



<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To:

- Pregnant Women Checklist ▾

Continue >>

## Pregnant Women and Fetuses

### (45 CFR Subpart B)

**Complete sections A and B as instructed to determine if the inclusion of pregnant women and fetuses in this study is approvable.**

#### SECTION A

All of the following must be answered "Yes" or "N/A" in order for this study to include pregnant women and fetuses:

- ☐ Yes ☐ No ☐ N/A [Clear](#)
- Where scientifically appropriate, have preclinical studies been conducted and provide data for assessing potential risks to pregnant women and fetuses?  
*Preclinical studies may include:*
- *Studies on pregnant animals*
  - *Clinical studies on non-pregnant women*

*N/A if preclinical studies are not appropriate for this study.*

- ☐ Yes ☐ No [Clear](#)
- Have the risks to pregnant woman and fetus been minimized, while still allowing the objectives of the research to be achieved?

- ☐ Yes ☐ No ☐ N/A [Clear](#)
- Will the individual(s) providing consent be fully informed regarding the reasonably foreseeable impact of the research on the fetus?  
*N/A if the study is minimal risk.*

- ☐ Yes ☐ No [Clear](#)
- Are individuals engaged in the research prohibited from offering inducements, monetary or otherwise, to terminate a pregnancy?

- ☐ Yes ☐ No [Clear](#)
- Are individuals engaged in the research prohibited from taking part in the decisions as to the timing, method, or procedures used to terminate a pregnancy?

- ☐ Yes ☐ No [Clear](#)
- Are individuals engaged in the research prohibited from determining the viability of a fetus?

#### SECTION B

*Please indicate the category (1 or 2) for which this research qualifies and answer the subsequent questions.*

##### Category 1 ☐

The research holds the prospect of direct benefit for the woman or the fetus. Any risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

##### Determination of Consent Process Method:

- ☐ The research holds the prospect of direct benefit to the **pregnant woman and fetus**. Consent will be obtained from the pregnant woman.
- ☐ The research holds the prospect of direct benefit to the **pregnant woman only**. Consent will be obtained from the pregnant woman.
- The research holds the prospect of direct benefit to the **fetus only**. Consent will be obtained from the pregnant woman and the father of the fetus.
- ☐ *The father's consent does not need to be obtained if he is unable to consent because of unavailability, incompetence, temporary incapacity, or if the pregnancy resulted from rape or incest.*
- [Clear](#)

##### Category 2 ☐

- The research holds NO prospect of direct benefit to the woman or the fetus, and
- The risk to the fetus is not greater than minimal, and
- The purpose of the research is to develop important biomedical knowledge which cannot be obtained by other means

##### Consent Process:

For research approved under category #2, consent from the pregnant woman only is required.

**Specific Concerns:** If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

**Resolutions to Concerns:** Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

**Reminder:** *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

**Determination:** Is the proposed involvement of pregnant women and fetuses approvable?

☐ Yes.

☐ Yes, if the above stipulation is met.

☐ No.

Clear

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To:

- Pregnant Women Checklist ▾

Continue >>