

**NORTHERN ILLINOIS
UNIVERSITY
INSTITUTIONAL REVIEW BOARD**

**POLICIES AND PROCEDURES FOR HUMAN SUBJECTS RESEARCH INVOLVING
PREGNANT WOMEN, WOMEN OF CHILDBEARING POTENTIAL, FETUSES, AND
NEONATES**

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Research that permits the enrollment of women who are or may become pregnant or that is directed toward a fetus or neonate requires special attention when it is necessary to protect the rights and welfare of pregnant women and/or the fetus and/or neonate.

Northern Illinois University (NIU) is required to comply with [45 CFR 46 Subpart B](#), "Additional Protections for Pregnant Women, Fetuses and Neonates Involved in Research," for non-Exempt research conducted or supported by the Department of Health and Human Services (DHHS).

RESEARCH CONDUCTED OR SUPPORTED BY THE DHHS INVOLVING PREGNANT WOMEN

The Institutional Review Board (IRB) will approve non-Exempt DHHS funded research involving pregnant women, fetuses and/or neonates if, in addition to meeting all other requirements and review considerations, the research satisfies the conditions of [45 CFR 46 Subpart B](#).

Definitions

Pregnancy: For purposes of this policy, the period of time from implantation until delivery.

Fetus: The product of conception from implantation until delivery.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Surrogate Consent: Consent for an individual to participate in research given by an appropriate surrogate (e.g., next of kin, spouse, parent, child, sibling) when an individual is assessed as not capable of providing fully informed and legally effective consent.

Assent (Children Under 18 Years of Age): A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Neonate: A newborn.

Nonviable neonate: A neonate after delivery that, although living, is not viable.

Viable: Pertaining to neonates and for purposes of this policy, the ability, 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, it may be included in research only to the extent permitted and in accordance with the requirements of Subparts A (Basic DHHS Policy for Protection of Human Research subjects) and D (Additional Protections for Children Involved as Subjects in Research) of 45 CFR 46.

Requirements for Approval of DHHS-funded Biomedical or Behavioral Research Involving Pregnant Women or Fetuses

Research involving pregnant women or women of childbearing potential may be approved by the IRB once the following determinations are made and the findings are documented:

1. 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 the potential risks for pregnant women and fetuses;
2. When the research has the potential of directly benefiting the woman or the fetus, a greater than minimal risk to the fetus is acceptable. If the research does not hold the prospect of directly benefiting the woman or fetus, then the research is allowed if 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;
3. Any risk is the least possible for achieving the objectives of the research;
4. The pregnant woman's consent is sufficient when there is the prospect of direct benefit for the pregnant woman, the pregnant woman and the fetus, or when there is no prospect of benefit for the woman or the fetus but the 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;
5. When the research has the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father of the fetus is required in accordance with the informed consent provisions, except that the father's consent is not required if he is unable to consent because of unavailability, incompetence, or temporary incapacity, or the pregnancy resulted from rape or incest;
6. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. In the case of pregnant females who are themselves minors (under age 18), assent and permission are obtained in accordance with the policy regarding participation of children in research;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. 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

10. Individuals engaged in the research will have no part in determining the viability of a neonate.

DHHS-funded biomedical or behavioral research that does not meet the above qualifications may only be conducted with approval of the Secretary of U.S. Department of Health and Human Services.

The IRB will approve research involving women who may become pregnant if appropriate safeguards are in place to protect against the risk of pregnancy, should pregnancy be a specific exclusionary criterion.

RESEARCH NOT CONDUCTED OR SUPPORTED BY THE DHHS INVOLVING PREGNANT WOMEN

For research not conducted or supported by the DHHS, or for Exempt DHHS-supported research, the IRB has flexibility in its decision-making with regard to the inclusion of pregnant women in research. The NIU IRB supports a policy of providing pregnant women the same opportunities as non-pregnant women to participate in research unless the exclusion of pregnant women is appropriately justified.

In general, pregnant women may be included in research on individual or group characteristics or behavior, or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies as described in expedited category 7 if the project meets all other requirements and review considerations for review of research not involving pregnant women.

During its review of proposed research, the IRB must judge whether participation as a research subject would pose any potential or suspected risks to pregnant female volunteers and/or their fetuses and, if so, whether the involvement of pregnant women would yield any direct or indirect benefit that would outweigh such risks. In some instances there may be potential or suspected risk sufficient to justify that pregnant women either be specifically excluded from the research or advised to seek consultation from their primary care physician or other qualified health-care provider prior to participation.

As part of risk assessment, the IRB regularly evaluates health-related exclusionary criteria, which includes a research protocol's potential to negatively impact the welfare of pregnant women and fetuses. As such, the IRB has the authority to approve protocols wherein pregnancy is listed as an exclusionary criterion and the exclusion is properly justified.

If it is determined that pregnant women should be excluded, the IRB must also assess whether the research team may rely on each female's self-report, or whether validation through a negative pregnancy test is required before female subjects of childbearing potential are involved in study-related activities. The screening process, as described within the protocol, must ensure that females are informed of the exclusionary conditions, including pregnancy.

If it is determined that pregnant women will be included, the IRB must assess whether female subjects who are or suspect they are pregnant should be advised to seek their primary care physician's consultation when considering whether or not to participate.

RESEARCH INVOLVING NEONATES

Requirements for Approval of Research Involving Neonates

Research involving newborns (neonates) of uncertain viability and nonviable newborns may be approved by the IRB once the following determinations are made and the findings are documented:

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 Section A or B below 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 Sections A and B below have been met, as applicable.

A. Neonates of uncertain viability

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:

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 IRB may approve the substitution of the informed consent of either parent's surrogate or legally authorized representative being obtained, except that the consent of the father or his surrogate or legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

B. Nonviable neonates

After delivery the nonviable neonate may not be involved in research 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 the policy regarding informed consent for human research, except that the waiver and alteration provisions 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, 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 these requirements.

C. 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 the policy regarding informed consent for human research, and the policy regarding the participation of children in research.

RESEARCH INVOLVING, AFTER DELIVERY, THE PLACENTA, THE DEAD FETUS, OR FETAL MATERIAL

The IRB is required to review and approve research involving the placenta, dead fetus or macerated fetal material, or cells, tissue, or organs excised from a dead fetus if information associated with this material is recorded for research purposes in a manner that living individuals (e.g., parents, siblings) can be identified, directly or through identifiers linked to those individuals. If such identification is possible, then those individuals are research subjects and all pertinent federal regulations involving human research subjects are applicable. (45 CFR 46.206). The research shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

RESEARCH NOT OTHERWISE APPROVABLE

Research involving pregnant women, human fetuses, or neonates that is funded by DHHS and does not meet the aforementioned approval criteria must be approved by the Secretary of Health and Human Services (45 CFR §46.207). If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, and the research is not approvable under the above provisions, then the research will be sent to Office for Human Protections for the review and approval by the Secretary of Health and Human Services.