Special Categories of Research: Pregnant Women, Human Fetuses, and Neonates

Content Applies To

Mayo Clinic Human Research Protection Program

Policy

It is the policy of the Mayo Clinic Office for Human Research Protection - Institutional Review Board (IRB) to review research involving pregnant women, human fetuses, and neonates and approve only research which satisfies the requirements of 45 CFR 46 Subpart B, *Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research*, or equivalent protections as allowed by law.

Key Terms

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.

Research Involving Pregnant Women or Fetuses

Pregnant women or fetuses may be involved in research if **all** of the following conditions are met:

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- 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 that the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;
- Any risk is the least possible for achieving the objectives of the research;
- 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 the IRB document *Informed Consent and the Research Subject.* If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions per IRB procedure on *Informed Consent and the Research Subject*, 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;

- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- For children who are pregnant, assent and/or consent are obtained in accord with the provisions of IRB document *Special Categories of Research: Children*.
- 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.

Research Involving Neonates

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 as described in this document is fully informed regarding the reasonably foreseeable impact of the research on the neonate; and
- Individuals engaged in the research will have no part in determining the viability of the neonate.

Neonates of uncertain viability may not be involved in research covered by this document unless the following additional conditions have been met and 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; and
- The legally effective informed consent of either parent of the neonate is 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 in accord with the IRB document *Informed Consent and the Research Subject* with the exception that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable neonate (after delivery) may not be involved in research covered by this document 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
- The legally effective informed consent of both parents of the nonviable neonate is obtained.

- The **waiver and alteration provisions** of IRB document *Planned Research in An Emergency Setting* **does 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 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 does not meet the requirements described here.

Viable neonate (after delivery) A neonate 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 45 CFR 46 Subparts *A: Basic HHS Policy for Protection of Human Research Subjects* and D: *Additional Protections for Children Involved as Subjects in Research*.

Research involving the placenta, the dead fetus, or fetal material (after delivery)

Research involving the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, may only be conducted in accord with any applicable Federal, State, or Local laws and regulations regarding such activities.

If information associated with this material 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 IRB policies are applicable.

Research not otherwise approvable

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 may be conducted if it meets the requirements of this document and:

- 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 Secretary of the Department of Health and Human Services (DHHS), 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, in fact, satisfies the conditions of 45 CFR 46.204, Research involving, after delivery, the placenta, the dead fetus or fetal material, as applicable;
    - 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 45 CFR 46 Subpart A: *Additional Protections for Pregnant*

Women, Human Fetuses and Neonates Involved in Research and other applicable subparts of 45 CFR 46.

Procedure

Investigator Responsibilities

1. Prior to IRB submission, the Investigator obtains review and approval from the appropriate departmental Research Committee responsible for the oversight of this population prior to IRB review.
2. The Investigator describes the population for the research project and provides justification for inclusion of any of the following potential subjects: pregnant women, fetuses, or neonates in the IRB application.
3. Following IRB review and approval, the Investigator obtains informed consent from the mother and father as described above.

IRB Responsibilities

1. The IRB reviews the proposed research project according to all applicable IRB policies and procedures, taking into consideration the additional requirements for involvement of pregnant women, fetuses, or neonates in research as set forth in IRB document *IRB Initial Approval of Research* and confirms that the investigator has provided approval from the appropriate research committees.
2. The IRB documents in its determination that additional protections necessary for this population are adequate.

Related Documents

Informed Consent and the Research Subject

Special Categories of Research: Children

IRB Initial Approval of Research

Planned Research in an Emergency Setting

References

45 CFR 46 Subparts A: *Basic HHS Policy for Protection of Human Research Subjects*

45 CFR 46 Subpart B, *Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research*

45 CFR 46 Subpart D, Additional Protections for Children Involved as Subjects in Research.