

Wayne State University Human Investigation Committee	
Subject	Research Involving Fetuses and Neonates
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Approvals	Steering Committee 11/12/97; Administrative Approval 05/05/98; Revised Steering Committee 11/03/06; Revised Administrative Approval 11/08/06; Administrative Approval 09/29/08; General Counsel Approval 10/01/08, Administrative Approval 9/30/10

Background

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research Report of July 1975 formed the basis for health and Human Services (HHS) regulation 45 CFR 46 subpart B (Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and In Vitro Fertilization). In 2001, HHS issued modifications to Federal Regulation 45 CFR 46 Subpart B, now entitled "Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research."

Scope

This Wayne State University (WSU) Institutional Review Board (IRB) policy/procedure applies to all research involving pregnant women, fetuses, whether *viable* or *nonviable* and neonates. Research in which the subject is a fetus, *in utero* or *ex utero* (including human fetal tissue) **must not be conducted by Veteran's Administration (VA) investigators** [VA Handbook 1200.5, Appendix D, 4(a)(b)].

Definitions

Pregnancy – The period of time from confirmation of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until delivery.

Fetus – The unborn product of conception from the time of implantation in the womb until expulsion or extraction.

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

Neonate – Newborn, from the time of birth through the first four weeks of life.

Viable Neonate – A neonate who is capable of surviving, given the benefit of available medical therapy, to the point of independently maintaining heart beat and respiration.

Nonviable Neonate – A neonate after delivery that, although living, is not viable despite medical therapy and unable to independently maintain a heartbeat and respiration.

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

Macerated (fetal) Materials – The process in which the skin is softened and broken down by extended exposure to wetness or moisture, as in a post-term infant or a dead fetus because of prolonged exposure to the amniotic fluid.

HIC Procedures

Research involving pregnant women or fetuses (in utero) may be conducted when the following conditions are met [45 CFR 46.204(a)-(j)]:

- Scientifically appropriate studies on animals and non-pregnant women have been conducted and data has been provided 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;
- If there is no benefit to the fetus, the risk 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;
- Any risk to the fetus is the least possible for achieving the objectives of the research;
- Research investigators are excluded from any decisions regarding the timing, methods, or procedures used to terminate a pregnancy, or determining the viability of the fetus at the termination of the pregnancy;
- No procedural changes which may cause greater than minimal risk to the fetus or pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interests of the research;
- No inducements, monetary or otherwise, have been offered to terminate the pregnancy for research purposes.

Research involving neonates of uncertain viability may be conducted when the following conditions have been met:

- Scientifically appropriate, preclinical, and clinical studies have been conducted and provide data for assessing potential risks to neonates;
- Consenting individuals have been fully informed regarding the reasonably foreseeable impact of the research on the neonate;
- Individuals involved in the research will have no part in determining the viability of the neonates;
- 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;
- There will be no added risk to the fetus as a result of the research activity and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.

Research involving nonviable neonates may be conducted when the following conditions have been 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 as a result of the research;
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
- Where scientifically appropriate, preclinical and clinical studies have been conducted and provided data for assessing potential risks to neonates.
- Individuals engaged in the research have no part in determining the viability of a neonate.

Research involving viable neonates may be conducted under the portions of the regulations involving infants and children (45 CFR 46 Subparts A and D). The WSU HIC Policy Procedure on "Vulnerable Participants: Children as Research Participants" applies when research is conducted on the viable neonate.

Research after delivery, involving the placenta, the dead fetus (including macerated fetal materials), or cells, tissue, or organs excised from a dead fetus will be conducted in accordance with applicable federal, state, or local laws (see HIC Policy/Procedure: "The Use of Biological Specimens for Research" for specific guidance).

Consent Requirements

Consent will be obtained from the mother or from both parents, only after she/they have been fully informed regarding the possible impact of the research on the fetus and neonate.

1. The consent will be required from the mother only
 - If the research has the prospect of direct benefit to the pregnant woman,
 - If the research has the prospect of direct benefit to both the pregnant woman and the fetus,
 - If the research has no direct benefit to either the pregnant 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 through other means.
2. For children who are pregnant, assent from the child and permission from the pregnant child's parent(s) are obtained under the guidance of 45 CFR 46.402(a) for research involving the pregnant child. However, the pregnant child is allowed to consent for research for her fetus and neonate.
3. The consent is required of both the pregnant woman and the father if the research holds out the prospect of direct benefit to the fetus solely. The father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest.
4. In research involving *neonates of uncertain viability*, legally effective consent may be obtained from 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 may be obtained. The father's consent or that of his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

5. Research involving *nonviable neonates* may be conducted only if the mother and father are legally competent and have both given their consent. 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 parents will not suffice for research involving a nonviable neonate. NOTE: Provisions for waiving or altering the consent process are not allowed for research involving non-viable neonates.
6. For research after delivery involving the placenta, the dead fetus or fetal material, if information associated with this material is recorded in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and afforded all protections under 45 CFR 46.
7. For research involving a *viable neonate* where there is greater than minimal risk and no prospect for direct benefit to the neonate, but it is likely to yield generalizable knowledge about the subject's disorder (research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition) [45 CFR 46.406] both parents must give their consent unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child [45 CFR 46.408(b)].