IRB SOP 902
Research Involving Pregnant Women, Fetuses and Neonates

Purpose

This Standard Operating Procedure (SOP) describes the additional responsibilities and procedures involved when reviewing research that involves pregnant women, human fetuses and neonates or women who become pregnant while on a study

Scope

This SOP applies to all research involving pregnant women, human fetuses, and neonates, regardless of funding source

Fetus: The product of conception, from implantation until delivery.

Neonate: A newborn.

Nonviable neonate: A neonate after delivery that, although living, is not viable.

Viability of a neonate: Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Policy

IRBs must consider that research involving women of childbearing potential might involve pregnant women (and viable fetuses), and should evaluate research protocols and risks, inclusion and exclusion criteria, and informed consent procedures, with this in mind.

For research involving pregnant women as participants, the USA IRB follows federal regulations at 45 CFR 46 Subpart B in addition to those imposed under other USA IRB policies and procedures, ethical considerations and other applicable federal, state and local laws for review and approval.

The USA IRB approves research involving pregnant women by following the "Investigator Checklist for Research Involving Pregnant Women".

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Consent Decision Chart for Pregnant Women and Fetuses

	Direct benefit to mother only	Direct benefit to mother and fetus	Direct benefit to fetus only	No direct benefit or societal benefits only
Risk is more than minimal	Mother's			

1. The IRB determines that:

   i. 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

   ii. 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

2. 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 this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

both of the parents of a nonviable neonate will not suffice to meet

in accord with 28.0: Informed Consent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. (45 CFR 46.205(b)(2))

4.0 Nonviable Neonates

After delivery a nonviable neonate may not be involved in research covered by this subpart unless all the following additional conditions are met:

- Vital functions of the neonate will not be artificially maintained; (45 CFR 46.205(c)(1))
- The research will not terminate the heartbeat or respiration of the neonate; (45 CFR 46.205(c)(2))
- There will be no added risk to the neonate resulting from the research; (45 CFR 46.205(c)(3))
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and (45 CFR 46.205(c)(4))
- The legally effective informed consent of both parents of the neonate is obtained in accord with 28.0: Informed Consent, 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. (45 CFR 46.205(c)(5))

5.0 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 subparts A and D of 45 CFR 46.

Procedures

1.0 Investigator Responsibilities

1.1 Provide accurate information in the IRB application about the inclusion of pregnant women, fetuses or neonates.

HISTORY

Effective Date:
RevisionsNovember, 2018

Responsible Party:

Office of Research Compliance and Assurance