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): 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/Assessment:

- The use of an HUD after review and approval by the IRB does not constitute human subject research.
- Collection of safety and efficacy data about an HUD to support an application for a pre-marketing approval constitutes a clinical investigation subject to 21 CFR 50, 56.
    - If data can be collected in a clinical investigation for the HDE-approved indication, no IDE is required. If a different indication, FDA-approved IDE is required.
    - If data is being collected in a clinical investigation for a different indication than the HDE-approved indication:
        - IRB required to make an SR/NSR determination.
        - If SR, IDE is required.

- Written informed consent is NOT required from patients receiving an HUD **if all the following are met:**
    1) Patient is confronted by life-threatening or severely debilitating situation necessitating use of a test article.
    2) Informed consent cannot be obtained from the patient due to the inability to communicate with or obtain legally effective consent.
    3) Time not sufficient to obtain consent from the patient's LAR.
    4) There is no alternative method available that is approved or generally recognized that provides equal or greater likelihood of saving the patient's life.