FORM: APPLICATIONS FOR RESEARCH INVOLVING PREGNANT WOMEN, HUMAN FETUSES, and/or NEONATES (II.4.C)

Adapted from forms used by Vanderbilt University and the University of Kentucky

NOTE: Investigators, please include this form with IRB application. Check the box that best fits your research and address the issues that immediately follow as they apply to your research. If your research involves women with more than one vulnerability (e.g., pregnant women who are children under Alabama law or pregnant women who are cognitively impaired), attach the supplementary application form for that population as well.

Definition of Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.

☐ Section 1. Research Involving Pregnant Women or Fetuses [45 CFR 46.204]

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

B. Check the box next to the item that best describes the anticipated risk to the fetus:

☐ 1. Not greater than minimal

☐ 2. 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.

C. Provide a rationale for the anticipated risk:

D. Explain why any risk is the least possible for achieving the objectives of the research:
E. Check the appropriate box as it applies to this research:

1. □ No □ Yes This research holds out the prospect of a direct benefit to the pregnant woman.

2. □ No □ Yes This research holds out the prospect of direct benefit both to the pregnant woman and the fetus.

3. □ 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 in “E”, informed consent must be obtained from the pregnant women or her legally authorized representative (LAR) as required in 45 CFR 46.116 & 117, but consent from the father is not required. The informed consent process should include a clear explanation of the reasonably foreseeable impact of the research on the fetus.

4. □ 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 nonavailability, incompetence or temporary incapacity or if the pregnancy resulted from rape or incest.

5. □ No □ Yes This research will involve individuals under the age of 18 who are pregnant and are not considered emancipated minors.

   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.

6. □ No □ Yes Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?

7. □ No □ Yes Will individuals performing research procedures have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?

8. □ No □ Yes Will individuals performing research procedures have any part in determining the viability of a fetus?

   “Yes” answers to 6-8 mean that the research cannot be approved.

Section 2. Research Involving Neonates [§ 46.205]
A. ☐ 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 45 CFR 46 Subpart B unless the IRB determines that 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. ☐ No ☐ Yes Will individuals engaged in the research have any part in determining the viability of a neonate?

   A “Yes” answer means that the research cannot be approved. Individuals engaged in the research may have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

3. ☐ No ☐ Yes Is any inducement, monetary or otherwise, offered to terminate a pregnancy?

   A “Yes” answer means that the research cannot be approved. No inducements, monetary or otherwise, may be offered to terminate a pregnancy.

B. ☐ Neonates of Uncertain Viability—Additional Requirements. Check if applicable.

1. ☐ 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

2. ☐ 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.

3. ☐ 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 LAR 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. The father’s informed consent need not be obtained if he is unable to consent because of nonavailability, incompetence or temporary incapacity or if the pregnancy resulted from rape or incest.

C. ☐ Nonviable Neonates—Additional Requirements. After delivery a nonviable neonate may not be involved in research covered by 45 CFR 46 Subpart B
unless the IRB determines that the following additional conditions are met. Please check if applicable to your research.

1. ☐ No  ☐ Yes  Will the vital functions of the neonate be artificially maintained?

2. ☐ No  ☐ Yes  Does the research include procedures to terminate the heartbeat or respiration of the neonate?

3. ☐ No  ☐ Yes  Will there be any added risk to the neonate from this research?

   “Yes” answers to 1-3 mean that the research cannot be approved.

4. ☐ No  ☐ Yes  Is the sole purpose of the research for the development of important biomedical knowledge that cannot be obtained by other means?

   If “Yes”, please explain:

   ____________________________________________

5. Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate.

   Note: 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. 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.

   ____________________________________________

D. 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 45 CFR 46 Subparts A and D. The neonate is now a child. Please follow policies and consenting process for research with children and attach FORM: APPLICATION FOR RESEARCH WITH CHILDREN.

Section 3. Research Involving After Delivery, The Placenta, The Dead Fetus, or Fetal Material [§ 46.206]

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

☐ Placenta  ☐ The dead fetus  ☐ Macerated fetal material

☐ Cells excised from dead fetus  ☐ Tissue excised from dead fetus
☐ Organs excised from dead fetus  ☐ Other: Describe:

*Note: 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.*

**B.**  ☐ No  ☐ Yes  Will any information associated with the above material be recorded for research purposes in such a manner that living individuals can be identified directly or through identifiers linked to those individuals?

If “Yes”, provide a rationale for the recording of identifiable information.

*Note: These individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.*

☐ **Section 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, § 46.208, §46.209, § 46.210]**

**A.**  If the study is Department of Health and Human Services (HHS) funded, or if funding by HHS is sought, review by the Secretary of HHS and posting in the Federal Register for public comments and review is required. If this category is applicable, the Research Compliance Office will prepare and submit a report of IRB review to the appropriate HHS institutional official.