SOP 1.4.2 **Research Involving Pregnant Women**

**General Description:**

Research activities at GMU involving humans must undergo some level of ethical review by the IRB office or the IRB. Per the federal regulations, at 45 CFR 46, pregnant women are considered a vulnerable population and research involving pregnant women requires additional considerations or protections. In general, the risk to the fetus from research procedures must not be greater than minimal. When risk is considered to be more than minimal, the risk must be justified by anticipated benefit(s) for the mother and/or fetus.

The federal regulations define pregnancy as the period of time from implantation until delivery. A fetus is defined as the product of conception, from implantation until delivery. A neonate is a newborn. A nonviable neonate is defined as a neonate after delivery that, although living, is not viable.

**Policy:**

1. Research involving pregnant women may qualify for an exempt determination or expedited review if it poses no more than minimal risk to participants and otherwise meets the necessary criteria.
    a. For research involving pregnant women, the IRB applies 45 CFR 46 Subpart B to studies. Under Subpart B, the IRB must review and approve the research under 45 CFR 46.204 and determine that the proposed research meets the following: Where scientifically appropriate, preclinical 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;
    b. 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;
    c. Any risk is the least possible for achieving the objectives of the research;
    d. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the 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, her consent is obtained in accord with the Mason IRB informed consent provisions;
    e. 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 the Mason IRB informed consent provisions. 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.
    f. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

g. For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with Mason IRB informed consent/assent provisions as well as subpart D of the regulations;
h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i. 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
j. Individuals engaged in the research will have no part in determining the viability of a neonate.

2. Research involving pregnant women that is not otherwise approvable based on the above conditions above but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates may be approvable by the Secretary of DHHS under 45 CFR 46.207.
3. For research involving neonates or non-viable fetuses, the IRB will review and approve the research under 45 CFR 46.205 and/or 45 CFR 46.206.
4. Women of childbearing age who are or believe they may be pregnant cannot participate in research studies in which they will be asked to undergo magnetic resonance imaging (MRI) procedures since the risk to the fetus from those procedures is unknown.
5. For research in which pregnancy is incidental to subject selection and the researcher is not specifically recruiting pregnant women for the study, these additional protections do not apply. However, additional protections may be necessary when a man or woman's participation could pose any risk to a potential fetus.

Consent Decision Chart for Pregnant Women and Fetuses

| | **Direct benefit to mother only** | **Direct benefit to mother and fetus** | **Direct benefit to fetus only** | **No direct benefit or societal benefits only** |
|---|---|---|---|---|
| **Risk is more than minimal** | Mother's consent | Mother's consent | Mother and father's consent | N/A- Not approvable |
| **Risk is no more than minimal** | Mother's consent | Mother's consent | Mother and father's consent | Mother's Consent |

**Procedures:**

1. If a research project involves pregnant women as participants, researchers must include this information in the applicable sections of the IRB application and complete Addendum C (Pregnant women, fetuses, and neonates).
2. The IRB will review the protocol in accordance with the applicable sections of 45 CFR 46 Subpart B. The IRB checklist for research involving pregnant women and/or research involving neonates will be completed by the IRB which will ensure that regulatory requirements for research involving pregnant women have been met.

3. The IRB will otherwise follow regular procedures for exempt, expedited or full board review as necessary.

**Related Forms, Guidance, and SOPs:**

- 45 CFR 46 Subpart B
- IRB application addendum C – Pregnant women, fetuses, and neonates
- 2.5.1 Full board review
- 2.5.2 Exempt and expedited

**Responsibility:**

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

**Approval and Version History:**

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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| Approved By | Title and Division | Date Approved |
|---|---|---|
| Aurali Dade | Associate Vice President, Research Development, Integrity and Assurance | May 24, 2017 |
| Laurie Meamber | IRB Chairperson | May 24, 2017 |