Humanitarian Use Device Policy and Procedure

This policy only applies only to the use of a HUD for diagnosis and treatment. If systematic safety or efficacy data are collected, the use is for research purposes and a complete IRB application must be submitted (and an IDE may be required). Research HIPAA Authorization is then also required.

As defined by 21 CFR 814.3(n), a Humanitarian Use Device (HUD) is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.” The HUD designation is granted by FDA Office of Orphan Products Development.

If the FDA Office of Device Evaluation makes the determination that the HUD does not pose unreasonable risk of injury to patients and that the probable benefit outweighs risk of injury from its use, it may grant a Humanitarian Device Exemption (HDE).

The labeling for the HUD must state that the device is a Humanitarian Use Device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

An HDE authorizes marketing of the HUD. However, a HUD may only be used in facilities that have established a local institutional review board (IRB) and after an IRB has approved the use of the device to treat or diagnose the specific disease.

Initial review of a HUD request must take place at a convened IRB meeting.

**Terms**

**Humanitarian Use Device (HUD):**
Designation made by FDA Office of Orphan Products Development. The HUD designation must be made in order for a device to qualify for an HDE.

**Humanitarian Device Exemption (HDE):**
Granted by FDA Office of Device Evaluation; A HDE authorizes an applicant to market a Humanitarian Use Device subject to certain restrictions

**HDE Holder:**
The entity that applied for and was granted the HDE; usually the device manufacturer

**Patient Information Packet:**
Most HDE holders develop patient information packets that contain a discussion of the potential risks and benefits of the HUD and any procedures associated with its use.

**Off-Label Use of a HUD:**
Use of the HUD for clinical care in a manner not consistent with the HDE approval order.

**Device Related Event:**
A device related death or adverse event is one in which the device caused or contributed to the death or adverse event.
Each of the following conditions must exist for the Einstein IRB to consider approval of a Humanitarian Use Device for clinical care or treatment of patients:

- No generally acceptable alternative for treating the patient is available; and
- The manufacturer of the device has received a Humanitarian Device Exemption; and
- The HUD is to be used according to its approved labeling and indication(s) to treat or diagnose patients;
- If the HUD is intended to be used for the care or treatment of pediatric patients (patients under 22 years of age), the HDE authorization specifically includes pediatric patients.
- No safety or efficacy data is to be collected beyond that mandated by the FDA as part of the humanitarian approval (any such data must be clearly specified in the submission); and
- The health care providers are qualified through training and expertise to use the device.

The following information will be provided by the applicant and reviewed by the Einstein IRB at a convened meeting. If any safety or efficacy data are being collected, the use of the device is investigational and additional documents must be submitted to the IRB so that use of the device may be reviewed as research. The following list of requirements is applicable only to the use of an HUD in clinical care and treatment, not investigational use.

- Copy of the HDE (if available);
- Approval by the Department Chair certifying that the providers are credentialed to use the device;
- Conflict of Interest forms
- Consent form for the use of the device;
  a. The consent for the use of the HUD must be the IRB-approved consent document.¹
- Product labeling;
- Patient information packet²

Adverse Event Reporting when using a Humanitarian Device for Treatment or Diagnosis

Providers must submit reports to FDA, the IRB, and the manufacturer whenever a HUD may have caused or contributed to a death, and must submit reports to the manufacturer (or to FDA and the IRB of record if the manufacturer is unknown) whenever a HUD may have caused or contributed to a serious injury (21 CFR 803.30 and 814.126(a)). Serious injury means an injury or illness that (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure (21 CFR 803.3).

Device related deaths should be reported to the FDA, IRB and manufacturer within 48 hours. Reports to the FDA are made using the Medical Device Reporting system at 21 CFR 803. Serious device related adverse events should be reported to the IRB and manufacturer within 10 days.

¹ Exceptions to this requirement may be approved by the IRB on a case-by-case basis and the HUD provider must then document that each patient receives the sponsor’s patient information packet. (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf)
² All FDA approved HUD Patient Information Packets are available at www.fda.gov under “Listing of CDRH Humanitarian Device Exemptions”. (Choose the HDE number and then “Consumer Information”.)
Off Label Use of an HDE

A HUD may be used off-label when the HUD is the only option available for a patient(s) faced with a serious or life-threatening condition. Off-label use requires preapproval from the IRB chair and HDE holder, unless it is an emergency. Emergency uses of an HUD must follow the emergency use policy.

Physician Responsibilities when using a Humanitarian Device for Treatment or Diagnosis:

- Obtain IRB approval and continuing approval
- Follow IRB requirements
- Document Informed Consent as above
- If the HDE holder has developed a patient information packet available, ensure it has been given to patients as part of the informed consent process
- Report deaths and adverse events as described above
- Obtain IRB and HDE holder preapproval for any "off label" use

Progress Reports
The IRB requires an annual progress report be submitted for the HUD. The IRB may also vote to accept Expedited review of Progress Reports. This decision must be documented in the minutes. Continuing approval is granted based on review of the Progress Report by the IRB.