1. PURPOSE

This procedure describes the requirements concerning review of research that involves pregnant women, unborn babies, and neonates. This group could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

2. PROCEDURE

Research involving pregnant women should receive special attention from the IRB because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the unborn baby. Special attention is justified because of the involvement of the unborn baby that may be affected but cannot give consent. The IRB will follow Subpart B of the DHHS regulation. For children who are pregnant, assent and permissions are obtained in accordance with the regulations.

3. DEFINITIONS

An unborn baby determined to be dead by prevailing medical standards: an unborn baby that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Unborn baby: the product of conception from implantation until delivery.

Neonate: newborn (birth to four (4) weeks).

Nonviable neonate: a neonate after delivery that, although living, is not viable as determined by prevailing medical standards.

Pregnancy: the period of time from implantation until delivery. A woman shall be assumed pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Viable, as it pertains to a neonate: being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

3.1 Pregnant Women and Unborn Baby

Pregnant women or unborn baby prior to delivery may be involved in research. The IRB members will use an applicable checklist to confirm that all the conditions and determinations are met.

3.2 Neonates

Neonates may be involved in research. The IRB members will use an applicable checklist to confirm all the conditions and determinations are met.

4. RESPONSIBILITY

IRB Staff are responsible for maintaining up-to-date review tools for the review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

Chair and IRB staff are responsible for ensuring that the IRB members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations.

IRB staff are responsible for selecting Primary Reviewers with appropriate expertise to conduct reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

Primary and Secondary Reviewers are responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of the potential for coercion, in consultation with any appropriate experts and resources.

IRB members are responsible for thorough review of the research and determining if the research meets all the applicable criteria.

5. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
45 CFR 46: Subpart B
21 CFR 56.111

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	8/6/2020	Avera Institutional Official	9/22/2020
• Removed the names of specific checklists. • Minor administrative updates.			
1.0	August 2016	Director HSRP / August 2016	