Emergency Use of a Test Article (HRPP 6.4)

Description:

This policy describes UNMC's requirements for utilization of a test article under emergency circumstances where there is not sufficient time to obtain IRB approval at a convened meeting.

Definitions:

Emergency Use: the use of a test article on a human patient in a life-threatening or severely disabling situation when:

- No standard medically accepted treatment is available, and
- There is not enough time to obtain full IRB approval

Life-threatening: diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

Severely Debilitating: diseases or conditions that would likely cause major irreversible morbidity *(e.g. loss of limb, paralysis, stroke, etc.)*

When Emergency Use is Allowed:

Before using an unapproved treatment in an emergency, **all of the following must be met:**

- The test article has not previously been used to date under FDA emergency use provisions
- The patient's condition is life-threatening or severely debilitating
- No other approved or generally recognized treatments/therapies provide equal or greater likelihood of survival or alleviating the condition
- When possible/required, the holder of the IND or Ide has authorized emergency use
- If it's a medical device, a second, uninvolved physician agrees the emergency use is necessary
- There's not enough time to obtain full IRB approval

FDA Notifications:

Industry sponsor holds the IND/IDE	Investigator holds the IND/IDE	No IND/IDE exists
Sponsor notifies the FDA	Investigator notifies the FDA	Treating physician notifies the drug/device developer who will notify the FDA

Procedures:

- The treating physician must **contact the IRB Executive Chair/designee** who will determine if requirements have been met
- The treating physician **completes section I of the Emergency Use of a Test Article Report** and **develops a consent form in RSS**
- ORA issues acknowledgement that use of a test article satisfies the requirements
- **If it's an investigational drug or biologic and time allows,** the treating physician must:
    - Obtain emergency use approval from the Chair of the P&T Committee
    - Inform the Executive Director of the Pharmacy or Investigational Drug Pharmacist and arrange for pharmacy costs of the test article
- The treating physician **completes section II of the Emergency Use of a Test Article Report** through RSS within 5 business days following initiation of treatment
- Any **future uses of the test article** must have prospective IRB approval
- If the physician decides NOT to use the test article, they must inform the ORA

Informed Consent Requirements:

- Before using the test article, the **treating physician should obtain written informed consent from the patient** or their legally authorized representative (LAR).
    - **The consent form must:**
        - Comply with the requirements of Basic and Additional Elements of Consent (21 CFR 50.25 and HRPP Policy 5.1, section 4.1)
        - Clearly explain the emergency situation

        - Include potential risks and financial obligations
        - Mention privacy (HIPAA) protections
- **Informed consent is NOT required if** both the treating physician and a second, unaffiliated physician certify **all of the following:**
    - The subject is confronted by a life-threatening situation necessitating the use of the test article
    - Informed consent cannot be obtained because of the inability to communicate with or obtain legally effective consent
    - There is not sufficient time to obtain consent from the subject's LAR
    - No other approved or generally recognized treatments/therapies provide equal or greater likelihood of survival or alleviating the condition
- **If time is not sufficient to obtain an independent physician determination before the use of a test article:**
    - Actions of the investigator must be reviewed and evaluated in writing by an independent physician within 5-6 working days
    - An IRB must be notified within 5 working days of when the emergency waiver is used