PREGNANT WOMEN/NEONATES/FETUSES

0 unresolved comment(s)

For studies involving pregnant women, human fetuses and/or neonates, check the option that best fits your research, then address the questions and requests for information.

☐ **Section 1: Research Involving Pregnant Women or Fetuses**

Research Involving Pregnant Women or Fetuses

A. Explain why the proposed research is scientifically appropriate, including descriptions of any pre-clinical studies on pregnant animals and any clinical studies on non-pregnant women that have been conducted and have provided data for assessing potential risks to pregnant women and fetuses.

B. Select the option that best describes the anticipated risk to the fetus:

○ Not greater than minimal; or
○ Greater than minimal risk and the 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.

C. Provide a rationale for anticipated risk:

D. Explain why any risk is the least possible for achieving the objectives of the research:

E. Select the options that apply:

○ Yes ○ No 1) This research holds out the prospect of direct benefit to the pregnant woman.

○ Yes ○ No 2) This research holds out the prospect of a direct benefit both to the pregnant woman and the fetus; or

○ Yes ○ No 3) This research does not hold out the prospect of direct benefit for the woman or the fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

If "Yes" to any of these three questions, informed consent must be obtained from the pregnant woman or her legally authorized representative, but consent from the father is not required. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus.

○ Yes ○ No 4) This research holds out the prospect of a direct benefit solely to the fetus.

If "Yes", informed consent must be obtained from the pregnant woman AND the father. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus. NOTE: The father's informed 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.

○ Yes ○ No 5) This research will involve individuals under the age of 18 who are pregnant and are not considered emancipated minors.

If "Yes", assent from the pregnant child and permission from her parent or legal guardian must be obtained.

○ Yes ○ No 6) Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?

○ Yes ○ No 7) Will individuals performing research procedures have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?

○ Yes ○ No 8) Will individuals performing research procedures have any part in determining the viability of a fetus?

☐ **Section 2. Research Involving Neonates**

Research Involving Neonates

A. Viable Neonates - A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirement of 45 CFR 46 Subpart A and Subpart D.

○ Yes ○ No Does your research involve viable neonates?

If yes, you will need to complete the Children subsection before submitting this application (if the Children subsection is not visible, go to the "Subject Demographics" section, checkmark "Children", and save).

B. Neonates of Uncertain Viability AND Nonviable Neonates - Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by 45 CFR 46 Subpart B unless the IRB determines that certain conditions are met. Your responses to the following will help the IRB determine whether the conditions are met.

Explain why the proposed research is scientifically appropriate and provide a description of any pre-clinical and clinical studies that have been conducted which provide data for assessing potential risks to neonates.
If not applicable, please enter "N/A".

○ Yes ○ No Will individuals engaged in the research have any part in determining the viability of a neonate?

C. Neonates of Uncertain Viability - Additional Requirements - Select the option that applies to your research.

☐ Not Applicable

○ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, **AND** any risk is the least possible for achieving that objective.

○ The research has the main purpose of the development of important biomedical knowledge, which cannot be obtained by other means **AND** there will be no added risk to the neonate resulting from the research.

Explain the procedures that will be used to obtain legally effective informed consent of either parent of the neonate.

NOTE: If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative will be obtained. **These procedures must ensure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate. The father's informed 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.**

D. Nonviable Neonates – Additional Requirements - After delivery, a nonviable neonate may not be involved in research covered by 45 CFR 46 Subpart B unless the IRB determines that the following additional conditions are met.

☐ Not Applicable

○ Yes ○ No 1) Will the vital functions of the neonate be artificially maintained?

If "Yes", please explain:

Yes No 2) Does the research include procedures to terminate the heartbeat or respiration of the neonate?

Yes No 3) Will there be any added risk to the neonate resulting from this research?

If "Yes", please explain:

Yes No 4) Is the sole purpose of the research for the development of important biomedical knowledge that cannot be obtained by other means?

If "Yes", please explain:

5) Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate.

Note: *If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.* ***These procedures must ensure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.***

Section 3. Research Involving After Delivery, The Placenta, The Dead Fetus, Or Fetal Material

Research Involving After Delivery, The Placenta, The Dead Fetus, Or Fetal Material

A. This research proposes to use the following: (Check all that apply)

- Placenta
- The Dead Fetus
- Macerated Fetal Material
- Cells Excised from Dead Fetus
- Tissue Excised from Dead Fetus
- Organs Excised from Dead Fetus
- Other

If 'Other' Describe:

NOTE: The use of any of the above must be conducted in accordance with any applicable Federal, State, or local laws, regulations, and institutional policies regarding such activities.

B. Yes No Will any information associated with the material identified above be recorded for research purposes in such a manner that living individuals can be identified, directly or through identifiers linked to those individuals?

If "Yes", provide a rationale for the recording of identifiable information [Note: those individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.]:

Section 4. Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem

Affecting the Health or Welfare of Pregnant Women, Human Fetuses, or Neonates

If the study is Department of Health and Human Services (HHS) funded, or funding by HHS is sought, review by the Secretary of HHS and posting in the Federal Register for public comments and review is required. If this category is applicable, the Office of Research Integrity will prepare and submit a report of IRB review to the appropriate HHS institutional official.

Select all that apply:

- ☐ Neonates
- ☐ Pregnant Women
- ☐ Fetal Material