Addendum Checklist: Pregnant Women/Fetus Research (Subpart B)

☐ Full Board Review ☐ Initial Review

☐ Expedited Review ☐ Continuing Review

Reviewer: Principal Investigator :

Protocol #: Submission ID:

1. If pregnant women/fetuses are included, the following must be true:

☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

AND

☐ Individuals engaged in the research will have no part in any decision as to the timing, method, or procedures used to terminate a pregnancy;

AND

☐ Individuals engaged in the research will have no part in determining the viability of the neonate;

AND

☐ Any risk **to the fetus** from the research is the least possible for achieving the objectives of the research

Discuss Concerns:

2. For the procedures to be performed on pregnant women, are preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, necessary to provide data for assessing potential risks to pregnant women and fetuses? Yes ☐ No ☐

a. If yes, have these studies been performed and are potential risks to fetuses clear? Yes ☐ No ☐

Discuss:

3. Does the proposal involve research on fetal or embryonic tissue? Yes ☐ No ☐

If yes, please make sure attachment U has been completed by the study team.

a. Will samples be received from an external entity? Yes ☐ No ☐

If yes, please make sure the human fetal tissue attestation has been submitted and a draft MTA has been submitted.

3. Risk Assessment: Either [a] or ([b] + [c]) must be met:

☐ **a.** There is potential benefit to the pregnant woman or fetus, 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;

OR

☐ **b.** There is no potential benefit to the pregnant woman or fetus, but the risk **to the fetus** is not greater than minimal; **AND**

☐ **c.** The purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

Addendum Checklist: Pregnant Women/Fetus Research (Subpart B)

Discuss determination:

Special Review Considerations (Expedited Review Only)

☐ Consent is waived in this study according to the criteria in 45 CFR 46.116
☐ This research does not involve the VA
☐ This research does not involve the placenta or dead fetal tissues

If the above determinations can be made, sign here and this checklist is complete; otherwise continue.

_____ _____
Chair signature Date

4. Consent:

a. Are the individuals providing consent fully informed regarding the reasonably foreseeable impact of the research on the fetus? Yes ☐ No ☐

If no, suggest changes:

b. For children who are pregnant, are assent and parental permission obtained in accordance with the regulations? Yes ☐ No ☐

Discuss determination:

c. The consent of only the mother can be obtained if:

☐ The research holds out the prospect of direct benefit to the pregnant woman
OR
☐ The prospect of direct benefit both to the pregnant woman and the fetus
OR
☐ No prospect of direct benefit for the woman or the fetus, when 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.

d. If the research holds out the prospect of direct benefit solely to the fetus:

☐ The consent of the pregnant woman and the consent of the father will be obtained in accordance with the regulations, except that the father's consent is not needed if he will be unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

5. Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material (Subpart B)

There is no applicable State or local laws in Colorado. If the study is being conducted outside of Colorado, University Legal Counsel will need to be contacted. Federal research must comply with US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

Addendum Checklist: Pregnant Women/Fetus Research (Subpart B)

The IRB must determine that an appropriate description has been provided as to how tissue/samples will be obtained. Yes ☐ No ☐

AND

If any information associated with the above material will be recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers then the IRB must determine that:

There is a plan to obtain appropriate consent	Yes ☐ No ☐
The individual's privacy has been appropriately protected	Yes ☐ No ☐
The individual's confidentiality has been appropriately protected	Yes ☐ No ☐

Describe the plan to ensure the above points:

6. VA Research:

a. Will this study be conducted by VA investigators while on official duty? Yes ☐ No ☐

b. Will this study be conducted at VA facilities? Yes ☐ No ☐

If yes to either question, address the following:

i. Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue), must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities. ☐ True

ii. Research related to in vitro fertilization must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities. ☐ True

<u>Additional VHA Regulations</u>: For research involving the participation of pregnant women as research subjects at the VHA, checklist points #1-#4 above must all be satisfied and all of the following must be adequately addressed:

c. Are there adequate provisions to monitor the risks to the subject and fetus? Yes ☐ No ☐

Discuss:

d. Has adequate consideration been given to the manner in which potential subjects are selected? Yes ☐ No ☐

Discuss:

e. Is adequate provision made to monitor the actual informed consent process by:

(i) Overseeing the actual process by which individual consents are obtained as required by VHA handbook 1200.5 Appendix D: by approving enrollment of each individual, or by verifying, perhaps through sampling, that approved procedures for enrollment of individuals into the activity are being followed. Yes ☐ No ☐

Discuss:

AND

(ii) Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen. Yes ☐ No ☐

Discuss:

f. Confirm that the risk to the fetus is minimal OR the research is intended to meet the health needs of the mother or fetus: Yes ☐ No ☐

Discuss:

g. Confirm that the risk to the fetus is the least possible risk for achieving the research objectives: Yes ☐ No ☐

Discuss:

h. Confirm that consent is obtained from the mother and father, *except that the father's consent need not be obtained if the purpose of the research activity is to meet the health needs of the mother, the father's identity or whereabouts cannot be readily ascertained, he is not reasonably available, or the pregnancy resulted from rape*: Yes ☐ No ☐

Discuss:

7. DoD Research:

- For purposes of applying Subpart B, the phrase "biomedical knowledge" shall be replaced with "generalizable knowledge."
- The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus or involves fetuses or neonates as participants.
- If applicable, please note: when reviewing research involving fetuses, the IRB must apply the same risk standard to fetuses that are intended to be aborted and fetuses that are intended to be carried to term.

a. Does the study involve research on a nonviable living human fetus ex utero, or a living human fetus ex utero, for whom viability has not been ascertained? Yes ☐ No ☐
    a. If YES, confirm that one of the following criteria are met:
        i. The research presents the prospect of meeting the health needs of the fetus, or of enhancing its well-being and/or probability of survival to viability.

        Yes ☐ No ☐

        OR

        ii. The research poses no added risk of suffering, injury, or death to the fetus, and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.

        Yes ☐ No ☐

Addendum Checklist: Pregnant Women/Fetus Research (Subpart B)

b. If neither of the above criteria are met, does the research present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates? Yes ☐ No ☐
    a. If YES, written approval from the Directorate of Human Research Protections (DOHRP) must be obtained through the Component Office of Human Research Protections (COHRP) prior to research starting.
        i. Instruct Coordinator to advise study team of this requirement in approval letter.

_ _____ _ _____

Reviewer Signature **Date**