Background:

Humanitarian Use Devices (HUDs) are a special class of device that is marketed under the Humanitarian Device Exemption (HDE) approval process by the FDA. HUDs are intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States per year. HUDs are given a special class of FDA approval because they probably effective for their intended condition. With this limited approval, the FDA requires IRB review and approval at full board before these devices can be used to treat patients.

SECTION I: Definitions

the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval

also called 'Expanded Access', a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available

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 8,000 individuals in the United States per year (FDA 21 CFR 814.3(n)).

An HDE application is a marketing application that is similar to a premarket approval (PMA) application in that the applicant must demonstrate a reasonable assurance of safety, but in an HDE application, the applicant seeks an exemption from the PMA requirement of demonstrating a reasonable assurance of effectiveness. A device that has received HUD designation is eligible for HDE approval if, among other criteria, the device 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, taking into account the probable risks and benefits of currently available devices and alternative forms of treatment.

A non-significant risk (NSR) device is one that does not meet the definition of a significant risk device.

when a FDA approved device or drug is used for a purpose that is not approved by the Food and Drug Administration.

device study involves an investigational device that either-

- is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a research subject;
- Is meant to be used to support or sustain human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Plays an important role in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject;

The above only refers to compassionate use for *devices*. Please refer to IRB SOP 1003: Compassionate/Treatment Use for information on compassionate use in drugs.

The emergency use of a HUD must be followed according to ***IRB SOP 1002: Emergency Use: Investigational Drugs, Biologics and Device***

After emergency use occurs, the physician must submit a follow-up report on the patient's condition and information regarding the patient protection measures to the USA IRB and to the manufacturer within five (5) working days. The reporting criteria is listed in IRB SOP 1002 noted above.

SECTION III: USA IRB HUD Application Requirements

The HUD user or designee must complete and submit the following documents:

- IRB Application
- Clinical informed consent or informed consent document from HDE holder
- Letter from FDA to the HDE holder (indicates that an application for the HUD has been reviewed and approved by the FDA)
- Device Operator's Manual, if applicable
- HUD brochure / patient labeling or other consumer information, if applicable
- HUD training certificate (see Section IV below)

It is a federal requirement to provide all HUD patients with the labeling and patient materials (such as patient information brochure) prepared by the HDE holder prior to the patient receiving the whenever feasible.

Section IV: HUD Training Requirements

The Investigator must ensure that physician/investigators possess the credentials necessary to use the device, are knowledgeable regarding the use of the device and abide by terms of the USA IRB approval letter.

- In the event the FDA requires training, the HUD user and all other health care providers that may potentially use the HUD device at USA must receive training by the HDE holder.
- The FDA approval orders of HDEs are available for review on their website, at (just select the HDE number): http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm#2

SECTION V: IRB Review

IRB review is required for several reasons, all related to patient safety. The statue and the regulations require initial review by a convened IRB. However, there is an exception to this rule for emergency situations in which the physician determines that approval cannot be obtained in time to previous serious harm or death to the patient. With respect to HUD review, the IRB will consider the ethical impact related to the use of the device and patient safety. The HUD IRB Application form must be

Yes, a HUD may be used for compassionate use. This is the third type of “use” as described above, i.e., off label, non-emergent. In addition to addressing the patient protection measures, prior FDA approval of the HUD for compassionate use is required just as it is for compassionate use of any unapproved device. According to the FDA’s policy on compassionate use, a physician who wishes to use a device for compassionate use should provide the HDE holder (manufacturer) with a description of the patient’s condition and the circumstances necessitating treatment with the device, a discussion of why alternative therapies are unsatisfactory, and information to address the patient protection measures. For compassionate use of a HUD, the physician should provide this information to the manufacturer, who would then submit a HDE amendment for FDA approval before the use occurs. FDA will review the information in an expeditious manner and issue its decision to the HDE holder. If the request is approved by FDA, the physician should devise an appropriate schedule for monitoring the patient, taking into consideration the limited information available regarding the potential risks and benefits of the device and the specific needs of the patient. The physician must submit a request to the IRB for the compassionate (off label) use of the device with the manufacture’s authorization, FDA authorization, and a written description for monitoring the patient following use. The IRB will expedite this request. The physician may not use the device until he as received concurrence from the IRB. 3 The physician must submit a report to the manufacturer and the IRB following use of the device reporting on the patient’s outcome and progress.