Vulnerable Populations: Pregnant Women, Fetuses, and Neonates - Subpart B (Policy HRPP 8.4)

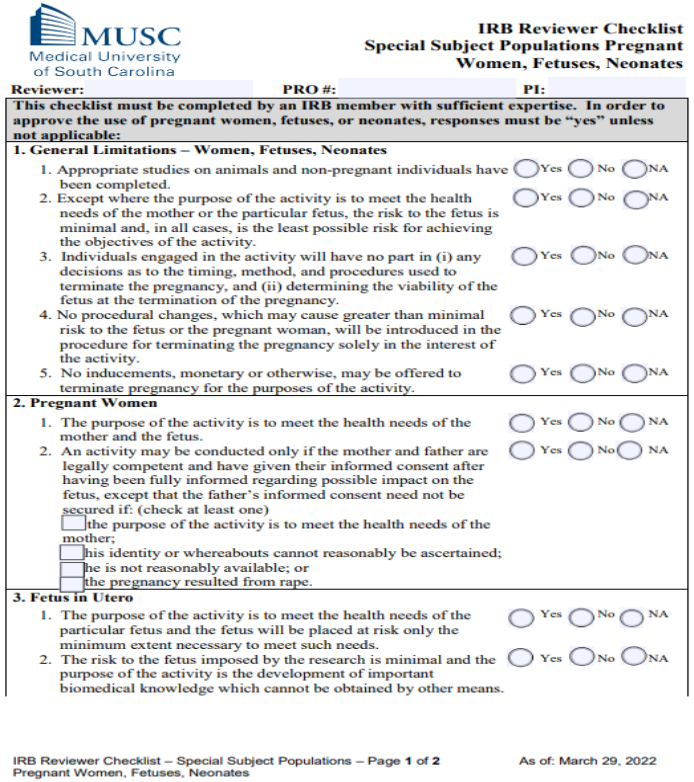
MARCH 2025 CONTINUING EDUCATION

Guidance on Additional Requirements of Federal Funding Agencies

- Additional operational and review requirements are needed for all protocols conducted by MUSC and sponsored by:
  - Department of Defense (DOD)
  - Department of Education
  - Department of Energy
  - Department of Justice (DOJ)/ National Institute of Justice (NIJ) and Bureau of Prisons (BOP)
  - Environmental Protection Agency (EPA)
- Information is available on MUSC IRB Resource & Guidance Webpage: https://research.musc.edu/resources/ori/irb/resources

Special Subject Population – Pregnant Women, Fetuses, Neonates Checklist

- Used as a guide for IRB evaluation and will be completed by the designated reviewers



MUSC
Medical University of South Carolina

IRB Reviewer Checklist
Special Subject Populations Pregnant Women, Fetuses, Neonates

Reviewer: **PRO #:** **PI:**

This checklist must be completed by an IRB member with sufficient expertise. In order to approve the use of pregnant women, fetuses, or neonates, responses must be "yes" unless not applicable:

1. General Limitations – Women, Fetuses, Neonates

1. Appropriate studies on animals and non-pregnant individuals have been completed. ◯Yes ◯No ◯NA
2. Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity. ◯Yes ◯No ◯NA
3. Individuals engaged in the activity will have no part in (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy. ◯Yes ◯No ◯NA
4. No procedural changes, which may cause greater than minimal risk to the fetus or the pregnant woman, will be introduced in the procedure for terminating the pregnancy solely in the interest of the activity. ◯Yes ◯No ◯NA
5. No inducements, monetary or otherwise, may be offered to terminate pregnancy for the purposes of the activity. ◯Yes ◯No ◯NA

2. Pregnant Women

1. The purpose of the activity is to meet the health needs of the mother and the fetus. ◯Yes ◯No ◯NA
2. An activity may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (check at least one) ◯Yes ◯No ◯NA
   - ☐ the purpose of the activity is to meet the health needs of the mother;
   - ☐ his identity or whereabouts cannot reasonably be ascertained;
   - ☐ he is not reasonably available; or
   - ☐ the pregnancy resulted from rape.

3. Fetus in Utero

1. The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only the minimum extent necessary to meet such needs. ◯Yes ◯No ◯NA
2. The risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. ◯Yes ◯No ◯NA
3. An activity may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (check at least one) ◯Yes ◯No ◯NA
   - ☐ the purpose of the activity is to meet the health needs of the mother;
   - ☐ his identity or whereabouts cannot reasonably be ascertained;
   - ☐ he is not reasonably available; or
   - ☐ the pregnancy resulted from rape.

4. Fetus ex Utero

1. The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only the minimum extent necessary to meet such needs. ◯Yes ◯No ◯NA
2. The risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. ◯Yes ◯No ◯NA
3. An activity may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (check at least one) ◯Yes ◯No ◯NA
   - ☐ the purpose of the activity is to meet the health needs of the mother;
   - ☐ his identity or whereabouts cannot reasonably be ascertained;
   - ☐ he is not reasonably available; or
   - ☐ the pregnancy resulted from rape.

5. Fetus ex Utero – uncertain viability / non-viable

1. Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity unless:
   1. There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. ◯Yes ◯No ◯NA
   2. The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability. ◯Yes ◯No ◯NA
2. No non-viable fetus will be involved as a subject in an activity unless vital functions of the fetus will not be artificially maintained, experimental activity which of themselves would terminate the heartbeat or respiration of the fetus will not be employed and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. ◯Yes ◯No ◯NA
3. An activity may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (check at least one) ◯Yes ◯No ◯NA
   - the purpose of the activity is to meet the health needs of the mother;
   - his identity or whereabouts cannot reasonably be ascertained;
   - he is not reasonably available; or
   - the pregnancy resulted from rape.
4. For non-viable neonates, consent waiver and alteration provisions are not applied. ◯Yes ◯No ◯NA

When Pregnancy is Coincidental to Subject Selection:

- Women of childbearing potential will be included in all study populations unless the investigator provides rationale for exclusion
  - If exclusion is justified, the protocol and informed consent document should include the reason for the exclusion
- Pregnancy test for eligibility screening
  - Required if the research study poses known risks and/or there is a lack of knowledge regarding the risks to a pregnant women and/or fetus
  - Will be performed throughout the woman's participation (if applicable)
- Information to include in the Informed Consent (when applicable):
  - The need for pregnancy testing before and during the study;
  - The recommended contraceptive methods based on the known risks;
  - The need to notify the Principal Investigator immediately if pregnancy occurs; and
  - The possibility of unforeseen risks to the subject and/or fetus

Studies Directed Primarily Toward the Mother's and/or Fetus's Health:

- If the research directly benefits the mother OR the mother + fetus
  - A greater than minimal risk to the fetus determination is acceptable if:
    - Where appropriate, data are available from prior animal studies and nonpregnant women clinical studies to assess potential risks to pregnant women and fetuses;
    - Risk to the fetus is caused solely by interventions or procedures that hold the prospect of direct benefit for the woman or the woman + fetus; and
    - 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

- Informed Consent Requirements:
  - Pregnant woman's consent is sufficient to enroll in the study
  - Fully describe the reasonably foreseeable impact of the research on the fetus or neonate

Studies Directed Primarily Toward the Mother's and/or Fetus's Health:

- If the research directly benefits the fetus
  - A greater than minimal risk to the fetus is acceptable if:
    - Where appropriate, data are available from prior animal studies and nonpregnant women clinical studies to assess potential risks to pregnant women and fetuses;
      - Risk to the fetus is caused solely by interventions or procedures that hold the prospect of direct benefit for the fetus; and
    - Any risk is the least possible for achieving the research objectives

- Informed Consent Requirements:
  - Informed consent needed from both mother and father
    - Exception – father is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest
      - The reason for not obtaining the father's informed consent must be documented in the research record
  - Fully describe the reasonably foreseeable impact of the research on the fetus or neonate

Studies Directed Primarily Toward the Mother's and/or Fetus's Health:

- If the research does not directly benefit the woman or fetus
  - The research is acceptable if the risk to the fetus is not greater than minimal and:
    - Where appropriate, data are available from prior animal studies and nonpregnant women clinical studies to assess potential risks to pregnant women and fetuses;
    - Study intends to develop important biomedical knowledge that cannot be obtained by any other means; and
    - Any risk is the least possible for achieving the research objectives

- Informed Consent Requirements:
  - The pregnant woman's consent is sufficient to enroll in the study
  - Fully describe the reasonably foreseeable impact of the research on the fetus or neonate

- Research involving pregnant women and fetuses can only be conducted if:
  - No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
  - 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
  - Individuals engaged in the research will have no part in determining the viability of a neonate

- Assent and permission will be obtained in accordance with the regulations for children who are pregnant

Research involving Viable or Non-viable Neonates

- Viable neonate
  - Neonate that has been determined to be viable after delivery may be included in research only to the extent permitted in accordance with the requirements of the applicable subpart

- Nonviable neonate
  - Neonate after delivery that although living is not viable may be involved in research if:
    - Where appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
    - Individuals engaged in the research will have no part in determining the viability of the neonate;
    - Vital functions of the neonate will not be artificially maintained;
    - Research will not terminate the heartbeat or respirations of the neonate;
    - There will be no added risk to the neonate resulting from the research; and
    - Purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means

  - Informed Consent Requirements:
    - Must fully describe the reasonably foreseeable impact of the research on the neonate
    - Informed consent of both parents is required
    - Consent of a legal representative of either parent is not acceptable
    - The reason for not obtaining both parents' informed consent must be documented in the research record
      - Exceptions:
        - One parent is unable to consent because of unavailability, incompetence, or temporary incapacity
        - Consent of the father is not required if the pregnancy resulted from rape or incest

Research Involving Neonates of Uncertain Viability

- Neonates of uncertain viability may be involved in research if:
  - Where appropriate, preclinical studies have been conducted and provide data for assessing potential risks to neonates;
  - Individuals engaged in the research will have no part in determining the viability of the neonate;
  - 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; and
  - The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means and there will be no added risk to the neonate resulting from the research
- Informed Consent Requirements:
  - Informed consent of one parent is acceptable if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity
  - Consent of a legal representative of either parent is not acceptable
  - Consent of the father is not required if the pregnancy resulted from rape or incest
  - Reason for not obtaining both parents' informed consent must be documented in the research record
  - Informed consent document will fully describe the reasonably foreseeable impact of the research on the neonate

Research involving Pregnant Women as Participants is not approved unless **ALL** the following conditions are met:

- Appropriate studies on animals and non-pregnant individuals have been completed
  - Data assessing risks to pregnant women and fetuses must be provided
- The purpose of the activity is to meet the health needs of the mother or the fetus
- The risk to the fetus is minimal
- The risk to the fetus is the least possible risk for achieving the objectives of the activity
- Individuals engaged in the activity have no part in:
  - Any decisions as to the timing, method, and procedures used to terminate the pregnancy
  - Determining the viability of the fetus at the termination of the pregnancy
  - Introducing any procedural changes, for research purposes, into the procedures for terminating the pregnancy
- No inducements, monetary or otherwise, are offered to terminate pregnancy for purposes of research
- One of the following is true:
  - The fetus is placed at risk only to the minimum extent necessary to meet the heath care needs of the mother
  - The risk to the fetus is minimal
- Consent is obtained from the mother and father, except that the father's consent need not be secured if:
  - The purpose of the activity is to meet the health needs of the mother
  - His identity or whereabouts cannot reasonably be ascertained
  - He is not reasonably available
  - The pregnancy resulted from rape

What questions do you have?