# Humanitarian Devices (HUD)
# IRB Approval and Use

**Definitions/Acronyms**

**HUD** – Humanitarian Use Device
**HDE** – Humanitarian Device Exemption
**IRB of Record** - the IRB approving the use of the HUD
**MDR** -
**The Act** – Food, Drug, and Cosmetic Act
**PMA** – Premarket Approval
**Serious Injury** (per 21 CFR 803.3) -
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

As defined in 21 CFR 814.3(n), a 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."

## INITIAL Review of a HUD

A HUD may only be used **after IRB approval at a convened meeting** has been obtain for the use of the device, except for an emergency use situation, **and only for the indication for which it is FDA-approved**.

Clinical investigation of a HUD **for a different indication** must be conducted in compliance with the IDE regulations at 21 CFR Part 812, in addition to requiring IRB approval (21 CFR Part 56) and protection of Human Subjects (21 CFR Part 50). Physicians wishing to study a HUD for a new indication must submit an IDE application to the FDA if the device is a significant risk device. Physicians may be either the sponsor or investigator of the study or they may want to involve the HDE holder as the sponsor. The investigational use of a HUD under these circumstances is a clinical investigation and must be conducted in accordance with 21 CFR Parts 812, 50, 54, and 56.

Information that is required for INITIAL Review of a Humanitarian Device Request

- Letter to IRB requesting review of a new HUD to include:
  - Discussion justifying the need for access to the HUD requested
  - Discussion comparing/contrasting other devices currently available for use at the facility.
  - A summary of how the physician proposes to use the device, including:
    - A description of any screening procedures
    - The HUD procedure
    - A patient follow-up visits, tests, or procedures
- A copy of the HDE approval order
- A description of the device
- The product labelling
- The patient information packet that may accompany the HUD
- A sample consent form for the use of the HUD, required by the IRB

The IRB is responsible for reviewing the risks to patients that are found in the product labeling, ensure the risks are minimized, and evaluate whether the risks are reasonable in relation to the proposed use of the device.

The IRB is not required to review and approve each individual use of a HUD. The IRB may use its discretion to determine how to approve use of a HUD. For example, with the input of members with the appropriate expertise in the clinical area (21 CFR Part 56), an IRB may specify:

- limitations on the use of the devise based upon one or more measures of disease progression, prior use and failure of any alternative treatment modalities
- reporting requirements to the IRB or IRB chairperson
- appropriate follow-up precautions and evaluations
- or any other criteria it determines to be appropriate

## Continuing Review

The IRB will conduct a continuing review of all HUDs at least annually

Information required for Continuing Review of a HUD include:

- # of uses of the HUD since the last review and the outcomes of each use
- Copies any safety information submitted to the FDA in the periodic reports required by 21 CFR 814.126(b)(1)

## Reporting Requirements

Device user facilities and manufacturers are required to submit medical device reports to the FDA and the "IRB of record" (the IRB approving the use of the HUD) (see 519(a) and (b) of the Act; 21 CFR 803.50, and 814.126(a)). Among these requirements, manufacturers must submit reports to the FDA and the IRB of record whenever a HUD may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (21 CFR 803.50 and 814.126(a)). User facilities must submit reports to the FDA, the IRB of record, and the manufacturer whenever a HUD may have caused or contributed to a death, and must submit reports to the manufacturer (or to the 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)).

## Informed Consent

The Navicent IRB requires informed consent be obtained that specifically informs the patient that they are being exposed to a device that is approved by the FDA for Humanitarian Use consistent with the approved labeling for that HUD.

The consent should include the following statement clarifying that the device is approved as a Humanitarian Use Device for its intended use and that effectiveness has not been demonstrated;

***"This is a Humanitarian Device. Authorized by Federal law for use in the [treatment or diagnosis] of [specify disease or condition]. The effectiveness of this device has not been proven."***

If the HDE holder has developed a patient information packet containing a discussion of the potential risks and benefits of the HUD and any procedures associated with its use, the IRB requires that such packet be distributed to patients prior to their receiving the HUD. The patient information packet is in addition to the required informed consent.

HUD patient information packets may be found by going to:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm#2 and select the HDE number

## Emergency Use of a HUD

In an emergency, the IRB chairperson should be contacted prior to use of the device whenever possible.
If a physician **in an emergency** determines that IRB approval for the use of the HUD at a Navicent Health facility cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used without prior IRB approval. The physician must report the emergency use immediately and within five (5) days of its use; provide written notification of the use to the IRB chairperson including identification of the patient involved, the date of the use, and the reason for the use. (See section 520(m)(4) of the Act; 21 CFR 814.124)

## After IRB approval: Use of HUD outside of its approved indication(s) in an emergency or if the physician determines there is no alternative device for the patient's condition

Physicians should be cognizant that the FDA has made a determination of safety and probable benefit for use of the HUD only within its approved indication(s). If a physician wants to use a HUD outside its approved indication(s), the physician should contact the IRB chairperson prior to its use whenever possible.

Based on FDA recommendation, the IRB requires that the physician obtain informed consent from the patient and ensure reasonable patient protection measures are followed, such as devising schedules to monitor the patient, taking into consideration the patient's specific needs and the limited information available about the risks and benefits of the device.

The physician should submit a follow-up report on the patient's condition to the HDE holder and IRB of record. In Addition, any required MDR reports must be submitted to the FDA and IRB of record if the device may have caused or contributed to death or serious injury and for certain malfunctions as required.