

<b>Michigan State University Human Research Protection Program</b>	
<i>Subject:</i> Special Categories of Research Subjects	
<i>Sub-Topic:</i> Pregnant Women, Human Fetuses and Neonates	
<i>Section:</i> 6-8-A	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by:</i> IRB, URC, UGC, MSU Legal Counsel; <i>Revision 1 reviewed by</i> IRB, Education Coordinator, <i>Director Compliance &amp; Standards, MSU Legal Counsel, HRPP Director, Asst. VP Regulatory Affairs</i>	<i>Approved by:</i> Vice President of Research and Graduate Studies, 3-3-2005. Revision 1 approved by VP Research & Graduate Studies on 3-9-2008.
<i>Related Sections:</i>	

## **Policy**

Special provisions of the federal regulations on human subject research govern research involving pregnant women, human fetuses and neonates (45 CFR 46, subpart B). The IRB follows the requirements of 45 CFR 46 Subpart B.

### **Pregnant women or fetuses**

Pregnant women or fetuses may be involved in research if all of the conditions under 45 CFR 46.204 are met (see Regulatory Requirements).

### **Research Involving Neonates**

Neonates of uncertain viability may be involved in research if all the conditions under 45 CFR 46.205(a) and 45 CFR 46.205(b) are met (see Regulatory Requirements).

Nonviable neonates may be involved in research if all the conditions under 45 CFR 46.205(a) and 45 CFR 46.205(c) are met (see Regulatory Requirements). Under this requirement, the waiver or alteration of consent (45 CFR 46.116) does not apply, and legally authorized representatives may not provide consent (see Regulatory Requirements).

Viable neonates may be involved in research if the conditions in 45 CFR 46 Subpart A and D are met. See Section 6, "IRB Evaluation Criteria," HRP Manual for requirements.

### **Research involving, after delivery, the placenta, the dead fetus or fetal material**

Research involving, after delivery, the placenta, the dead fetus or fetal material must be conducted in accordance with 45 CFR 46.206 (see Regulatory Requirements).

### **Review and Documentation**

Reviewer(s) shall review the application and materials and determine if the appropriate criteria have been satisfied. If the reviewer has any questions, a reviewer comment will be sent to the investigator addressing the issue(s).

If the reviewer(s) determine that the requirements under Subpart B have been satisfied, the IRB member or the IRB chair will document that the conditions have been met and why the materials met the criteria. A standard form shall be used for documentation.

For full board review protocols, the discussion and documentation shall be recorded in the minutes of the IRB meetings

## Definitions

For the purposes of such research, the following definitions apply:

**“Dead fetus** means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord” 45 CFR 46.202(a)

**“Delivery** means complete separation of the fetus from the woman by expulsion or extraction or any other means.” 45 CFR 46.202(b)

**“Fetus** means the product of conception from implantation until delivery.” 45 CFR 46.202(c)

**“Neonate** means a newborn.” 45 CFR 46.202(d)

**“Nonviable neonate** means a neonate after delivery that, although living, is not viable.” 45 CFR 46.202(e)

**“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.” 45 CFR 46.202(f)

**“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. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. 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 this part.” 45 CFR 46.202(h)

## Regulatory Requirements

**“45 CFR 46.204. Pregnant women or fetuses may be involved in research if all of the following conditions are met:”**

- “(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant 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 informed consent provisions of [subpart A](#) of this part;”
- “(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 informed consent provisions of [subpart A](#) of [this part](#), 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.”
- “(f) Each individual providing consent under paragraph (d) or (e) of this section 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 the provisions of [subpart D](#) of [this part](#);”
- “(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.”

#### **“46.205 Research involving neonates”**

- “(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met”
  - “(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates”
  - “(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section 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 paragraph (b) or (c) of this section have been met as applicable”
- “(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met”
  - “(1) The IRB determines that”
    - “(i) 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”
    - “(ii) 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 in accord with [subpart A](#) of [this part](#), except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest”

“(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of 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 in accord with [subpart A](#) of [this part](#), except that the waiver and alteration provisions of [§46.116\(c\)](#) and [\(d\)](#) do not apply. 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 (c)(5), 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 the requirements of this paragraph (c)(5).”

“(d) 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 [subparts A](#) and [D](#) of [this part](#).”

**“46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.”**

“(a) 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.”

“(b) If information associated with material described in paragraph [\(a\)](#) 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 research subjects and all pertinent subparts of [this part](#) are applicable”