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 debilitating circumstance where no standard medically acceptable treatment is available and there is not sufficient time to obtain full IRB approval for use of the test article to treat the patient.

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.)

IRB Requirements:

All of the following must be met:

- The test article **hasn't previously been used** to date under FDA emergency use provisions.
- A patient is suffering from **a life-threatening or severely debilitating condition.**
- There is **no available alternative** method of approved or generally recognized therapy that provides equal or greater likelihood of saving the patient's life and/or alleviating a debilitating condition.
- When possible and/or required, the **holder of the IND or IDE has authorized emergency use.**
- When the test article is a medical device, an **independent assessment, as appropriate, has been obtained from an uninvolved physician** that use of a test article is necessary.
- There **isn't sufficient time to obtain full IRB approval** of the protocol.

FDA Notification:

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 directly or thru the ORA who will determine if the 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.
- The ORA issues an acknowledgement that use of a test article satisfies the requirements.
- If the test article is an investigational drug/biologic and there is sufficient time, the treating physician must:
    - Contact the Chair of the P&T Committee and obtain emergency use approval.
    - Notify the Executive Director of the Pharmacy or Investigational Drug Pharmacist of the emergency use and include information regarding financial responsibility for the 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 the treatment.
- Any subsequent use of the test article must have prospective IRB review and approval.
- If the physician decides NOT to use the test article, they must notify the ORA.

Informed Consent:

- The treating physician should obtain written informed consent from the patient (or their LAR).
- Informed consent is NOT required if both the treating physician and the physician who is not participating in the use of the agent certify in writing:
    - The subject is confronted by a life-threatening situation necessitating the use of a test article.
    - Informed consent cannot be obtained because of the inability to communicate with or obtain legally effective consent.

    - Time not sufficient to obtain consent from the subject's LAR.
    - No available alternative method of approved or generally recognized therapy that provides equal or greater likelihood of saving the patient's life and/or alleviating a debilitating 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.
    - The IRB must be notified within 5 working days of when the emergency waiver is used.