Principal Investigator:

Study Title:

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

**§ 46.204 Research Involving Pregnant Women or Fetuses**

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 provided data for assessing potential risks to pregnant women and fetuses.

1. Place a check beside the box 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.

Provide a rationale for anticipated risk.

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

1. 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 of a 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

***NOTE: If the answer to 5, 6, or 7 is “Yes”, the research will not be approved.***

**§ 46.205 Research Involving Neonates**

**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.

1. 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 either parent 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.

**NOTE: 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.**

**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

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

No Yes *If “Yes”, please describe:*

1. 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 explain:*

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.

**NOTE: 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.**

**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.”