

Humanitarian Use Device Responsibilities

A WMed IRB Guidance Document

When the HUD regulations were passed in 1996, the goal was to provide incentives to manufacturers to produce devices for small groups of patients. The equivalent on the drug side is the orphan drug regulations. As a last minute addition, FDA decided to have a local committee review the use as an additional protection for these patients given that the manufacturer only has to provide some limited safety data to FDA, not efficacy data.

An approved HDE (Humanitarian Device Exemption) authorizes the manufacturer (HDE holder) to market the HUD for clinical use. The following responsibilities are required by FDA.

Physician Responsibilities

- Obtain Institutional Review Board (IRB) approval **before** a HUD is used. Approval must be institution specific
- Control availability of the device within the institution
- Ensure that the HUD is used within the scope of its labeling (i.e., Indication listed in the Directions for Use)
- Protect patients' rights and welfare
- Retain specific records and issue reports according to IRB conditions
- Report device malfunctions and device related serious injuries/deaths to the IRB and the manufacturer
- Obtain authorization for emergency device use from the IRB and the HDE holder **prior** to device use.⁴

IRB Responsibilities

- Protect patients' rights and welfare
- Perform initial review of the HUD (must be a **full board** review) and provide approval for licensed physicians meeting the requirements of the FDA labeling
- Perform continuing annual review, at a minimum, using the expedited review procedures unless the IRB determines that a full board review is required
- Maintain awareness that HUD use should not exceed the scope of the FDA-approved indication
- Control availability of the device within the institution upon the termination of use of the HUD
- Assign special controls, if determined necessary (e.g., specific physicians, quantity limitations, semi-annual reviews)
- Ensure physicians promptly report unanticipated problems involving risk to patients to the IRB and to HDE holder

HDE Holder Responsibilities

- Ensure that the HUD is used only in facilities with IRB approval and by designated individuals approved for using the HUD
- Maintain records of the names and addresses of the facilities to which the HUD is shipped
- Maintain records of correspondence with reviewing IRBs as well as other information requested by a reviewing IRB or by FDA
- Submit annual reports to FDA of device clinical experience, including safety, Medical Device Reporting (MDRs), data generated from post-market studies, and information (whether published or unpublished) that affects an evaluation of the safety of the device or that affect the statement of contraindications, warnings, precautions, and adverse reactions in the device's labeling
- Report device malfunctions, device related serious injuries/death as MDR reports to FDA and the IRB of record
- Report any emergency or compassionate device use to FDA
- Refrain from all off-label promotion

Emergency Use

A HUD may be used in an emergency situation or prior to full IRB committee review and approval, provided certain conditions are met **prior to device use**. Emergency situations are those in which:

- The patient has a life-threatening condition that needs immediate treatment
- No generally acceptable alternative treatment for the condition exists
- There is no time to use existing procedures to get FDA approval for the use

The following are requirements for:

Physician prior to device use

- Complete training
- Obtain IRB chairperson's concurrence
- Obtain informed consent from the patient/legal guardian
- Obtain independent assessment from an uninvolved physician
- Obtain authorization from the HDE holder

Physician following device use

- Report the emergency use to their IRB within five days of HUD use
- Submit a written report on conditions constituting the emergency, patient protection measures taken, and results of the case to the HDE holder

HDE holder

- Authorize access of HUD to the physician prior to each emergency use
- Obtain a follow-up report from the physician
- Report the emergency use to FDA