

**Nova Southeastern University
Institutional Review Board
Policies and Procedures**

**Research with Pregnant Women, Neonates, Fetuses, and Fetal Material
Effective 10/01/2008; Revised 9/16/2011
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Purpose:

To establish policy and procedures related to the IRB's role in reviewing research that involves Pregnant Women, Neonates, Fetuses, and Fetal Material and to provide researchers with information regarding research that may be conducted with these groups.

Definitions:

1. Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).
2. Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means.
3. Fetus: the product of conception from implantation until delivery.
4. Neonate: a newborn baby.
5. Nonviable neonate: a neonate after delivery that, although living, is not viable.
6. 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.
7. Secretary: means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
8. 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 (Federal Policy for the Protection of Human Subjects [Basic DHHS Policy for Protection of Human Research Subjects]) and D (Additional DHHS Protections for Children Involved as Subjects in Research) of 45 CFR 46.

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Policy:

1. Pregnant Women as Subjects

Studies that do not place the mother or fetus at greater than minimal risk and are reviewed and determined as exempt at the center level (as allowed by 45 CFR 46.101(b)(1)-(6)) may include pregnant women as subjects. Routine exclusion of women who are or may be pregnant reduces research generalizability and is not recommended; however, when there are risks, or the risks are unknown or there is concern for liability, the researcher may be justified or may be required to use pregnancy or potential for pregnancy as exclusionary criteria.

The NSU IRB follows federal regulations (45 CFR 46.204) which are cited below.

Pregnant women or fetuses may be involved in research if all of the following conditions are met and subject to any state statute including Florida Statute F.S. 390.0111(6):

- “(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;”

The following conditions apply to obtaining consent and to determining whether only the pregnant woman will sign the consent, or if the father of the fetus must also sign the consent form.

“(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 45 CFR 46 and the informed consent policy.”

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- “(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 45 CFR 46, 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.”
- The persons who are asked to provide informed consent must be fully informed about all reasonably foreseeable risks to the fetus or neonate.
- “(g) For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of 45 CFR 46.”

The following additional considerations also apply:

- 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

Coincidental Pregnancy: Some studies may involve pregnant women as a *part of the general population*, for example when the potential participants are recruited from a population that includes, but is not limited to, women with child-bearing potential. In these circumstances, the NSU IRB shall determine such matters as:

- whether participants should be advised on the unique risks of participation in the study if they are or become pregnant;
- whether pregnant women will be excluded from participation and if participants should be advised to notify the principal investigator immediately should they become pregnant, and if the subject’s participation will be discontinued if the participant becomes pregnant;
- whether participants should be advised to avoid pregnancy or nursing during or following participation in the study;
- whether pregnancy testing is required as part of the study, and if so, who bears the cost of that testing;
- whether specified methods of contraception should be required during or following participation in the research and if so, who bears the cost of the contraception.

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2. Neonates

A. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- Individuals engaged in the research will have no part in determining the viability of a neonate.
- Sections B and C below also apply.

B. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the following additional conditions have been met:

- The IRB determines that:
 - 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
 - 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.
- If one of these two conditions is met, then legally effective informed consent from either parent of the neonate must be obtained. 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. The researcher must follow the rules of the IRB's Informed Consent policy, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

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C. Nonviable neonates. After delivery a nonviable neonate may not be involved in research unless all of the following additional conditions are met:

- Vital functions of the neonate will not be artificially maintained;
- The research will not terminate the heartbeat or respiration of the neonate;
- There will be no added risk to the neonate resulting from the research;
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- The legally effective informed consent of both parents of the neonate is obtained in accord with the NSU IRB Informed Consent Policy, except that the provisions within that policy related to waiving informed consent requirements and waiving the requirement for signed consents 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, except that the consent of the father or his legally authorized representative 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 about research on nonviable neonates.

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 outlined in the informed consent and research with children policies.

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

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.

If the research record links the fetus, fetal material, or placenta to a living person in a way that allows that person to be identified, then that living person must consent to the research study, and all other NSU IRB policies on human subjects research apply.

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4. Blood Draws on Pregnant Women and Neonates

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from pregnant adult women and children that exceed the lesser of 50 ml or 3 ml per kg in an 8 week period or occur more frequently than 2 times per week must be reviewed at a convened IRB meeting. For studies involving the collection of the lesser of 50 ml or 3 ml per kg in an 8 week period or not occurring more frequently than 2 times per week may be reviewed via expedited procedure.

References:

45 CFR 46.116
45 CFR 46.117
45 CFR 46.201
45 CFR 46.202
45 CFR 46.203
45 CFR 46.204
45 CFR 46.205
45 CFR 462.06

Procedures:

1. Protocols related to Pregnant Women Neonates, Fetuses, and Fetal Material will be reviewed only at convened IRB meetings where at least one member present is a physician.
2. The Board will define which federally permissible research category approved research studies falls within and note this in the minutes. The Board will ensure that the study adheres to all federally required policies and procedures.