Pregnant Women and Human Subjects Research

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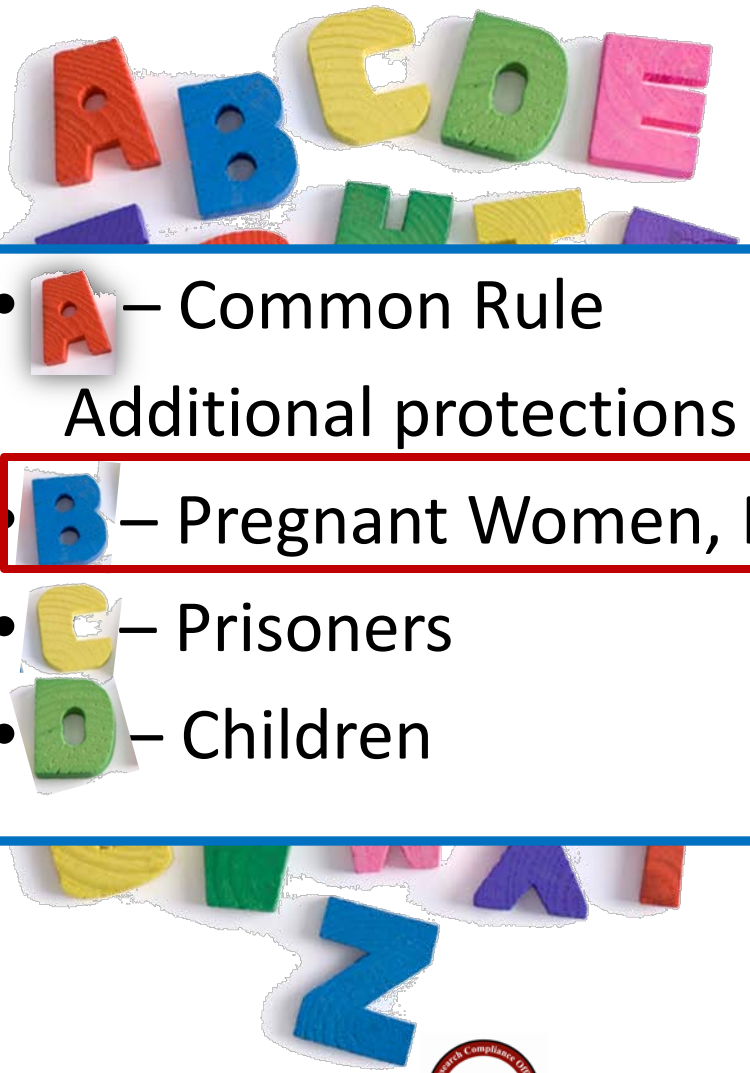
45 CFR 46 (Subparts)



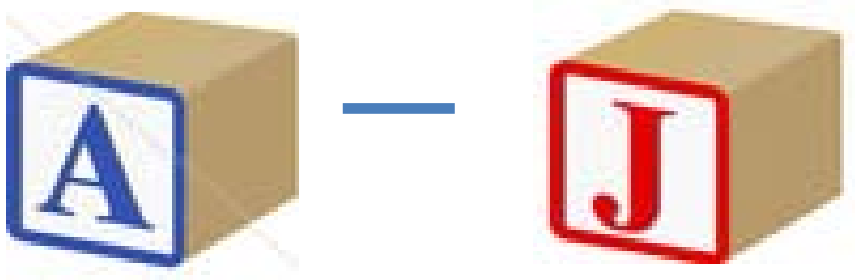
- A – Common Rule

Additional protections for:

- B – Pregnant Women, Fetuses and Neonates
- C – Prisoners
- D – Children

Research Involving Pregnant Women or Fetuses

Pregnant women or fetuses may be involved in research if ALL of the following conditions are met:



Conditions

Where scientifically appropriate,
…studies…have been conducted
and provide data for assessing potential
risks to pregnant women and fetuses

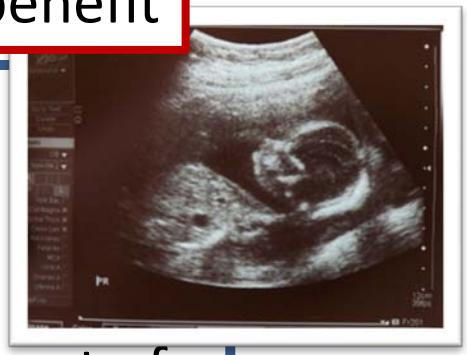
(including studies on pregnant animals and
clinical studies on non-pregnant women)

Conditions, cont.

The risk to the fetus:

- is caused solely by the interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;

Or , when there is no such prospect of direct benefit



- the risk is not greater than minimal

and

the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means

Conditions, cont.

- Any risk is the least possible for achieving the objectives of the research

Conditions, cont.

(if) the conditions for B have been met…

her consent is obtained in accord with the provisions of subpart A

Conditions, cont.

If the research holds out the prospect of direct benefit solely to the fetus

then the consent of the pregnant woman and the father is obtained

Father's consent need not be obtained :

due to unavailability, incompetence, or temporary incapacity, or the pregnancy resulted from rape or incest.

Conditions, cont.

Each individual providing consent … is fully informed on the reasonably foreseeable impact of the research on the fetus or neonate.

For children…who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D

Conditions, cont.

No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

Individuals engaged in the research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy, and

Individuals engaged in the research will have no part in determining the viability of a neonate

Question: To allow exclusion of a particular subject population (e.g., pregnant women) in an FDA-regulated study, the IRB must:

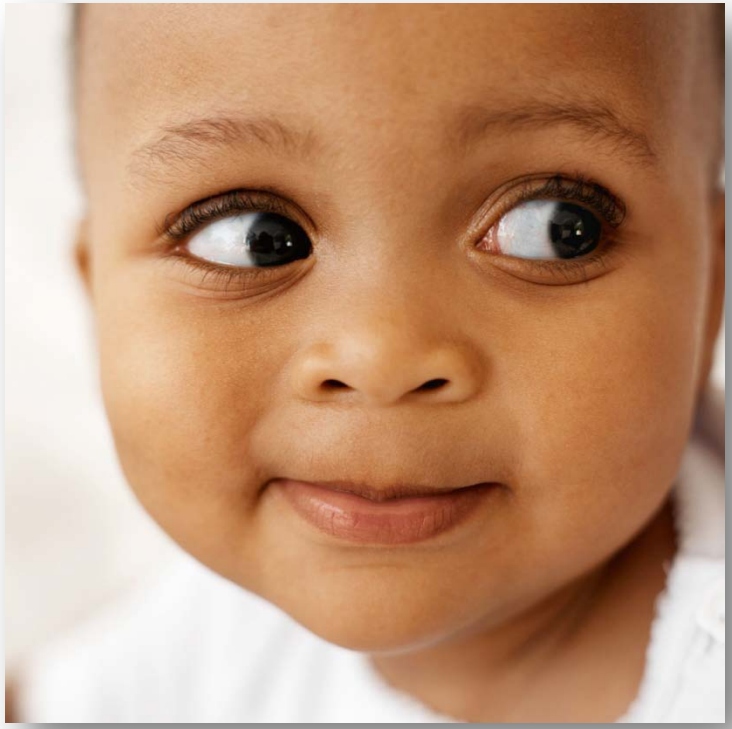
a) Consider the rationale for the exclusion criteria
b) Accept the sponsor's eligibility criteria
c) Consider the economic burden on the PD to do equitable recruitment

A study involves a drug for treating high cholesterol. This drug has been tested on pregnant rats, and a few abnormalities resulted.

The PD is excluding pregnant women. Why is this exclusion reasonable?

- Women are not as likely as men to develop problems with high cholesterol.
- There is a significant harm to the fetus from the drug
- Protecting the health of the fetus from a possible harm is a clear and compelling reason.

• 2006 BLOOPERS CONTEST:



In a study of men with hormone refractory prostate cancer, both males and females were checked as being included in the study population.

Question: If the subject population does not exclude pregnant women, and a participant becomes pregnant during the study, what safeguards can be put in place by the PD to mitigate risk to the fetus?

All studies at Stanford

No Harm	Unknown	May cause harm	Do cause harm

9c. Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus, if applicable).

What you may encounter in a consent form

Study on Drug X in Healthy Adults 18 to 45 Years of Age

If you are a female who is able to become pregnant, you will be given a pregnancy test to make sure you are not pregnant prior to each treatment.

This vaccine may harm a fetus. It is important that both male and female volunteers in this study use approved birth control.

If you are pregnant or currently breast feeding, you may not participate in this study.

You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

If you become pregnant or father a child,, you agree to notify the investigator as soon as possible. You will no longer receive additional study vaccine but we will ask that you continue to be followed for the duration of your pregnancy and for the rest of the study.