

Research Involving Neonates (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).

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 individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- Individuals involved in the research will have no part in determining the viability of the neonate.
- The research holds out prospect of enhancing the probability of survival of the neonate to the point of viability and any risk is the least possible for achieving the objective OR the purpose of the research cannot be obtained through any other means and there is no added risk to the neonate.

Obtaining Consent:

Consent may be obtained from EITHER parent.

- If neither parent is able to consent, the consent must be obtained from either parent's LAR.
- The consent of the father (or their LAR) is not required 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 individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

- Individuals involved in the research will have no part in determining the viability of the neonate.
- Vitals of the neonate will not be artificially maintained.
- The research will not terminate the heartbeat or respiration of the neonate.
- 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 either parent is unable to consent, the consent of 1 parent is fine.
- Consent cannot be waived.
- Consent of the father is not required if the pregnancy resulted from rape or incest.
- Consent of a LAR of either or both parents is NOT permitted.