MCW IRB Committee Procedures

RESEARCH INVOLVING PREGNANT WOMEN AND FETUSES

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

PURPOSE:
To outline criteria IRB Committee Members should apply when reviewing studies that seek to enroll or that may enroll pregnant women. Pregnant women are populations that require additional safeguards.

The IRB will include one or more individuals who are knowledgeable about or experienced in working with pregnant women when reviewing research that involves individuals from this populations.

For Department of Defense supported research only, the applicability of Subpart B and requirements described in this procedure is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

For projects following EPA regulations, research involving intentional exposure of pregnant women or children to any substance is prohibited and will not be approved by the IRB.

DEFINITIONS:
Pregnancy: 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.

Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means

Fetus: the product of conception from implantation until delivery

Deceased fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord

Neonate: a newborn

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. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of Subparts A and D of 45 CFR 46.

PROCEDURE:

Pregnant Women

1. Pregnant women or fetuses may be involved in federally funded projects only if the IRB finds that all of the ten (10) elements outlined in 45 CFR 46.204 are met. The same ten (10) elements should be evaluated for all other projects, but are not binding.
2. The Investigator must address all ten (10) elements in their eBridge SmartForm application to allow the IRB to evaluate and document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist*.

Research Involving Neonates of Uncertain Viability

1. Neonates of uncertain viability and nonviable neonates may be involved in a research project only if the IRB finds that all four (4) of the elements required in 45 CFR 46.205 are met for federally funded projects. The same four (4) elements should be evaluated for all other projects, but are not binding.
2. The Investigator must address all four (4) elements in their eBridge SmartForm application to allow the IRB to evaluate and document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist.*

Neonates of uncertain viability

1. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in a research project unless the IRB finds that the two (2) additional elements are met for federally funded projects. The same two (2) additional elements should be evaluated for all other projects, but are not binding.
2. The Investigator should address the two (2) additional elements in their eBridge SmartForm application to allow the IRB to evaluate and document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist.*

Nonviable neonates

1. After delivery, a nonviable neonate may not be involved in research project unless the IRB finds that all of the five (5) additional elements required under 45 CFR 46.205 (c) are met for federally funded projects. The same five (5) additional elements should be evaluated for all other projects, but are not binding. he Investigator should address the five (5) additional elements in their SmartForm application to allow the IRB to document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist.*
    a. 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 of this paragraph 46 CFR46.205(c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.
    b. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph 45 CFR 46.205(c)(5).
    c. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

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 accord with the requirements of 45 CFR 46 subparts A and D. *See IRB Member SOP: Research Involving Children*

Projects Involving After Delivery, the Placenta, the Dead Fetus or Fetal Material

1. Projects involving the following items after delivery, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
    a. The placenta
    b. A deceased fetus
    c. Macerated fetal material
    d. Cells, tissue, or organs excised from a deceased fetus
2. If information associated with the material described in the above paragraph of this section 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 subjects and the provisions of 45 CFR 46, subparts A and D, must be met as applicable.
3. Projects which propose the use of human fetal tissue may not be eligible for an exempt determination per institutional policy. *See IRB SOP: Use of Human Fetal Tissue in Research* for additional requirements.

Other Federal Agency Requirements:

1. For research intended for submission to the Environmental Protection Agency (EPA), any research involving the intentional exposure of pregnant women or children to any substance is prohibited and will not be approved by the IRB.
    a. For observational research (research which does not involve intentional exposure to substances) which is being conducted for or supported by the EPA, the IRB must also consider and apply 40 CFR 26 subparts C and/or D in providing additional protections to pregnant women and/or children.
2. For Environmental Protection Agency (EPA) supported projects, the IRB will review observational research involving pregnant women and fetuses using 40 CFR 26 in addition to 45 CFR 46, Subpart B.
3. Any additional federal agency requirements are documented via the *IRB Member Form: Additional Federal Agency Requirements Checklist*.

IRB Committee Review

1. The IRB shall include representation, either as members or ad hoc consultants, individual(s) interested in or who have experience with the vulnerable populations involved in a project.
2. The IRB will review the Investigators justifications for including vulnerable populations in the research project to assess appropriateness of the proposal.
3. The IRB must ensure that appropriate safeguards have been included in each research project at the time of initial review in order to protect the rights and welfare of vulnerable subjects.
4. The IRB shall continue to review the research project at intervals appropriate to the degree of risk and determine whether the proposed project continues to fulfill criteria for approval. Information reviewed should include the number of vulnerable subjects.
5. For studies that do not have or are not required to have a Data and Safety Monitoring Board (DSMB) or a Data Monitoring Committee and plan to enroll vulnerable subjects, the IRB needs to carefully review the data and safety monitoring plan.
6. The IRB will assess the adequacy of additional protections for vulnerable populations provided by the Investigator.
7. The IRB should be knowledgeable about and experienced in working with populations that are vulnerable to coercion and undue influence. If the IRB requires additional qualification or expertise to review a protocol, it should obtain consultation.

Documentation of IRB Review

1. Documentation of the member's review will be uploaded to the workspace within eBridge prior to the convened Committee IRB meeting.
2. The assigned reviewer will structure and focus their review of the project around meeting the requirements of Subpart B. The recommendations will be discussed and a final decision made by the IRB Committee.

REFERENCES:

45 CFR 46 Subpart A
45 CFR 46 Subpart B
45 CFR 46.116
45 CFR 46 Subpart D
45 CFR 46.204
45 CFR 46.205
45 CFR 46.205 (c)
45 CFR 46.205 (c)(5)
45 CFR 46.404-407
45 CFR 46.408-409
21 CRF 50.50-56
40 CFR 26

SUPPORTING DOCUMENTS:

IRB SOP: Use of Human Fetal Tissue in Research
IRB Member SOP: Research involving Children
IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist
IRB Member Form: Additional Federal Agency Requirements Checklist

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Approved By
HRPP Authorized Official: Ryan Spellecy, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin