**The Christ Hospital IRB**
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# STANDARD OPERATING PROCEDURE

## Humanitarian Use Device

## DESCRIPTION

A Humanitarian Use Device (HUD) is a medical device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. The Office of Orphan Products Development (OOPD) determines if a device meets specific requirements, including scientific rationale and population prevalence, for designation as a HUD.

A HUD that has been granted a Humanitarian Device Exemption (HDE) by the FDA may be administered only if such use has been approved by the Institutional Review Board (IRB). Once IRB approval has been granted, use of the HUD within the approved indication(s), as well as other clinical uses that are intended solely to address the specific needs of an individual patient is allowed. If IRB approval cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB. (For more information on Emergency Use, refer to *IRB SOP 1.10 Emergency Use*). All uses of the HUD for clinical treatment and diagnosis at the institution are to be reported to the IRB at the time of continuing review.

## RESPONSIBILITY

The IRB approval must verify that the use of the HUD, as proposed, is congruent with current labeling of the device and does not exceed the scope of the FDA approved indication. The labeling for a 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 specific indication has not been demonstrated. The IRB may impose more stringent restrictions for use of the HUD as a means of additional protections, as deemed necessary.

## PROCEDURE

Note: See Figure 1: HUD Decision tree (page 4) for determination whether HUD use constitutes Emergency Use, Standard IRB Submission for Clincial Research or Standard Humanitarian Use of the HUD

### 1. Emergency Use of a HUD

If IRB approval cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB. In such an emergency situation, the HDE holder shall, within 5 days after the use of the device, provide written notification to the IRB Chair of such use. Such written notification shall include the identification of the patient

involved, the date on which the device was used, and the reason for the use. (For more information on Emergency Use, refer to IRB *SOP 1.10 Emergency Use*)

## 2. Physician Responsibilities

a) For initial review of the proposed HUD clinical use, the clinician must submit an e-application for Humanitarian Use Device with the following accompanying submission documents and information:
- The FDA HDE (Humanitarian Device Exemption) number and approval letter
- A description of the device
- The product labeling
- The clinical brochure
- Patient information packet that may accompany the HUD

b) Confirm initial TCH IRB approval for clinical use of the HUD at the institution.

c) Obtain and document clinical informed consent (if applicable as required by the institution). (When the use of a HUD is for clinical diagnosis or treatment, i.e. not associated with human subject research activity, research informed consent and HIPAA regulations do not apply).

d) Provide patient information packets (when available) to patients prior to their receiving the HUD. If no packet is available, the patient should be provided with the following information:
- An explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition
- A description of any ancillary procedures associated with the use of the HUD.
- A description of the use of the HUD
- All known risks and discomforts
- Information reflecting the HUD status of the device including a statement indicating that the effectiveness of the device for this use has not been demonstrated

e) Comply with requirements for continuing review at the intervals determined by the IRB. Continuing review for HUD use is reviewed by the expedited review mechanism.

f) Comply with the following reporting requirements:
- Submit the applicable forms to the FDA, TCH IRB, and manufacturer 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). TCH IRB requires the submission of a Reportable Event form. (For more information on Reportable Events, refer to IRB *SOP 2.05 Reporting Unanticipated Problems (UAPs) Involving Risks to Subjects or Others.*
- Promptly report any FDA action(s) regarding the HUD to the IRB.

- Promptly report any modifications to the HUD or the clinical use of the HUD, in accordance with the IRB procedures.
- Notify the FDA of any withdrawal of approval for the use of a HUD by the IRB within 5 working days after being notified of the withdrawal of approval.

### 3. Initial IRB Review

The initial review of a HUD request is to be completed by full board review with quorum present. The Board will review the submission documents and information provided by the clinician. The IRB may approve, approve with modifications (contingently approve), or disapprove the use of the HUD at TCH, or it may defer (table) the matter to another meeting.

Decisions of the IRB will be communicated to the clinician through a letter outlining the approval status and/or the concerns, questions and/or comments of the IRB, and date of continuing review (if approved for use at the site). Decisions from a full board meeting will be verbally available the next day; however written communications are not released until the minutes of the meeting are reviewed and approved by the Chair. The latter requirement typically necessitates a period of three (3) working days from the IRB meeting date. For HUD requests that are disapproved by the IRB, the clinician will be notified in writing of the IRB's rationale for the decision and the PI will be given an opportunity to respond in writing to the IRB regarding the IRB's determinations.

***Applicable Regulations, Document(s):***
21 CFR 814.124
21 CFR 814.126(a)
21 CFR 803.3
21 CFR 803.30
TCH SOP 1.10 Emergency Use
TCH SOP 2.05 Reporting Unanticipated Problems (UAPs) Involving Risks to Subjects or Others
Humanitarian Device Exemption (HDE) Program – Guidance for Industry and Food and Drug Administration Staff issued on September 6, 2019

**Figure 1: HUD Decision Tree**