

DEPARTMENT: INSTITUTIONAL REVIEW BOARD  
POLICY NUMBER: 024  
SECTION: GENERAL IRB POLICIES  
REVIEW RESPONSIBILITY: IRB  
EFFECTIVE DATE: AUGUST 13, 2003  
REVISION DATE:  
LW IMPLEMENTED: 45 CFR 46.204 – 207

SUBJECT: Research Involving Pregnant Women, Human Fetuses and Neonates

1. This policy applies to all research, development, and related activities involving pregnant women, the fetus, and neonates. The requirements within this policy are in addition to those imposed under existing IRB policies and other applicable federal, state, or local laws.
2. Definitions as used in this policy shall mean as follows:
  - a) “Pregnancy” encompasses the period of time from implantation until delivery. A woman shall be presumed 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.
  - b) “Fetus” means the product of conception from implantation until delivery.
  - c) “Neonate” means a newborn.
  - d) “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.
  - e) “Dead fetus” means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
  - f) “Nonviable neonate” means a neonate after delivery that, although living is not viable.
3. Pregnant women or fetuses may be involved in research if all of the following conditions are met:
  - a) 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;

- 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 objectives of the research;
  - d) 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 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 by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of 45 CFR 46.
  - 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 provisions of subpart A of 45 CFR 46, 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.
  - f) Each individual providing consent under paragraphs (d) or (e) above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
  - g) For children as defined in 45 CFR 46.402 (a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of 45 CFR 46.
  - h) No inducements, 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 a neonate.
4. Additional protection is required for research involving neonates. A neonate 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 as required in this paragraph (4) have been met as applicable.
  - c) Pertaining 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 covered by this subpart unless the following additional conditions are met:

- 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
  - 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 of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
- d) Pertaining to nonviable neonates, after delivery nonviable neonates may not be involved in research covered by this subpart 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; and
  - The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of 45 CFR 46, except that the waiver and alteration provisions of 45 CFR 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 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 requirements of this paragraph.
- e) Pertaining to 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 by the requirements of subparts A and D of 45 CFR 46.

- 5) 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. Note: If information associated with material described here within 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 45 CFR 46 are applicable.
- 6) 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. Note that such research may be conducted or funded by HHS pursuant to the requirements set out in 45 CFR 46.207.

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SUBJECT: Special Categories of Research: Children in Research

1. The special vulnerability of children makes consideration of involving children as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving children. The IRB may approve research involving children only if special provisions are met. The IRB must classify research involving children into one of four categories and document their discussions of the risks and benefits of the research study. The four categories of research that may be approved by the IRB are based on degree of risk and benefit to individual subjects, and are set out in the paragraphs below. Note: Under this policy, “children” includes all those who have not yet reached their 18<sup>th</sup> birthday.
2. Category One – Research Not Involving More than Minimal Risk. When the IRB finds that no greater than minimal risk to children is present, the IRB may approve the proposal only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in this policy herein.
3. Category Two – Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subject. If the IRB finds that more than minimal risk to children is presented by an intervention or procedure but that the intervention or procedure holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject’s well-being, the IRB may approve the research, provided the IRB finds that:
  - a) the risk is justified by the anticipated benefit to the subjects;
  - b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
  - c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in this policy herein.
4. Category Three – 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. If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure