

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-006.1
Policy Title: Additional Protections for Certain Populations: Pregnant Women, Fetuses or Neonates

Purpose

The purpose of this policy is to set forth the requirements of the HSPP for review and approval by the Institutional Review Board of non-exempt studies intending to involve pregnant women, fetuses or neonates.

Definitions

See Policy 2011-007.0 for definitions of the following:

Delivery	Pregnancy
Secretary	Fetus
Fetus, Dead	Neonate
Neonate, Nonviable	Neonate, Viable
Pregnant Woman	

Policy

The additional protections for the inclusion of pregnant women in non-exempt research apply in the following circumstances:

- The research is federally funded or supported; or
- The research involves pregnant women as the recipient of a drug, device or biologic.
 - The additional protections are not applicable when a woman becomes pregnant while enrolled in a non-federally funded or supported study, the intervention is stopped, and the remaining activity is limited to the collection of long-term follow-up data on the pregnancy,

When the protections apply, the IRB may approve research involving pregnant women, fetuses or neonates if the IRB finds that the research satisfies the conditions of all applicable sections noted below.

Pregnant Women or Fetuses:

Pregnant women or fetuses may be involved in research only if the IRB finds that:

- a. where scientifically appropriate, preclinical studies, including studies in pregnant animals, and clinical studies, including studies on pregnant women, have been conducted and provide data for assessing potential risks to pregnant woman 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 objective of the research;
- d. the woman's consent is obtained in accordance with regulations if the research holds out 1) the prospect of direct benefit to the pregnant woman, 2) the prospect of a direct benefit to both the pregnant woman and the fetus, or 3) no prospect of direct 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;
- 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 provision set forth in regulation. 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 who are pregnant, assent and permission are obtained in accord with the regulations regarding children involved as subjects in research;
 - h. no inducement, 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 neonates.

Neonates of Uncertain Viability:

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

- a. where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- b. each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
 - For neonates of uncertain viability, 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 the either parent's legally authorized representative is obtained in accordance with regulation, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
 - For nonviable neonates, the legally effective informed consent of both parents of the neonate is obtained in accord with regulation. The provisions to request a waiver or alteration of consent do not apply. 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. 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.
- c. individual engaged in the research will have no part in determining the viability of a neonate.
- d. the following requirements have been met as applicable to 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 IRB determines that 1) the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and 2) any risk is the least possible for achieving that objective; or 1) the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and 2) there will be no added risk to the neonate resulting from the research;

- 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 the either parent's legally authorized representative is obtained in accordance with regulation, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable Neonates:

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

- a. vital functions of the neonate will not be artificially maintained;
- b. the research will not terminate the heartbeat or respiration of the neonate;
- c. there will be no added risk to the neonate resulting from the research;
- d. the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- e. the legally effective informed consent of both parents of the neonate is obtained in accord with subpart regulation. The provisions for a waiver or alteration of consent 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.
- f. 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 the nonviable neonate will not suffice.

Viable Neonates:

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 for the inclusion of children in research.

Placenta, Dead Fetus, Fetal Material:

Research involving, after delivery, the placenta, the dead fetus, or fetal material may be conducted only if the IRB finds that:

- 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 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 must be afforded the applicable protections of the regulation and its subparts as applicable.

Research involving pregnant women, fetuses or neonates that does not fit into one of the above categories may only be conducted if the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problems affecting the health or welfare of pregnant women, fetuses or neonates and, for DHHS funded or supported research, after the Secretary has consulted with an expert panel and there has been opportunity for public review and comment. The required findings for such research are that the research does present the aforementioned opportunity, the research will be conducted in accord with sound ethical principles and informed consent will be obtained.

Proposed studies involving pregnant women, fetuses or neonates may qualify for exempt or expedited review when no more than minimal risk is involved. The Chair will make the final determination.

Consent of the Father:

Unavailability of the father as related to consent issues is interpreted to mean that he is either deceased or that his whereabouts are not known and cannot be determined with a reasonable amount of effort.

Procedure

See 2011 – 006.0 – Additional Protections for Certain Populations - General Policy

Related Policies

- 2011-006.0 – Additional Protections for Certain Populations - General Policy
- 2011-006.3 – Additional Protections for Certain Populations - Children
- 2011-007.0 – Definitions Applied to Policies
- 2011-008.0 – Informed Consent Forms
- 2011-008.2 - Assent
- 2011-008.5 – Informed Consent – Providing and Obtaining Informed Consent
- 2011-009.2 – Institutional Review Board – Exemptions
- 2011-009.3 – Institutional Review Board – Expedited Reviews
- 2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

- 45 CFR 46
- 21 CFR 50

Document Attributes

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Signed by Richard H. Simon

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Reviewed and Approved By
Richard Simon, MD
Director Human Subjects Protection Office

Date: