

# 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 that requires prior written FDA authorization to proceed and involves subject(s) who are in a life-threatening situation for which available treatments or in vitro diagnostic tests are unproved or unsatisfactory.

## Conditions for Granting Waiver of Consent:

- The potential human subject is in a **life-threatening situation, available treatments are unproven or unsatisfactory**, and collection of valid **scientific evidence is necessary to determine safety and effectiveness** of particular interventions.
- **Obtaining consent is not feasible** because:
  - Subjects are not able to give consent due to medical condition
  - It is not feasible to obtain informed consent from the subject's LAR before the research intervention must be administered, and
  - There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation/research.
- **Participation in the research holds out the prospect for direct benefit** because:
  - Subjects are facing a life-threatening situation that needs intervention.
  - Appropriate animal and other pre-clinical studies have been conducted and evidence supports the potential for direct benefit.
  - Risks associated with the investigation are reasonable in relation to what's known about the medical condition, risks and benefits of standard therapy, if any, and what's known about the risks and benefits of the proposed intervention/activity.
- **The clinical investigation could not practicably be carried out without the waiver of consent.**
- The protocol defines the length of the potential therapeutic window.

- The PI will attempt to contact the LAR for each subject within the therapeutic window and, if feasible, ask the LAR for informed consent within that window rather than proceeding without consent.
- The PI will summarize efforts made to contact LARs and inform the IRB during continuing review.
- The IRB has reviewed and approved:
  - Informed consent procedures and 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 of the rights and welfare of subjects includes at least:
  - Consultation with representatives of the community prior to beginning the research.
  - Prior to beginning the research, public disclosure to the community of the plans, risks, and benefits.
  - Public disclosure of information following the completion of the investigation including demographic information of subjects and its results.
  - Establishment of an independent data monitoring committee.
  - If (a) obtaining informed consent is not feasible and (b) an LAR is not reasonably available:
    - The PI committed, if feasible, to attempting to contact a subject's family member who is not a LAR, asking whether they object to the subject's participation.
  - The PI will summarize efforts made to contact family members and inform the IRB during continuing review.

### **General Considerations:**

- Procedures must be in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the consent form, including that the subject, LAR or family member may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- If a LAR or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed.
- If the subject enters an investigation with waiver of informed consent and the subject dies before a LAR or family member can be contacted, information is to be provided to the LAR or family member, at the earliest feasible opportunity.

## **Protocols Subject to FDA Regulations:**

If a protocol involves a waiver of informed consent, it must be performed under an FDA approved separate investigational new drug (IND) application or investigational device exemption (IDE)

- Must clearly identify that the protocol may include subjects unable to give informed consent.
- Submission of these in a separate IND/IDE is required even if an IND for the same drug or IDE for the same device already exists.