pregnancy occurs?

- Unblinding
- Informed consent
- Discussion of risks and benefits
- Description of continuing procedures
- Permission to follow
What about pregnant partners of research participants?
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