**Subject: Procedure for Special Categories of Research: Pregnant Women, Human Fetuses, Neonates, and Transplantation of Fetal Tissue**

**Procedure:**
The purpose of this procedure is to provide guidance on the requirements for review and approval for pregnant women, human fetuses, neonates, and transplantation of fetal tissue activities in human subjects research under the Human Research Protections Program (HRPP) jurisdiction.

**I. Investigator Responsibilities.**
A. The Investigator will submit supplemental information for this population(s) with a new study submission in which the target population for research includes pregnant women, fetuses, neonates, or research on transplantation of fetal tissue.
B. Once the full IRB Committee approves the study, the Investigator will obtain informed consent from the mother and father as outlined in HRPP Policy IX.C.
C. It is the Investigator’s responsibility to provide the extra declarations in the consent document as outlined in the HRPP Policy IX.C when conducting research on transplanted fetal tissue.

**II. IRB Committee Responsibilities.**
A. The IRB Committee must review the proposed research taking into consideration all applicable HRPP polices and the requirements for involvement of pregnant women, fetuses, neonates, and fetal tissue transplantation activities in research.
B. The IRB Committee will review and approve research in accordance with the federal regulations at 45 CFR 46 Subpart A.
C. The IRB will discuss the additional protections necessary for this population. The Primary Reviewer will be responsible for documenting these added protections with the completion of the “Supplemental Reviewer’s Comments for Pregnant Women, Human Fetuses, & Neonates.”
D. When the research involves fetal tissue for transplantation, the IRB must obtain and review the required written and signed statements by the research participant, the Investigator and the attending physician obtaining the tissue from the woman involved as described in HRPP Policy IX.C.

**III. Regulatory Compliance Analyst (RCA) Responsibilities.**
A. The RCA will verify that the supplemental information is completed as part of the initial study documents.
B. The RCA will conduct a pre-review and will take into consideration the additional requirements under Subpart B for research activities involving pregnant women, fetuses, neonates, or research involving transplantation of fetal tissue.
C. Notification requesting pre-review changes to the informed consent documents are to be sent to the Investigator by the RCA.
D. Once the pre-review revisions are received from the Investigator, the RCA will place the new study on the next available Committee agenda assign Reviewers with the appropriate expertise and assure appropriate materials are available. Reviewers are electronically notified once assigned.

References:
HRPP Policy IX.C, “Special Categories of Research: Pregnant Women, Human Fetuses, Neonates and Transplantation of Fetal Tissue”