UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
HUMANITARIAN USE DEVICES (HUD)

I. PURPOSE

To document the review procedures for a submission regarding a Humanitarian Use Device. IRB review and approval is required for this use.

II. SCOPE

This SOP applies to the IRB administrative staff, IRB members, investigators and sponsors.

Personnel Responsible:

University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) administrative staff, members, investigators

III. BACKGROUND

A humanitarian use device (HUD) is one that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States in a calendar year. The FDA authorizes the marketing of HUDs through the issuance of a Humanitarian Device Exemption (HDE). HDEs are intended to encourage the discovery and use of devices intended for the treatment or diagnosis of diseases or conditions that afflict small numbers of individuals who would be left without satisfactory treatment options in the absence of the availability of such devices. HDEs accomplish this goal by allowing device manufacturers to market a HUD in the absence of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. Rather, the manufacturer must only provide information indicating that the device will not expose patients to an unreasonable or significant risk, the probable benefit to health outweighs the risks associated with its use, and there is no comparable device available.

Although use of HUDs does not constitute research, FDA regulations governing their use require that the healthcare provider who will use a HUD obtain IRB approval before the HUD is used to treat or diagnose patients. The IRB is responsible for both initial and continuing review of the HUD use. In conducting its initial review, the IRB must determine that use of the HUD will be consistent with the approved labeling for the device. For continuing review, the IRB must follow the requirements at 21 CFR 56, but may use expedited review procedures unless it determines that full board review should be performed. The IRB may also use its discretion in determining whether to approve the use of an HUD for a given period of time, for a specified number of patients, or on

a case-by-case basis. However, the HUD regulations require that the use of the HUD be reviewed by the IRB no less frequently than once a year. After approval by the IRB< the regulations require that the healthcare provider transmit to the IRB any medical device reports related to the occurrence with the reporting requirements of 21 CFR 803.

The HUD regulations do not address informed consent requirements for the use of a HUD. However, local IRB policy and applicable law require the informed consent of patients who will receive a HUD. The informed consent disclosure must indicate that the device is a HUD and that its effectiveness for the labeled indication has not been demonstrated. It must also contain a discussion of the potential benefits and risks of receiving the device and the availability of alternative treatments for the disease or condition.

A HUD cannot be sold for an amount that exceeds the costs of research and development, fabrication and distribution.

Any clinical investigation of a HUD requires a separate IRB application and approval.

In Accordance With:

21 CFR 50; 21 CFR 56; 21 CFR 803; 21 CFR 814, Subpart H

FDA Guidance Documents located at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm127067.pdf

FDA Guidance on Humanitarian Device Exemption (HDE) Regulation: Questions and Answers, located at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm110194.htm

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. Full Board review is required for submission of a humanitarian use device.

2. Investigators will submit the application to the IRB through iMedRIS, the electronic system. The following documents will be submitted for a humanitarian use device:
   a. UTGSM IRB Application

b. FDA IDE Letter approving the Humanitarian Use Device
c. Summary of Safety and Probable Benefits (from Sponsor)
d. Labeling for the device
e. A written statement from the applicant specifying that use of the HUD will be limited to the clinical indications listed in the FDA-approved product labeling; Prior annual reports of the manufacturer regarding the use of the device;
f. Information describing the applicant's clinical experience with the device, any training completed or required, and a list of physicians who will be using the device
g. Any cost information relevant to patient concerns (is the device billable, will it be provided by the Sponsor for free, etc.)
h. Any advertisements or other descriptive materials used by the HDE holder or private label distributor

3. Informed consent of the patient or the patient's legally authorized representative is required prior to the use of the HUD. The UTGSM IRB provides a consent form template if one is not available from the sponsor.

4. At the time of initial review, the IRB will determine if continuing review may be expedited (per 21 CFR 56.110) or if full board review is to be required.

5. Investigators / applicants will be required to submit a continuing review report to the IRB according to a time frame determined by the IRB, but at least annually. This report will include information describing the applicant's clinical experience(s) with the device.

6. Investigators / applicants will submit the following to UTGSM IRB:
   a. Any amendments or supplements to the HDE;
   b. Annual reports from the Sponsor;
   c. Unanticipated adverse effects;
   d. Reports of device failures necessitating a labeling, manufacturing or device modification;
   e. Any further results of animal / laboratory or clinical testing that may affect the risk-benefit ratio for use of the device;
   f. Final report from Sponsor; and
   g. Final report from applicant.

7. If the HUD is used in an emergency situation (off label) to save the life or protect the physical well-being of a patient, the procedures outlined in FDA regulations and local IRB policy must be followed as specified in SOP #023: UTGSM IRB Emergency Use.

8. If the HUD is employed for compassionate use, the procedures outlined in FDA regulations and local IRB policy must be followed as specified in SOP# 024: UTGSM IRB Compassionate Use/Treatment Use of Drugs, Biologics, and Devices.

10. IRB, sponsor and applicant correspondence is subject to the same record-keeping requirements of other submissions to UTGSM IRB.