Appendix B-
Pregnant Women, Human Fetuses and Neonates Involved in Research

This application form is based on the University of Minnesota IRB's *Appendix B* form.

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*Inclusion of the above referenced populations as subjects requires that the investigator comply with the additional protections provided in 45 CFR 46 Subpart B.* [*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)

Check the Category (1-4) that best fits your proposed research and answer the questions for that category only:

**[ ]  Category 1: Research Involving Pregnant Women or Fetuses (§ 46.204)**

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

2) Place a check beside the box that best describes the anticipated risk to the fetus:

[ ]  not greater than minimal. There are no direct benefits associated with the research and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means; 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.

Provide a rationale for anticipated risk.

1. Confirm that any risk is the least possible for achieving the objectives of the research.
2. Place a check in the appropriate box as it applies to this research:

[ ] No [ ] Yes This research holds out the prospect of a direct benefit to the pregnant woman;

[ ] No [ ] Yes This research holds out the prospect of a direct benefit **both** to the pregnant woman and the fetus; or

[ ] No [ ] Yes This research does not hold out the prospect a 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 the above, informed consent must be obtained from the pregnant woman or her legally authorized representative as required in 45 CFR 46.116 & 117. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus.

[ ] No [ ] Yes 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 as required in 45 CFR 46.116 & 117. 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.**

[ ] No [ ] Yes This research will involve participants who are pregnant and meet the definition of “children” as defined in 45 CFR 46.402.

If ”Yes”, assent from the pregnant child and permission from her parent or legal guardian must be obtained in accordance with the provisions of 45 CFR 46, Subpart D.

1. Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?

[ ] No [ ] Yes

1. Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?

[ ] No [ ] Yes

1. Will individuals engaged in the research have any part in determining the viability of a fetus?

[ ] No [ ] Yes

**[ ]  Category2: Research Involving Neonates (§ 46.205)**

*Place a check in the box beside the category of neonates that best fits your proposed research and answer the questions that immediately follow:*

**[ ]  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 Subpart B unless the following conditions are met:

1. 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:
2. Will individuals engaged in the research have any part in determining the viability of a neonate?

 [ ] No [ ] Yes

 **[ ]  Neonates of Uncertain Viability - Additional Requirements**

1. Place a check in the appropriate box as it applies to this research:

 [ ]  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, or

 [ ]  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.

1. Explain the procedures that will be used to obtain legally effective informed consent of the parents of the neonate or, 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 as required by 45 CFR 46.116 & 117.

These procedures must assure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

**[ ]  Nonviable Neonates – Additional Requirements**

After delivery, a nonviable neonate may not be involved in research covered by Subpart B unless all of the following additional conditions are met:

1. Will the vital functions of the neonate be artificially maintained?

[ ] No [ ] Yes *If “Yes”, please describe*:

1. Does the research include procedures to terminate the heartbeat or respiration of the neonate?

[ ] No [ ] Yes *If “Yes”, please describe*:

1. Will there be any added risk to the neonate resulting from the research?

[ ] No [ ] Yes *If “Yes”, please describe*:

 Is the sole purpose of the research for the development of important biomedical knowledge that cannot be obtained by other means?

[ ] No [ ] Yes *If “Yes”, please describe*:

1. Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate, or 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 except that 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 assure 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.

**[ ]  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 subparts A and D of 45 CFR 46. Please complete the “Vulnerable Population Supplemental Form for Children”

**[ ]  Category 3: Research Involving, After Delivery, The Placenta, The Dead Fetus, or Fetal Material (§ 46.206)**

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

**[ ]** Placenta

[ ]  The Dead Fetus

 [ ]  Macerated Fetal Material

 [ ]  Cells Excised from the Dead Fetus

 [ ]  Tissue Excised from the Dead Fetus

 [ ]  Organs Excised from Dead Fetus

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.

1. 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? [ ] No [ ] Yes

Provide a rationale for the response.

If “Yes”, those individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.

**[ ]  Category 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 (§ 46.207)**

This requires review by the Secretary of the Department of Health and Human Services (DHHS) and posting in the Federal Register for public comments and review.