

Summary of Pregnant Women, Fetuses, & Neonates Regulations 45 CFR 46 Subpart B

Research Involving Pregnant Women or Fetuses

For the IRB to Issue Approval, Ten Conditions Must Be Met:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provided 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 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 risk 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;
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 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 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 the provisions of subpart D of this part;
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.

**Research With Neonates of Uncertain Viability
Five Conditions Must Be Met:**

1. Where appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks;
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;
4. 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
5. The legally effective informed consent of either parent 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.

Definitions:

“Neonate” means a newborn.

“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. 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 45 CFR 46.

**Research With Nonviable Neonates
Eight Conditions Must Be Met:**

1. Where appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks;
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;
4. Vital functions of the neonate will not be artificially maintained;
5. The research will not terminate the heartbeat or respiration of the neonate;
6. There will be no added risk to the neonate resulting from the research;
7. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
8. The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A, except that the waiver and alteration provisions of Sec. 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 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 informed consent requirements.

Definitions:

“Neonate” means a newborn.

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

Research With Viable Neonates:

“Viable Neonate” is considered to be a “child.” Subparts A and D of the regulations apply (i.e. Additional Protections for Children)

**Research After Delivery, Involving Placenta, Dead Fetus or Fetal Material
Two Conditions Must Be Met:**

1. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissues, 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;
2. 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.

**Research Not Otherwise Approvable
Two Conditions Must Be Met:**

1. 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
2. The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
 - 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;
 - The research will be conducted in accord with sound ethical principles; and
 - Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

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