



Research Involving Pregnant Women, Human Fetuses and Neonates, and Fetal Tissue

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Approved by: Human Protections Administrator, Director
of OPRS, and Executive IRB Chair

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AAHRPP Elements: II.4.A., II.4.B, III.1.C, III.1.F

POLICY:

- I. Pregnant women represent a vulnerable population when involved in human subjects research and require additional safeguards from the investigator and IRB, because of women's additional health concerns during pregnancy and the need to avoid unnecessary risk to the fetus. The IRB must apply additional federal and state regulations and laws.
- II. To safeguard their interests and protect them from harm, additional regulatory protections exist for research involving pregnant women, human fetuses and neonates. The UIC IRBs approve research involving these vulnerable groups only if the research complies with the safeguards described in this policy and 45 CFR 46 Subpart B regardless of funding.
- III. The UIC IRBs review and consider research involving pregnant women, human fetuses, and neonates of uncertain viability or nonviable neonates in accordance with the federal regulations at 45 CFR 46 Subpart B, UIC HSPP policies and procedures, and other applicable federal, state and local laws regardless of funding.
- IV. Research involving pregnant women as subjects may be exempt from the requirements of subpart B when the research meets the exemption criteria at 45 CFR 46.101(b).
- V. The UIC IRBs also consider the need for additional safeguards when reviewing research in which women of childbearing potential are possible subjects as the potential exists for these women to become pregnant during the course of the research.
- VI. Definitions. The following definitions are taken from 45 CFR 46.202.
 - A. **DEAD FETUS:** a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.



- B. DELIVERY: complete separation of the fetus from the woman by expulsion or extraction or any other means.
- C. FETUS: the product of conception from implantation until delivery.
- D. NEONATE: a newborn.
- E. NONVIABLE NEONATE: a neonate after delivery that, although living, is not viable.
- F. PREGNANCY: the period of time from implantation until delivery. A woman is 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.
- G. 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.

VII. The Illinois Consent by Minors to Medical Procedures Act (410 ILCS 210/1) permits a pregnant minor to provide her own informed consent to the performance of a medical or surgical procedure performed by: (i) a physician licensed to practice medicine and surgery, (ii) an advanced practice nurse who has a written collaborative agreement with a collaborating physician that authorizes provision of services for minors, or (iii) a physician assistant who has been delegated authority to provide services for minors. The UIC IRB extends the provisions of the Minors Medical Treatment Act to research. Specifically, under the circumstances or for the conditions stipulated in the Act, the UIC IRB views the minor to have the same legal capacity to act and as having the same powers and obligations as a person of legal age to consent for research involving such medical or surgical procedures. The minor is not deemed to be able to provide consent for research involving conditions not stipulated by the Act or involving medical or surgical procedures not covered by the Act. In these instances, assent from the pregnant minor and permission from the parent or guardian must be obtained as described in the UIC HSPP policy [Research Involving Children \(including Wards of the State\)](#).

VIII. Additional VA Requirements for research reviewed by CHAIRb. In addition to the requirements provided in 45 CFR 46 Subpart B and those conveyed in this policy, the following VA regulations from Handbook 1200.05, Paragraphs 45.c.(1) and (2) and 46 are followed for research to be conducted at JBVAMC.

- A. Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue), must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.
- B. Research related to in vitro fertilization must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.
- C. Women of childbearing potential:
 - 1. may be entered into studies, including studies whose interventions include FDA's Categories for Drug Use in Pregnancy's Category C drugs;



2. may not be entered into studies involving use of FDA Categories for Drug Use in Pregnancy's Category D or X drugs unless a waiver is obtained from the CRADO
- D. For research involving the participation of pregnant women as research subjects, the IRB must find and document that the criteria at 45 CFR 46.204 are met in the meeting minutes or, when review occurs under expedited conditions, review guides.

IX. Department of Defense (DoD)

The DoD applies subpart B with some modifications. Please refer to UIC HSPP Policy [Research Involving Department of Defense Components](#) for more detail.

PROCEDURES:

- I. Studies in Which Pregnancy is Coincidental to Subject Selection. When the research population may include women of child bearing potential, the possibility exists for the inadvertent inclusion of pregnant women. For these studies, the IRB will consider:
 - A. Whether it is appropriate to provide a statement as part of the informed consent process that the particular treatment or procedure may involve risks to the subject (or to the embryo, fetus or nursing infant) that are unforeseeable;
 - B. Whether the mother's participation would pose any risk to the fetus or nursing infant;
 - C. Whether there is a need to ensure that nonpregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research;
 - D. Whether there is a need for the investigator to advise the subject to immediately contact the investigator should they become pregnant; AND
 - E. Whether the potential risk is sufficient to justify requiring either excluding pregnant women from the research or requiring specified methods of contraception during and following participation in the research.
- II. Research Involving Pregnant Women or Fetuses. The two primary considerations of the IRB in evaluating research involving pregnant women or fetuses are (1) whether the research is directed to the mother's or fetus' health and (2) the risk to the woman and fetus. Pregnant women or fetuses may be involved in research if the IRB determines and documents in a protocol specific manner in the meeting minutes or review guide (as appropriate) that all of the following conditions are met:
 - A. 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 (45 CFR 46.204(a));
 - 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 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; and
- C. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; and
 - D. 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
 - E. Individuals engaged in the research will have no part in determining the viability of a neonate; and
 - F. Any risk is the least possible for achieving the objectives of the research.
 - G. Consent of the pregnant woman solely is obtained in accord with the informed consent provisions of 45 CFR 46 Subpart A when the research holds out:
 - a. The prospect of a direct benefit to the pregnant woman,
 - b. The prospect of direct benefit both to the pregnant woman and the fetus, or
 - c. No prospect of benefit for the woman or the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important medical knowledge which cannot be obtained by any other means.
 - H. Consent of the pregnant woman and father is obtained in accord with the informed consent provisions of 45 CFR 46 Subpart A when the research holds out prospect of direct benefit solely to the fetus, 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; and
 - a. Each individual providing consent as stated above, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
 - b. For pregnant women under 18 years of age, consent may be obtained from the minor subject when the research relates to expected medical or surgical procedures performed in pregnant women by the individuals and under the circumstances stipulated Illinois Consent by Minors to Medical Procedures Act (410 ILCS 210/1). When the research does not fall within the Act, assent from the pregnant minor and permission from the parent or guardian must be obtained as described in the UIC HSPP policy and procedure [Research Involving Children \(including Wards of the State\)](#).

III. Research Involving Neonates.

- A. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
 - 1. Where scientifically appropriate, pre-clinical 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 reasonable foreseeable impact of the research on the neonate;



3. Individuals engaged in the research will have no part in determining the viability of the neonate; AND
 4. The requirements of paragraph B or C of this section (refer below) have been met as applicable.
- B. 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 policy unless the following additional conditions have been met:
1. The IRB must determine that:
 - a. 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
 - b. 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
 - c. 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 45 CFR 46 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.
- C. Nonviable neonates. After delivery, a nonviable neonate may not be involved in research covered by this policy unless 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 any other means; and
 5. The legally effective informed consent of both parents of the neonate is obtained in accord with 45 CFR 46 Subpart A, except that the waiver and alteration provisions of §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 requirements of this paragraph.



- D. 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 with the requirements of 45 CFR 46 Subparts A and D.
- IV. Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material.
- A. 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, which may include the Illinois Anatomical Gift Act (755 ILCS 50).
 - B. 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 participants and all pertinent subparts of the regulations are applicable.
- V. 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.
- A. For research which is not federally funded 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 research is not approvable under the above provisions (sections II and III), the IRB will provide copies of the protocol and the IRB minutes to the HPA for a determination regarding whether an *ad hoc* panel of experts should be convened to review the research. In this case, UIC IRB approval will not be released until either the HPA determines that an *ad hoc* panel is not necessary or the *ad hoc* panel issues a recommendation that the research is acceptable based on either:
 - 1. That the research in fact satisfies the conditions above, as applicable; or
 - 2. The following:
 - a. 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;
 - b. The research will be conducted in accord with sound ethical principles; and
 - c. Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.
 - 3. Research which is federally funded and meets the conditions described in III(A) above must be sent to the Secretary of Health and Human Services for review and approval. The secretary will



determine the approvability based on the criteria stated in 45 CFR 46.207 (b).

VI. Modification or Waiver of Specific Requirements. Upon the request of the investigator (with the approval of the IRB), the Secretary of the Department of Health and Human Services may modify or waive any of the above requirements of federal law but not requirements of State law.

REFERENCES:

45 CFR 46.202, 45 CFR 46.116 (c)-(d), 45 CFR 46 Subparts A and D,
45 CFR 46 Subpart B, 45 CFR 46.202
The Illinois Anatomical Gift Act, 755 ILCS 50
The Illinois Consent by Minors to Medical Procedures Act, 410 ILCS 210/1
VHA Handbook 1200.05

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 3/10/12	1.0, 2/11/09	Updated VA requirements due to 2010 revision of VHA Handbook 1200.05; Added reference to Department of Defense regulations
1.2, 2/28/17	1.1, 3/10/12	Editorial revisions (logo, hyperlinks).