Waiving Consent for Emergency Research (HRPP 5.6)

Description:

This policy describes UNMC's requirements for IRB review and approval of a waiver of consent for emergency research.

Definitions:
Emergency Research: a planned clinical investigation involving subjects in life-threatening situations, requiring FDA pre-authorization, where existing treatments are unproven or unsatisfactory.

Conditions for Granting Waiver of Consent:

The IRB **must find ALL the following:**

- The potential subject is in a **life-threatening situation** with **no satisfactory or proven treatment**, and collection of valid scientific evidence is necessary to determine safety and effectiveness of particular interventions
- **Informed consent not feasible due** to:
  - Subject incapacity,
  - Inability to reach the subject's LAR in time, and
  - Inability to prospectively identify eligible subjects
- Research **offers potential direct benefit** because:
  - Subjects are facing a life-threatening situation that needs intervention
  - Appropriate preclinical studies were conducted and evidence supports potential for direct benefit
  - Risks are reasonable in relation to what's known about the medical condition, risks/benefits of standard therapy (if any), and what's known about the risks/benefits of the proposed intervention
- Research **could not be practicable conducted without the waiver**

- Protocol must define the length of the potential therapeutic window
- The PI must attempt to contact LAR during that window and, if feasible, ask them for informed consent within the window rather than proceeding without consent
- Summary of efforts to contact the LAR must be reported to IRB at continuing review
- **IRB must review and approve:**
    - Consent procedures & informed consent form to be used when feasible
    - Procedures and information to be used providing an opportunity for a family member to object to a subject's participation
- **Additional protections include at least:**
    - Consultation with representatives of the community prior to beginning the research
    - Public disclosure to the community of plans, risks, and benefits prior to beginning the research
    - Establishment of an independent Data Monitoring Committee
    - If obtaining informed consent is not feasible AND an LAR is not reasonably available, the PI is committed, if feasible, to attempting to contact a subject's family member who is not an LAR, asking whether they object to the subject's participation
    - PI will summarize efforts made to contact family members and inform the IRB during continuing review

Informing Subjects or Families:

- **If the subject remains incapacitated and the LAR or family are available:** inform them ASAP of the subject's participation and allow withdrawal
- **If the subject regains capacity:** inform them of their participation and consent rights
- **If the subject dies before the family/LAR are contacted:** inform the family/LAR of participation, if feasible

Protocols Subject to FDA Regulations:

- Protocol must be performed under a separate IND/IDE
- Must clearly identify the protocol as involving subjects unable to give informed consent
- Required even if an IND/IDE for the same drug/device already exists