Tarrant County College District
Institutional Review Board
Vulnerable Populations: Pregnant Women, Human Fetuses or Neonates

Researcher: **IRB#:**

Study Title:

Please read the Department of Health and Human Services' 45 CFR 46, Subpart B for information regarding pregnant women in research studies.

Select the category that best fits your proposed research and answer the questions associated with that category:

Note: If you will study both pregnant women and their child after it is born, you will need to complete this form and the *Vulnerable Populations – Children form*.

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

1) Explain why the proposed research is scientifically appropriate; include descriptions of pre-clinical studies conducted on pregnant animals and any clinical studies conducted on non-pregnant women that provide useful data to assess the potential risks to pregnant women and fetuses.

2) Select which best describes the risk and anticipated benefits *[If the research does not meet one of these two categories, it is not approvable.]*:

☐ (a) The risk to the fetus is *not greater than minimal* and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

Justify why the risk to the fetus is not greater than minimal:

Justify why purpose of the research is the development of important biomedical knowledge, which cannot be obtained by any other means:

☐ (b) The risk to the fetus is *greater than minimal* 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 (requires full Committee review).

Explain why 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:

3) Explain why the risks involved are the least possible to the pregnant woman and fetus for achieving the objectives of the research.

4) **Select the appropriate choice that applies to this research:**

☐ a) This research holds out the prospect of a direct benefit to the pregnant woman only. *The pregnant woman's consent is required.*

☐ b) This research holds out the prospect of a direct benefit **both** to the pregnant woman and the fetus. *The pregnant woman's consent is required.*

☐ c) This research involves no prospect of benefit to the woman or the fetus, but the risk to the fetus is minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means. *The pregnant woman's consent is required.*

☐ d) This research holds out the prospect of a direct benefit solely to the fetus. *The pregnant woman and the father's consent are required. The fathers' consent need not be obtained if he is unable to consent because of unavailability, incompetence, temporary incapacity or if the pregnancy resulted from rape or incest.*

5) Explain how each individual providing consent under (#4 above) will be fully informed regarding the reasonably foreseeable impact of the research on the fetus:

6) Will the research involve subjects who are pregnant and meet the definition of "children" (Under Texas law, a minor is a person under the age of 18.)
☐ No
☐ 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.*

7) Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?
☐ No ☐ Yes *[If yes, research with this population is not approvable]*

8) 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 *[If yes, research with this population is not approvable]*

9) Will individuals engaged in the research have any part in determining the viability of a fetus?

☐ No ☐ Yes *[If yes, research with this population is not approvable]*

☐ **§ 46.205(a)&(b) Research Involving Neonates of Uncertain Viability**

Neonate: The definition of a neonate is a newborn child less than one month old.

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 *[If yes, research with this population is not approvable]*

3) Select the appropriate choice as it applies to this research: *[If the research does not meet one of these two categories, it is not approvable.]*
☐ *(a) 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*

if (a) is selected above, justify that the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability:

if (a) is selected above, justify that any risk is the least possible for achieving that objective:

☐ *(b) 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.*

if (b) is selected above, justify that the research has the main purpose of the development of important biomedical knowledge, which cannot be obtained by other means:

if (b) is selected above, justify that there will be no added risk to the neonate resulting from the research:

4) 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 may be obtained. 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.

5) Explain how each individual providing consent under (#4 above) is fully informed regarding the reasonably foreseeable impact of the research on the neonate:

☐ **§ 46.205(c) Research Involving Nonviable Neonates**

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 - *[If yes, research with this population is not approvable.]*

3) Will the vital functions of the neonate be artificially maintained?

☐ No
☐ Yes - *[If yes, research with this population is not approvable.]*

4) Does the research include procedures to terminate the heartbeat or respiration of the neonate?

☐ No
☐ Yes - *[If yes, research with this population is not approvable.]*

5) Will there be any added risk to the neonate resulting from this research?

☐ No
☐ Yes - *[If yes, research with this population is not approvable.]*

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

☐ No
☐ Yes – please explain

7) Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate. 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.
NOTE: The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice for this type of research.

8) Explain how each individual providing consent under (#7 above) is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

☐ **§ 46.205(d) Research Involving 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 federal and state regulations. Please complete the *Vulnerable Population – Children* form.