

## Institutional Review Board (IRB) - Humanitarian Use Device

### I. Policy Statement:

Clinical use of a HUD is not considered to be research; however, Trinity Health requires IRB review prior to the use of an HUD. The sponsor of the device must complete an HDE application with the FDA to be considered for HUD status. The FDA approval of an HDE allows a HUD to be marketed, and labeling must state the effectiveness of the device has not been determined. IRB approval is required before a HUD approved under an HDE can be used, except for emergency use.

The purpose of this policy is to describe Humanitarian Use Device (HUD) requirements for the investigator/physician and the Institutional Review Board (IRB). This policy applies to all HUDs administered when the Trinity Health West Region (THWR) Institutional Review Board (IRB) is the IRB of record and the HUD is used at a THWR clinical site.

### II. Definitions:

#### **Humanitarian Device Exemption (HDE):**

An HDE application is similar to a premarketing application (PMA) but is exempt from the effectiveness requirements of a PMA. An HDE is not required to contain results of scientifically valid clinical investigations demonstrating that the device is effective for the intended purpose. The HDE must contain enough information for the FDA to determine that the probability of benefit to health outweighs the risk of injury or illnesses, considering the probable risks and benefits of currently available devices or alternative forms of treatment.

#### **Humanitarian use device (HUD):**

A device that is 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. HUDs can be used (i.e., marketed) without having been shown to meet the standard effectiveness criteria applied to other devices. Clinical use of a HUD is not considered to be research, but the FDA nonetheless requires IRB review prior to use.

#### **HDE holder:**

The person who obtains the approval of a humanitarian device exemption (HDE) from the FDA. Once HDE is approved, the HDE holder is responsible for ensuring that the HUD is used only under the review and oversight of an IRB.

#### **Premarket Approval (PMA):**

Devices requiring premarketing applications are Class III high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process (21CFR814). The PMA process is more involved and includes the submission of clinical data to support claims made for the device.

### III. Equipment: None

#### IV. Procedure:

##### A. On Label Use of a HUD

###### 1. Clinical Care

- a. When a HUD is used *on label* for clinical care and no safety and effectiveness data is being collected, having an investigator is not necessarily a requirement, and the physician utilizing the device would be considered the HUD holder.
- b. If the device is being used within the scope of the FDA HDE Approval Order it does not constitute a clinical investigation. The IRB may approve the device for any qualified physician at the hospital or limit the use to only certain physicians.
- c. Submission of a protocol to the IRB is not required for the use of a HUD in this manner, but IRB review is required and the following should be included with the HUD application within IRB Manager.
  - A summary of how the physician will use the device, including screening measures and activities.
  - A copy of the HDE approval and identity of the holder.
  - A description of patient follow-up visits, planned tests or other procedures required when the HUD is used.
  - A description of the screening procedure and the HUD procedure.
  - Product labeling.
  - Patient information packet including the device implant identification card.
  - Brochures including Summary of Safety and Probable Benefits (if available)
  - Patient letter of acknowledgement and Authorization of HIPAA (Note: An informed consent document is not required by the regulations; however, the THWR IRB does require the use of an informed consent for treatment.

###### 2. Safety & Efficacy

- a. If safety and effectiveness data is being collected when a HUD is used *on label* as part of clinical care to support a PMA, the project should be submitted to and reviewed by the IRB via submission of an IRB application (See references section for further information).
- b. The FDA considers HUDs studied *on label* for safety and efficacy to be exempt from the requirement for an IDE if the HUD is used in accordance with its approved indications.

###### 3. Emergency Use

- a. If a physician, in an emergency situation, determines that IRB approval for the *on label* use a HUD cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used without prior IRB approval.
- b. If this should occur, the physician must submit written notification within 5 days after the HUD is administered.
- c. Written notification should be made through submission of the **Single Patient Emergent Use Form** within IRB Manager and include a description of the date the HUD was used, the reason for use and a description of the patient's condition.
- d. Follow-up reporting is required and is described within ***Trinity Health West Region IRB Policy: Emergency Use of FDA-Regulated Test Articles.***

##### B. Off Label Use of a HUD

1. Off-label use is commonly used in clinical care for patients who are experiencing an emergency situation, and this type of use is not under the purview of the IRB.

2. Submission of an IRB Application for Review is required when using a HUD to study a new indication (off-label) and collecting safety and efficacy data. This is considered a clinical investigation and subject to IRB oversight.

**C. IRB Review of a HUD**

1. Prior IRB review is required when using HUDs, with the exception of emergency use.
2. Initial review of a HUD will be conducted at a convened meeting.
3. Continuing reviews for an on-label HUD may be conducted utilizing the expedited review process, as the use of the HUD within its approved labeling does not constitute research. This is permissible by the FDA.
4. Continuing review of a HUD used off-label will be reviewed by the full-board IRB, unless eligible for expedited review.
5. Continuing review materials should include submission of any medical device reports and/or the sponsor/manufacturer's annual report to FDA.
6. Serious adverse events including device malfunctions or any unanticipated device effects must be submitted to the IRB for review by the physician as soon as they become aware that the device may have caused or contributed to a death or serious injury. These events must be sent to the FDA by the HDE holder.

**D. Documentation & Correspondence**

1. The holder of the HDE will be notified in writing of the IRB review and determinations.
2. The type of review will be documented in the IRB meeting minutes or the IRB determination letter as well as the approval status by the IRB.
3. A holder of an approved HDE shall notify FDA of any withdrawal of approval for the use of a HUD by the reviewing IRB within 5 working days after being notified of the withdrawal of approval.

**V. Ministry Specific Related Addendums, Procedures, and/or Policies:**

- A. Saint Agnes Medical Center: None
- B. Saint Alphonsus Health System: None

**VI. Additional Approval:** Not applicable.

**VII. References**

Humanitarian Use Devices 21CFR814.124

Humanitarian Device Exemption (HDE) Program Guidance for Industry and Food and Drug Administration Staff