6.3 Humanitarian Use Device (HUD)

Last Revised: 5/26/2021

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for the use of a medical device that has a Humanitarian Use Device (HUD) designation.

2.0 Policy

It is the policy of the Organization that all uses of an HUD will be reviewed and approved in accordance with FDA regulations at 21 CFR 50, 56 and 814 Subpart H, as well as HHS regulations at 45 CFR 46.

3.0 Definitions

- **3.1.** ***Humanitarian Use Devices (HUD):*** HUDs are 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 is not investigational.
- **3.2.** ***Humanitarian Device Exemption (HDE):*** HDE is a Pre-Market Approval application which is exempt from the requirement of establishing a reasonable assurance of effectiveness. HDE approval is based upon, among other criteria, a determination by FDA that the HUD will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use while taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

4.0 IRB Review Procedures

- **4.1.** The use of a HUD after review and approval by the IRB does not constitute human subject research.
- **4.2.** The 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.
  - **4.2.1.** If data can be collected in a clinical investigation for the HDE-approved indication no IDE is required. If data is being collected for a different indication than

the HDE-approved indication, the clinical investigation requires an FDA-approved IDE.
    - **4.2.2.** If data is being collected in a clinical investigation for a different indication than the HDE-approved indication, then the IRB is required to make an SR/NSR determination (as required by 21 CFR 812.66). If the IRB, the sponsor or the FDA has made a SR determination then the clinical investigation requires an IDE.
- **4.3.** The convenved IRB will review and approve the use of an HUD before it is used within the organnization. Expedited review will not be used.
- **4.4.** The IRB will review the HUD application, which must include a summary of how the physician proposes to use the device, a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures; the consent form; and any additional materials supplied by the sponsor including the product labeling; and any patient information.
- **4.5.** The IRB will review the use of the HUD following the review criteria in 21 CFR 56.111.
- **4.6.** Once an HUD is reviewed and approved within the organization, subsequent use of the HUD does not require additional review.
- **4.7.** An HUD may be used outside its approved indication once it has been reviewed and approved within the organization.
- **4.8.** An HUD may be used in an emergency situation without prior IRB approval in accordance with the applicable sections of HRPP policy 6.4 (Emergency Use of a Test Article).
- **4.9.** The UNMC IRB requires that written informed consent be obtained from patients who will be recipients of HUDs, except as described in section 4.10.
    - **4.9.1.** The Consent Form should include at least (1) an explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition; (2) a statement that effectiveness of this device for this use has not been demonstrated; (3) a description of any ancillary procedures associated with the use of the HUD; (4) a description of the use of the HUD; (5) all known risks or discomforts; (6) and an explanation of the postulated mechanism of action of the HUD in relation to the disease or condition.
    - **4.9.2.** If the HUD is being used outside its approved indication the Consent Form must be modified to state that the HUD is being used outside its approved indication (for example, “the device is safe and probably effective for X, but it is being used for Y …”)
- **4.10.** Written informed consent is not required from patients who will be recipients of HUDs if all of the following conditions are met:
    - **4.10.1.** The patient is confronted by a life-threatening or severely debilitating situation necessitating the use of the test article.
    - **4.10.2.** Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from the patient.
    - **4.10.3.** Time is not sufficient to obtain consent from the patient’s LAR.
    - **4.10.4.** There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the patient’s life.
- **4.11.** Continuing review of the use of the HUD is required no less often than annually. The Continuing Review application will be reviewed via expedited process (as per HRPP policy 2.3; Expedited Review).

DOCUMENT HISTORY:

? Written: 1/12/2016 (Approved: 1/12/2016) - original author not recorded

? Revised: 2/12/2018 - revision not documented

? Revised: 5/26/2021 - Clarified requirement for IDE and for SR/NSR determination when conducting a clinical investigation with an HUD; clarified materials to be reviewed by the IRB; clarified that use of HUD off-label is allowable without additional review; described specific additional information to be included in the CF if HUD is used outside its approved indication; stylistic and organization changes.

Revision #7
Created 24 October 2019 21:41:38 by Autumn M Eberly
Updated 17 April 2025 16:07:47 by Robert A Lewis