

Research Involving Neonates (nonviable or uncertain viability)

(HRPP 4.2)

(45 CFR 46 Subpart B)

Description:

This policy describes UNMC's requirements for IRB review and approval of research involving neonates (nonviable or of uncertain viability).

Definitions:

Viable Neonate: a neonate, after delivery, that can survive, with the benefit of available medical therapy, to the point of independently maintaining heartbeat and respiration.

Nonviable Neonate: a neonate, after delivery, that is living but not viable- that is, cannot survive independently, even with available medical therapy.

Research Involving Neonates of Uncertain Viability:

Neonates of uncertain viability may only be involved in research if:

- Where appropriate, preclinical studies have been conducted and provide data for assessing potential risks to neonates
- Each person providing Informed consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate
- Research staff have no part in determining the viability of a neonate
- The research:
 - Offers a prospect of survival to the point of viability, and any risk is the least possible, or
 - Aims to develop important biomedical knowledge, with no added risk to the neonate

OBTAINING CONSENT:

- Consent is needed from either parent
- If a parent is unavailable/incompetent/incapacitated, a LAR may consent
- Consent of the father/LAR is not needed if the pregnancy resulted from rape or incest

Research Involving Nonviable Neonates:

Nonviable neonates may be involved in research if:

- Where appropriate, preclinical studies have been conducted and provide data for assessing potential risks to neonates
- Each person providing Informed consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate
- Research staff have no part in determining the viability of a neonate
- Neonate's vital functions are not artificially maintained
- Research does not terminate heartbeat or respiration
- No additional risk to the neonate will result from the research
- The purpose of the research cannot be obtained by any other means

OBTAINING CONSENT:

Consent is needed from BOTH parents.

- If one parent is unavailable, incompetent, or incapacitated, then consent of one parent is fine
- Waiver of consent is NOT permitted
- Consent of the father/LAR is not needed if the pregnancy resulted from rape or incest
- LARs cannot substitute for the parents