

Consent Requirements in Research with Pregnant Women

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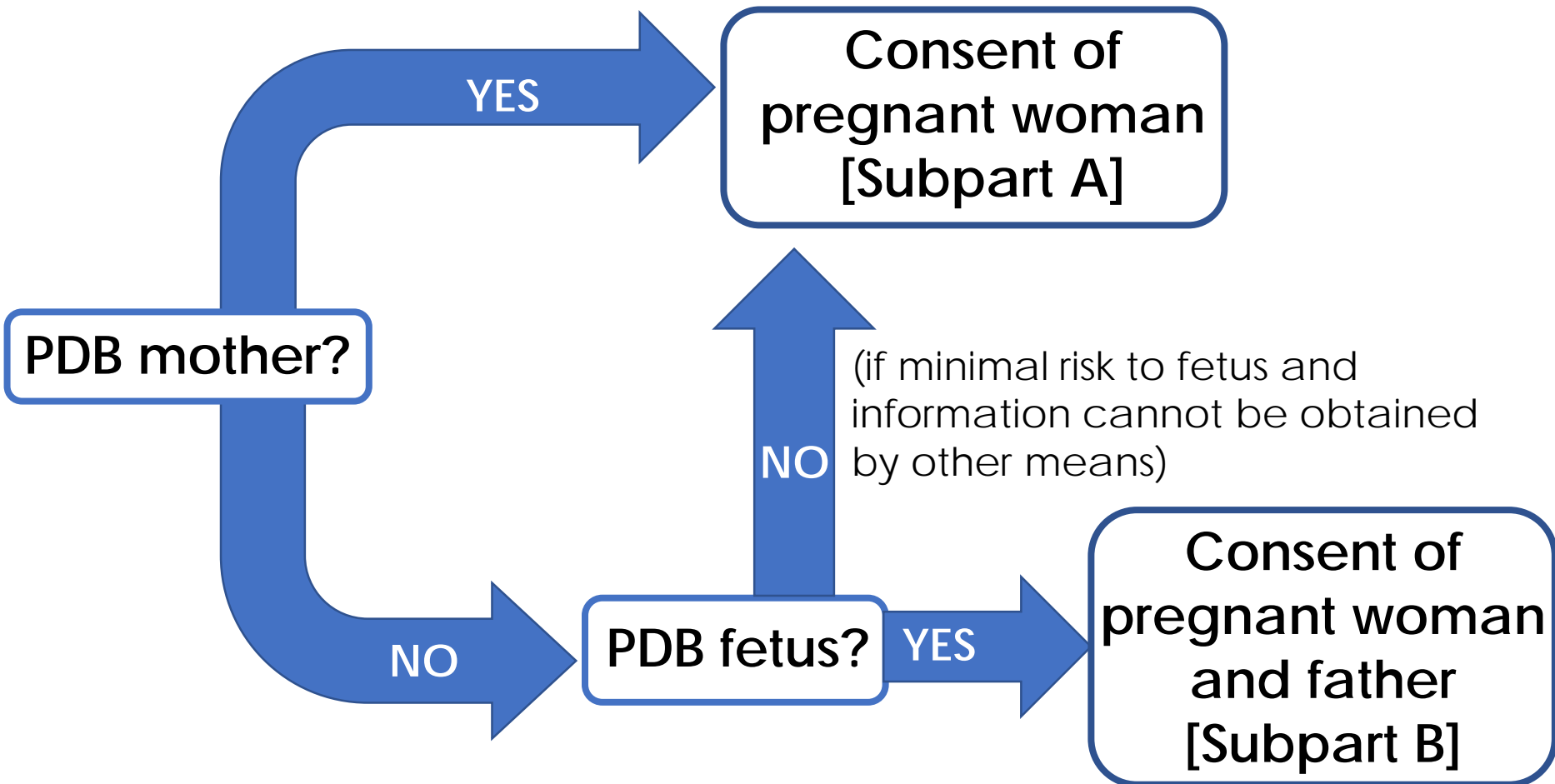
Overview

- In many ways informed consent in pregnancy is similar to other contexts
 - Pregnancy does not interfere with capacity for informed decision-making

EXCEPT:

- Research in pregnancy takes place in context of profoundly limited evidence base
- Pregnancy may entail research involving an entity who cannot consent for itself (fetus)

HHS requirements – paternal consent



In favor of paternal consent

- [paternal consent in fetal-benefit research] is “most **respectful of the parents’ joint interests** in their fetus’s health.”
 - Federal Register, November 2001

Objections to paternal consent

1. Potential barrier to research participation

- “The department recognizes and encourages paternal involvement in decisions affecting the pregnant woman and fetus prior to delivery,” but “in some cases **the father’s consent has been a barrier to participation.**”

➤ Federal Register, January 2001

Objections to paternal consent

2. Doesn't respect pregnant women's autonomy

➤ Recognition of the rights of the nongestational intended parent during pregnancy **may infringe upon and weaken maternal autonomy**. As in other clinical situations, the pregnant woman's consent should be sufficient for research interventions that affect her or her fetus.

➤ ACOG Committee Opinion 645, 2015

3. Inconsistent with standards for clinical care

➤ e.g., cesarean, transfusion

Objections to paternal consent

4. **May compromise privacy and safety of pregnant woman**
 - e.g., maternal HIV status

5. **Maternal and fetal benefit not separable**
 - bodies, life trajectories intertwined

6. **Fails to account for range of relationships**

Exceptions to PC requirement

45CFR46.204e

- father's consent need not be obtained if he is unable to consent because of **unavailability, incompetence, or temporary incapacity** or the **pregnancy resulted from rape or incest**.

Contrast with pediatric research



*where research holds PDB for offspring



TWO PARENTS



ONE PARENT

Another model for paternal involvement

- Some research involving pregnant women may be directed at the health of the fetus. In such cases, the **role of the woman remains the same: she is the decision-maker for any interventions that affect her.** This does not exclude the possibility of the woman **consulting with the father of the fetus, if she wishes.**

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Toward the Responsible Inclusion of
Pregnant Women in Medical Research

THE SECOND WAVE INITIATIVE

PHASES
PREGNANCY + HIV/AIDS
SEEKING EQUITABLE STUDY



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