

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/06/2020
	Research Involving Pregnant Women, Human Fetuses and Neonates		Policy 602

POLICY

1. Purpose

Define the special ethical and regulatory considerations that apply when reviewing research involving pregnant women, human fetuses and neonates.

2. Scope

This policy applies to federally funded research involving pregnant women, human fetuses and neonates, as well as federally funded research involving after delivery placenta, the dead fetus or fetal material. When the RSRB is the Reviewing IRB, the RSRB may also apply this policy to non-federally funded or non-medical research as guidance.

3. Definitions

- 3.1. Dead Fetus – A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
- 3.2. Delivery – Complete separation of the fetus from the woman by expulsion or extraction or any other means.
- 3.3. Fetus – The product of conception from implantation until delivery.
- 3.4. Neonate – A new born who is between the stage of delivery and determination of viability.
- 3.5. Nonviable Neonate – A neonate after delivery that, although living, is not viable.
- 3.6. Pregnancy – The period of time from confirmation of implantation of a fertilized egg within the uterus until delivery. A woman shall be 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.
- 3.7. 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.

4. References

- 4.1. HHS 45 CFR 46 Subpart B (46.201 – 46.207); FDA 21 CFR 50 subpart D; EPA 40 CFR 26 Subpart C
- 4.2. [Policy 601 Research Involving Children](#)

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5. Responsibilities

5.1. The Reviewing IRB is responsible for determining that the additional regulatory protections are satisfied during its review and approval of research involving pregnant women, fetuses and neonates (see Section 6), as well as the following additional considerations, as applicable to the proposed research:

- Whether women are appropriately represented in the research;
- Whether there is reason to exclude pregnant or lactating women and, if so, that the screening measures are adequate;
- For studies of breast-feeding women, that the process of lactation is not impeded;
- For studies of conception or contraception, whether the risks, benefits, reversibility, and alternatives are reasonably and adequately explained in the consent document;
- For contraceptive studies, whether there is adequate explanation to potential subjects of possible failure and of the options available for dealing with unintended pregnancies;
- For research conducted or supported by the Environmental Protection Agency (EPA), whether the protections under 40 CFR 26 Subpart C have been applied.

5.2. The Reviewing IRB is responsible for documenting their determinations supporting the approval of research referenced in this policy as applicable to the required conditions for the research population.

5.3. Investigators are responsible for ensuring that research is not proposed that involves the intentional exposure of pregnant or nursing women to any substance according to 40 CFR 26 Subpart C.

6. Requirements

Pregnant Women or Fetuses

6.1. *Pregnant women or fetuses* may be involved in research only if the Reviewing IRB finds that each of the following ten (10) conditions are met, as applicable, as per 45 CFR 46.204:

- 6.1.1. Scientific appropriateness – preclinical and clinical studies have been conducted (e.g., research involving pregnant animals and non-pregnant women) to provide sufficient data to assess potential risks to pregnant women and fetuses, as applicable to the proposed research.
- 6.1.2. Acceptability of potential risks and benefits – any risks are minimized to the extent possible in order to meet the research objectives.
- 6.1.3. Risks to the fetus are minimized – risks to the fetus are caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

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- 6.1.3.1. If there is no such prospect of benefit to the woman or to the fetus, the risk to the fetus is minimal, **and** the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- 6.1.4. Consent of the pregnant woman is obtained – consent is obtained in accordance with 45 CFR 46.116 and 117 if:
 - 6.1.4.1. The research has prospect of direct benefit to the pregnant woman; or,
 - 6.1.4.2. The research has prospect of direct benefit to both the pregnant woman and the fetus; or,
 - 6.1.4.3. There is no prospect of benefit for the woman nor the fetus, the risk to the fetus is minimal, **and** the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
- 6.1.5. Consent of the pregnant woman and father is obtained – consent is obtained per 45 CFR 46.116 and 117, if the research has the prospect of direct benefit solely to the fetus.
 - 6.1.5.1. Father’s consent is not required if he is unable to consent because of unavailability (e.g., deployed in the military), incompetence, or temporary incapacity, or the pregnancy resulted from rape or incest.
- 6.1.6. Individual(s) providing consent (i.e., the mother and father) are fully informed – the consent adequately presents the reasonably foreseeable impact of the research on the fetus or neonate.
- 6.1.7. Assent and permission obtained from pregnant children – for research that involves pregnant children, assent and permission are obtained per *Policy 601 Research Involving Children*.
- 6.1.8. Absence of any inducements to terminate a pregnancy.
- 6.1.9. Independence of researchers from decisions related to termination of pregnancy - no individual engaged in the research may have any part in decisions regarding termination of pregnancy (e.g., timing, method or procedures).
- 6.1.10. Independence of researchers from decisions related to determination of viability - no individual engaged in the research may have any part in decisions regarding viability of a neonate.

Neonates of Uncertain Viability / Nonviable Neonates

- 6.2. *Neonates of Uncertain Viability and Nonviable Neonates* – May be involved in research only if the Reviewing IRB finds that all four (4) of the following conditions are met [45 CFR 46.205]:
 - 6.2.1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
 - 6.2.2. The consent adequately presents the reasonably foreseeable impact of the research on the neonate.

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6.2.3. No individual engaged in the research may have any part in decisions regarding viability of a neonate.

6.2.4. The requirements of section 6.3 or 6.4 below have been met, as applicable.

6.3. *Neonates of Uncertain Viability* – Until it has been ascertained whether or not a neonate is viable, a neonate **may not** be involved in research unless the Reviewing IRB finds that the following additional conditions are met [45 CFR 46.205]:

6.3.1. The Reviewing IRB determines that:

6.3.1.1. 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

6.3.1.2. 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

6.3.2. Informed consent of either parent of the neonate is obtained or, if neither parent is able to consent because of unavailability (e.g., deployed in the military), incompetence, or temporary incapacity, informed consent of either parent’s legally authorized representative is obtained [45 CFR 46 subpart A].

6.3.2.1. Consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

6.4. *Non-Viable Neonates* – After delivery, a nonviable neonate **may not** be involved in research unless the Reviewing IRB finds that the following five (5) additional conditions are met [45 CFR 46.205]:

6.4.1. Vital functions of the neonate will not be artificially maintained;

6.4.2. The research will not terminate the heartbeat or respiration of the neonate;

6.4.3. There will be no added risk to the neonate resulting from the research;

6.4.4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

6.4.5. Informed consent of both parents of the neonate is obtained [45 CFR 46 subpart A], or if either parent is unable to consent because of unavailability (e.g., deployed in the military), incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will meet the requirements of this paragraph (6.4.5), except that the waiver and alteration provisions of 45 CFR 46.116(e) and (f) do not apply.

6.4.5.1. Consent of the father need not be obtained if the pregnancy resulted from rape or incest.

6.4.5.2. Consent of a legally authorized representative of either or both of the parents of a nonviable neonate does not meet the requirements of paragraph 6.4.5.

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6.5. *Viable Neonates* – After delivery, a neonate that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirements of 45 CFR 46 subparts A and D, 21 CFR 50 subpart D, and Policy 601 Research in Children.

Materials Used Involving After Delivery, Placenta, Dead Fetus or Fetal Material

6.6. 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 the regulations regarding such activities [45 CFR 46.206].

6.7. If information associated with material described above in section 6.6 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 the provisions of 45 CFR 46, subparts A and D, must be met as applicable.

Research That Must Be Presented to Department of Health and Human Services

6.8. Research that 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 may not otherwise be approved by the Reviewing IRB under the requirements presented under sections 6.1 – 6.6 of this policy, will be presented to the Department of Health and Human Services (DHHS) for further consultation with a panel of experts. Following an opportunity for public review and comment, DHHS will make a determination whether to approve the proposed research for funding under the requirements of 45 CFR 46.207(b)(1) or 46.207(b)(2).

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Appendices:

None

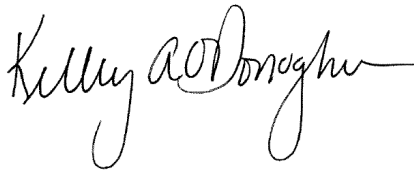
Revision History:

01/2015: Sect 4.1 and 5.1 EPA regulations added and Sect 5.3 added per AAHRPP
01/2018: Sect 4.2 add hyperlink; update throughout to reference Reviewing IRB
06/2020: Sect 6.4.5 Updated references per revised Common Rule; Update signatories

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01/30/2015

Approved By:



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11/06/2020

Date

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Date