Policy Statement: If investigators plan to include pregnant women, human fetuses, and neonates in their research, 45 CFR Part 46, Subpart B provides special protections. Under these regulations, IRBs are required to document specific findings to minimize the potential for risk or harm to this population, and additional attention must be given to the conditions for obtaining informed consent. In general the research should be assessed and provide protections for the least possible risk as it applies to status and viability.

Procedure:

I. Pregnant Women, Human Fetuses, and Neonates.
   The IRB must determine which of the following categories the research should be evaluated under. In some cases, the IRB may determine that pregnant women, human fetuses, and neonates will not be included in the research population. Documentation in the meeting minutes and approvals will state the approval criterion and special conditions to minimize potential risk or harm.

A. Research involving pregnant women or fetuses prior to delivery.
   Pregnant women or fetuses may be involved in research if all of the following conditions, outlined in Subpart B of 45 CFR 46, are met:

   1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
   2. 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, if there is no such prospect of benefit, 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;
   3. Any risk is the least possible for achieving the objectives of the research;
   4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the woman and her fetus, or no prospect of benefit for the woman nor 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 that cannot be obtained by any other means, the consent of the pregnant woman is obtained in accord with informed consent policies;
5. If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with informed consent policies, except that the father's 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;

6. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

7. For children who are pregnant, assent and permission are obtained in accord with the provisions of federal and state regulations as well as the SARMC policy on children in research;

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

9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

10. Individuals engaged in the research will have no part in determining the viability of a neonate.

**B. Research involving neonates after delivery.** After delivery, neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate;

3. Individuals engaged in the research will have no part in determining the viability of a neonate;

4. The requirements of sections I.C, I.D. or I.E. below have been met as applicable.

**C. Neonates of uncertain viability.** After delivery, and until it has been established whether or not a neonate is viable, a neonate may not be involved in research unless the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;

2. The research will not terminate the heartbeat or respiration of the neonate;

3. There will be no added risk to the neonate resulting from the research;

4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

5. The legally effective informed consent of both parents of the neonate is obtained, except that the provisions for waiver and
alteration of informed consent are not applicable. However, 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 to meet the requirements for consent, except that 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 to meet these requirements.

D. Nonviable neonates. After delivery, a neonate may not be involved in research until it has been ascertained whether or not a neonate is viable, and if nonviable, the following additional conditions must be met:

1. The IRB determines that:
   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, OR
   b. The purpose of the research is 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; and,
2. The legally effective informed consent of either parent of the neonate or, 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 is obtained, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
3. Vital functions of the fetus will not be artificially maintained;
4. The research will not terminate the heartbeat or the respiration of the fetus.

E. Viable neonates. A fetus, after delivery, that has been determined to be viable is a child as defined by DHHS 45 CFR Part §46.402(a) and may be included in research only to the extent permitted by and in accord with the requirements of DHHS 45 CFR Part 46 Subparts A and D.

F. Research involving, after delivery, the placenta, the dead fetus, or fetal material.

1. Research involving, after delivery, the placenta, the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
2. If information associated with material described above is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research
3. Research shall not knowingly be performed on tissue that is obtained from a miscarried fetus unless the consent of the mother has first been obtained. Consent is conclusively presumed to have been granted by a written statement, signed by the mother that she consents to the use of her dead embryo, fetus, or neonate for research.
4. Research on tissue obtained from an electively aborted fetus is prohibited at SARMC.

II. **Fetal Tissue Transplantation Research.** Public Law 103–43 governs human fetal transplantation research that is supported by DHHS. **This category of research is prohibited at SARMC.**

III. **DHHS 45 CFR 46.202 Definitions**

A. **Dead fetus** means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
B. **Delivery** means complete separation of the fetus from the woman by expulsion or extraction or any other means.
C. **Fetus** means the product of conception from implantation until delivery.
D. **Neonate** means a newborn.
E. **Nonviable neonate** means a neonate after delivery that, although living, is not viable.
F. **Pregnancy** encompasses the period of time from implantation until delivery. A woman shall be assumed to be 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.
G. **Viable,** as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

**Related Policies:** Vulnerable Populations; Vulnerable Populations: Children.

**Related Forms:** Informed Consent/HIPAA Authorization Template.


**References:**

Code of Federal Regulations. (Last revised January 15, 2010). Title 45A – Department of Health and Human Services; Part 46 – Protection of Human Subjects; Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research