Humanitarian Use Device (HUD) (HRPP 6.3)

Description:

This policy describes UNMC's requirements for the use of a medical device that has a Humanitarian Use Device (HUD) designation.

Definitions:

Humanitarian Use Device (HUD): a medical device intended to benefit patients by treating or diagnosing a disease or condition that affects not more than 8,000 individuals in the US per year. ***An HUD is a legally marketed device and not investigational.***

Humanitarian Device Exemption (HDE): Pre-Market approval application which is exempt from the requirement of establishing a reasonable assurance of effectiveness.

IRB Review Procedures:

- Using a HUD after review and approval by the IRB is **not considered human subjects research**
- **If doctors collect data about the safety or effectiveness** of an HUD to support an application for a pre-marketing approval constitutes a clinical investigation subject to FDA regulations:
    - If the data can be collected for the HDE-approved indication, no IDE required. If a different indication, FDA-approved IDE is required.
    - If the data is for a different use than what the HUD is approved for:
        - IRB required to make an SR/NSR determination
        - If SR, IDE is required
- The **full IRB must review and approve** HUD use before it can be used at the organization
    - **NOTE**: expedited review is NOT allowed

- **The IRB will review the HUD application, which must include:**
    - *A summary of how the doctor plans to use the HUD*
    - *Any screening procedures*
    - *The HUD procedure*
    - *Any tests or follow-up care*
    - *The consent form*
    - *Any product information or labels from the sponsor*
- **Once a HUD is approved for use at the organization,** subsequent use of the HUD does not require additional review
- **An HUD may be used outside its approved indication once it is approved for use within the Organization**
- In **emergency situations,** a HUD can be used without prior IRB approval in accordance with HRPP Policy 6.4
- Written informed consent is usually required before a HUD is used on a patient. The **consent form must:**
    - *Explain that the device is designed to diagnose or treat the disease/condition and there are no comparable options*
    - *State the device's effectiveness for this use has not been developed*
    - *Describe any related procedures*
    - *Describe how the device is used*
    - *List any known risks or discomforts*
    - *Explain how the device is thought to work in relation to the disease/condition*
    - If the HUD is being used for something it's not approved for, the consent form must clearly say so *(Ex. "The device is approved for X, but is being used for Y.")*
- **Written informed consent is not required if ALL the following are true:**
    - *The patient is in a life-threatening or severely debilitating situation*
    - *The patient can't communicate or legally consent*
    - *There's no time to get consent from an LAR*
    - *No other approved or generally recognized therapy offers the same or better chance of saving the patient's life*
- Continuing review of the use of the HUD is required annually
    - **NOTE**: this re-review may be done through an expedited process