

**RESEARCH INVOLVING SPECIAL POPULATIONS:
PREGNANT WOMEN, HUMAN FETUSES AND NEONATES**

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THIS POLICY PERTAINS TO:			ALL RESEARCH SUBMITTED TO THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT; IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB MEMBERS					
LAST REVIEWED ON:		/ /	RESULTS:	REVISED			
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:					DATE:	/ /	

1. POLICY

This policy applies to all research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human in vitro fertilization and is based on the Federal Regulations at [45 CFR 46 Subpart B](#). The requirements in this policy are in addition to those imposed under the other IRB policies and other applicable federal, state, and local laws.

Research involving women who are pregnant should receive special attention from the IRB because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. Special attention is justified because of the involvement of a third party (the fetus) who may be affected but cannot give consent. Investigators should include in the research proposal the rationale and details for the inclusion of pregnant women, fetuses, or neonates in research activities. Researchers should ensure that the informed consent process adequately addresses the risk to the fetus or neonate and pregnant women. Procedural protections beyond the basic requirements for protecting human subjects are prescribed in federal regulations for research involving pregnant women.

2. SPECIFIC POLICY

2.1 Definitions

The definitions in 45 CFR 46.102 are applicable to this subpart, in addition to the following definitions:

Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

Fetus means the product of conception from implantation until delivery.

Neonate means a newborn.

Nonviable neonate means a neonate after delivery that, although living, is not viable.

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.

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.

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 45 CFR 46 Subparts A and D.

2.2 Pregnant Women and Fetuses

2.2.1 Pregnant women or fetuses prior to delivery may be involved in research if all of the following conditions are met ([45 CFR 46.204](#)):

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 assessing potential risks to pregnant women and fetuses;
2. 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;
3. Any risk is the least possible for achieving the objectives of the research;
4. 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, the woman's consent is obtained;
5. 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, 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;
6. Each individual providing consent under (4) or (5) above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission are obtained in accord with [Subpart D of 45 CFR 46](#) for studies involving children;
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;
10. Individuals engaged in the research will have no part in determining the viability of a neonate, and
11. A data safety monitoring plan has been established to monitor participants.

2.2.2 Research involving neonates:

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met ([45 CFR 46.205a](#)):

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 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; AND if the neonate is of uncertain viability ([45 CFR 46.205\(b\)](#)), until it has been ascertained whether or not a neonate is viable, the following additional conditions are met:
 - a. 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 which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
 - b. 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, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. OR

According to [45 CFR 46.205\(c\)](#) if the neonate is nonviable after delivery, 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, except that the waiver and alteration provisions of Subpart A 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, 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 requirement of this paragraph.

According to [45 CFR 46.207\(b\)](#) research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates can be sent to the Secretary of DHHS by the Investigator for review. The Secretary will determine the approvability of the research based on the conditions stated in [45 CFR 46.207 \(b\)](#).

Viable neonates. A neonate, after delivery, that has been determined to be viable is a child as defined by [45 CFR 46.402\(a\)](#) and may be included in research only to the extent permitted by and in accord with the requirements of 45 CFR 46 Subparts A and D.

3. RESPONSIBILITY

The IRB Coordinator is responsible for maintaining up-to-date review tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

The IRB Chairperson and the IRB Coordinator are responsible for ensuring the IRB members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations.

The IRB Chairperson, IRB Coordinator, and/or IRB Secretary is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

The Primary Reviewer is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

IRB Members are responsible for review of the research thoroughly enough to participate in the discussion at the convened IRB meeting.

4. APPLICABLE REGULATIONS AND GUIDELINES

- The Belmont Report
- 45 CFR 46: Subpart B
- 45 CFR 46.305
- 45 CFR 46.122
- 21 CFR 56.111
- OHRP IRB Guidebook

5. ATTACHMENT

SC 501-A Checklist for Research Involving Pregnant Women & Fetuses

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Coordinator</i>	Maintain and update checklist to conform to applicable regulations and guidelines.
<i>IRB Chairperson, IRB Coordinator, IRB Secretary</i>	Select appropriate Primary Reviewers or obtain expert consultant.
<i>IRB Secretary</i>	Provide Primary Reviewers with appropriate checklist.
<i>Primary Reviewers</i>	Complete checklist during review of research and present recommendations at convened meeting. Confirm that proposal has informed consent documents as appropriate.