



Procedure Number: 308

**Institutional Review Board Review of
Research Involving Pregnant Women, Fetuses
and Nonviable Neonates**

Adopted: 11/2005

Revised: 03/2015

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INSTITUTIONAL REVIEW BOARD REVIEW OF RESEARCH INVOLVING PREGNANT WOMEN, FETUSES AND NONVIABLE NEONATES

DESCRIPTION

It is possible that pregnant women, fetuses, and neonates may be more vulnerable to harm from research participation than other populations. Additional protections may be needed because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. The University of Cincinnati (UC) Institutional Review Board (IRB) will ensure that appropriate additional protections are provided so the rights and welfare of these populations are maintained.

PREGNANT WOMEN, FETUSES, AND NEONATES:

- Includes pregnant women, human fetuses, neonates of uncertain viability and nonviable neonates. Viable neonates are included under Human Research Protection Program (HRPP) Procedure 332 *Institutional Review Board Review of Research Involving Minors* rather than under this Procedure;
- Includes the product of conception from implantation through birth;
- Does not include the placenta or dead fetus or fetal material after delivery.

RESPONSIBILITY

The IRB Chair or designee shall determine whether or not pregnant women, fetuses, or neonates will be recruited as participants in a research study and, if so, shall ensure that review processes described in HRPP Policy V.01 *Protecting Vulnerable Populations in Human Subject Research* are followed.

The IRB Chair or designee shall also determine when informed consent of the father is required for the woman, fetus or neonate to participate in a research study.

HRPP staff shall ensure that required documentation is maintained in the IRB's study records and meeting minutes.



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PROCESS

DEFINITIONS

Dead Fetus: A fetus that does not exhibit spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord (if still attached).

Delivery: Complete separation of the fetus from the mother by expulsion or extraction or any other means.

Fetus: The product of conception from implantation until delivery.

Neonate: A newborn.

Nonviable Neonate: A newborn after delivery that, although living, is not capable of independently maintaining heartbeat and respiration even with medical therapy.

Pregnancy: The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the presumptive signs of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.

Viable: As it pertains to the neonate, the ability, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

REVIEW CONSIDERATIONS

1. Is this vulnerable population specifically targeted for enrollment?

The IRB may determine that pregnancy is incidental to participation in the research and there will be no risk related to the woman's pregnancy, to the fetus, or to the neonate from participation. Research meeting this description may include, but is not be limited to, non-medical research involving questionnaire or interview procedures, or normal educational practices. In such a circumstance, the IRB may determine that additional protections identified in 45 CFR 46 Subpart B: *Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research*; HRPP Policy V.01 *Protecting Vulnerable Populations in Human Subject Research*; and this Procedure are not necessary and may be waived.



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2. Does the scientific or scholarly design of the study support inclusion of this vulnerable population?
3. Are there risks to participation in the research that are related to the vulnerability?

When potential participants are recruited from a population that includes women of child bearing potential who may not be pregnant at the time of enrollment into the study, the IRB shall determine if it is appropriate to inform participants that:

- Risks to the women, fetus, or nursing infants are currently unknown.
 - Becoming pregnant or causing a pregnancy should be avoided and, if a pregnancy occurs, the principal investigator (PI) should be notified immediately.
 - Becoming pregnant or causing a pregnancy must be avoided due to known harm to the developing fetus and, if a pregnancy occurs, the PI should be notified immediately.
 - The woman should not breastfeed an infant during or following participation in the research.
4. Will the vulnerable population receive direct benefit from participating in the research?
 5. Are the population-specific risks reasonable in relation to the anticipated benefits?
 6. Are protections adequate to avoid coercion during recruitment and consenting of this vulnerable population?
 7. Are these vulnerable participants able to withdraw from the study without penalty, undue influence or loss of benefits they would otherwise have?

REQUIREMENTS OF RESEARCH CONDUCTED AT VAMC

When research involves the Veterans Administration Medical Center (VAMC), additional protections or restrictions will apply as described in the Veterans Health Administration Handbook (VHA) 1200.5, Appendix D

- a. Research in which the participant is a fetus, in-utero or ex-utero (including human fetal tissue) must not be conducted by VAMC investigators while on official duty,



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or at VAMC facilities, or at approved off-site facilities.

- b. Research related to in vitro fertilization could not be conducted by VAMC investigators while on official duty, at VAMC facilities, or at approved off-site facilities.
- c. For research involving participation of pregnant women as research participants, the IRB must:
 - i. Determine that the proposed research meets the requirements as outlined in the VHA Handbook 1200.5, Appendix D.
 - ii. Determine that adequate provision has been made to monitor the risks to the participant and the fetus
 - iii. Determine that adequate consideration has been given to the manner in which potential participants are going to be selected, and that adequate provision has been made to monitor the actual informed consent process

DETERMINATIONS REQUIRING DOCUMENTATION

1. Pregnant women or fetuses may be involved in research only 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 non-pregnant 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 pregnant 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 risk to the fetus is not



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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 *HRPP Policy II.01 Obtaining Informed Consent In Human Subjects Research* and *HRPP Procedure 204 Obtaining Informed Consent In Human Subjects Research*

- e) The consent of the mother is obtained in accordance with the regulations. 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 *HRPP Policy II.01 Obtaining Informed Consent In Human Subjects Research* and *HRPP Procedure 204 Obtaining Informed Consent In Human Subjects Research* 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 (d) or (e) above, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
 - g) For minors who are pregnant, assent and permission are obtained in accord with the provisions of *HRPP Procedure 332 Institutional Review Board Review of Research Involving Minors*;
 - 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;
 - j) Individuals engaged in the research will have no part in determining the viability of a neonate.
2. Neonates 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 under (e) or (f) below is fully informed regarding the reasonably foreseeable impact of the research on the neonate;
 - c) Individuals engaged in the research will have no part in determining the viability



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of the neonate;

- d) The requirements of paragraph e or f below have been met as applicable.
- e) 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:
 - i. The IRB must determine 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;
 - ii. The legally effective consent of either parent of the neonate is obtained in accordance with the regulations. 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 HRPP Policy II.01 *Obtaining Informed Consent In Human Subjects Research* and HRPP Procedure 204 *Obtaining Informed Consent In Human Subjects Research*, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
- f) After delivery, a nonviable neonate may not be involved in research covered by this policy unless all of the following additional conditions are met:
 - i. Vital functions of the neonate will not be artificially maintained;
 - ii. The research will not terminate the heartbeat or respiration of the neonate;
 - iii. There will be no added risk to the neonate resulting from the research;
 - iv. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means;



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- v. The legally effective informed consent of both parents of the neonate is obtained in accord with HRPP Policy II.01 *Obtaining Informed Consent In Human Subjects Research* and HRPP Procedure 204 *Obtaining Informed Consent In Human Subjects Research*, except that the waiver and alteration provisions of informed consent 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 this requirement.
- g) If a neonate is judged viable, it is then called an infant and should be treated as a minor for purpose of research participation. All requirements of human subjects research, including special protections for minors will apply.
3. Research involving the placenta, the dead fetus, macerated fetal material or cells, tissue, or organs excised from a dead fetus after delivery shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities. Ohio Revised Code 2919.14 makes it a misdemeanor of the first degree to “experiment upon or sell the product of human conception which is aborted.” Autopsies are specifically permitted.

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 pertinent research participant protections are applicable.

4. Research that is 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 will be sent to the Secretary of the Department of Health and Human Services for review. The Secretary will determine the approvability of the research based on the conditions stated in 45 CFR 46.207.

Applicable Regulations and Documents:

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

Policy II.01 *Obtaining Informed Consent In Human Subjects Research*

Policy V.01 *Protecting Vulnerable Populations in Human Subjects Research*

Procedure 332 *Institutional Review Board Review of Research Involving Minors*

HRPP Procedure 204 *Obtaining Informed Consent In Human Subjects Research*



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Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/2005	C. Fabby	07/2007	M. Linke	Updated information on the Community Advisory Board involvement with protocol reviews.
		07/2008	M.Linke	Updated information with regard to epidemiologic research as 5 th category of research reviewed for prisoners
		07/2008	J. Gerlach	Updated information on the review of behavioral research including participants who are mentally disabled or with impaired decision-making capacity. Referenced relevant IRB Policies and Procedures for review of research involving vulnerable populations
	J. Gerlach	07/2009	J. Gerlach	Included information regarding Policy V.07
		04/2014	C.Norman	Major revision to change Procedure 308 (vulnerable populations in general) to address only Subpart B and Policy V.05 (Pregnant), and establish separate Procedures for other vulnerable populations.
		9/2014	A.Braggs-Brown	Revised to include AAHRPP recommendations
3/2015		3/2015	J. Strasser	Revisions for clarification

Date Adopted March 2015 Signature signed copy on file