



Investigator Checklist for Research Involving Pregnant Women and Fetuses

PROTOCOL TITLE: _____

INVESTIGATOR: _____

This checklist is designed to assist the IRB in determining if your research fulfills all the requirements of the federal regulations as outlined in 45 CFR 46 Subpart provides for “Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research..” IRBs must consider risk/benefits to the pregnant women and the fetus when evaluating the research.

Viable neonates fall under the purview of 45 CFR 46 Subpart D, “Additional Protections for Children Involved as Subjects of Research.” The Investigator Checklist for Research Involving Children should therefore be completed for research with viable neonates.

1. STUDY POPULATION

- a. To assist the IRB in their consideration of the proposed research, indicate below the population(s) to be targeted by the research. *Note: if the study involves pregnant women, the IRB may consider fetuses to be participating in the research whether or not they are specifically targeted.*

Pregnant Women Fetuses Neonates
(Complete Checklist for Research Involving Children)

- b. Does this research involve the study, after delivery, of the placenta, dead fetus, or fetal material?

YES* NO**

* If yes, complete the remainder of this section

** If no, proceed to Question 2.

- c. Will researchers obtain information such that living individuals can be identified, either directly or indirectly through identifiers linked to those living individuals? YES* NO

** If living individuals may be identified from the placenta, dead fetus, fetal material, the living individual is considered a research subjects, and all applicable regulations apply. Please ensure that consent is either obtained or waived appropriately.*

2. JUSTIFICATION

Justify the inclusion of the population(s) selected in Question 1 by describing any preclinical studies and/or clinical studies (including any studies on nonpregnant women) that have been conducted which provide data for assessing potential risks and benefits to subjects to be enrolled in this study.

In addition, identify the safeguards in place to protect the rights and welfare of this vulnerable population.

3. RISK/BENEFIT ASSESSMENT

Minimal Risk: The FDA and Office of Human Research Protections (OHRP) define minimal risk as risk where the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations or tests. Example: the risk of drawing blood from a healthy individuals for research purposes is no greater than the risk of doing so as part of a routine physical examination.

a. In your opinion, the research presents:

- Greater than minimal risk with prospect of direct benefit to pregnant women OR both pregnant women and fetus
- Greater than minimal risk with prospect of direct benefit ONLY to fetus (** See notation below)
- Minimal risk with prospect of direct benefit to pregnant women OR pregnant women and fetus
- Minimal risk with prospect of direct benefit ONLY to fetus (** See notation below)
- Minimal risk to fetus without prospect of direct benefit but the research proposes the development of important biomedical knowledge which cannot be obtained by any other means

**** Notation:** *Per federal regulations, the consent of the father must be obtained for research involving the prospect of direct benefit solely to the fetus, except in such cases where he is unable to consent because of unavailability, incompetence, or temporary incapacity or in cases of pregnancy resulting from rape. Written consent forms for research involving direct benefit solely to the fetus will require provision for the consent of both the pregnant women and the father of the fetus.*

If the research does NOT fall under one of the above categories, it will require submission to OHRP prior to any IRB approval. Please consult the Office of Research Compliance and Assurance for further guidance.

4. CONSENT

a. Confirm that the consent form includes signature lines as follows:

- Pregnant Women Only 45 CFR 46.204(d): Research holds out the prospect of direct benefit to the pregnant women, the prospect of a direct benefit both to the pregnant women and the fetus, or no prospect of benefit for the women nor the fetus when risk to the fetus is not greater than minimal risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means
- Both parents 45 CFR 46.204(e): Research holds out the prospect of direct benefit solely to the fetus

b. State how it will be verified that each individual providing consent will be fully informed and kept fully informed regarding the reasonably foreseeable impact of the research on the fetus.

5. CERTIFICATIONS

Select the following boxes to confirm that the statements are true for your research study:

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

If you are unable to select any of the points listed above because your statement is not true, your research is not currently approvable. Please contact the IRB for further guidance.

PI signature

Date

IRB Use Only: (IRB Reviewer to Complete)

_____ I Agree with the Principal Investigator's Assessment.

_____ I Do Not Agree with the Principal Investigator's Assessment. (comment below)

COMMENTS: _____

Reviewer's Signature

Date