1. POLICY

As defined in the Federal Food, Drug, and Cosmetic Act, and updated by the 21st Century Cures Act, a Humanitarian Use Device (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 not more than 8,000 individuals in the United States per year.” A Humanitarian Device Exemption (HDE) is the approval process provided by the FDA that allows a medical device to be marketed without requiring evidence of effectiveness. An HDE is granted, even though the efficacy of the device has not been tested or proven, because it is not financially feasible to do the usual clinical testing when so few individuals are affected.

The IRB shall review all submissions for HUDs, even though the use is not considered research. Before using a HUD, the investigator must obtain IRB approval, unless an emergency situation exists.

NOTE: An IRB approved use of a HUD at a facility to treat or diagnose patients does not mean the IRB has approved investigational use of the HUD (i.e., in a clinical investigation) for the collection of safety and effectiveness data.

Specific Policies

1.1 HUD

Humanitarian use of investigational devices must be prospectively reviewed by the IRB, except for an emergency use situation. The investigator shall submit a new submission for IRB review that must include evidence that the investigator/sponsor has obtained a Humanitarian Device Exemption (HDE) from the FDA.

a. HUD projects are not considered research. However, HUD projects are subject to continuing review requirements at the University.

b. Generally, a HIPAA Authorization form for research is not required unless the use of the HUD is clinical and is for obtaining safety or efficacy data.

c. If the IRB suspends or terminates approval of the HUD project, the investigator shall notify the HDE holder.

1.2 Consent of the Patient

The investigator shall obtain informed consent from the patient or the patient’s legally authorized representative, as applicable. If obtaining such consent is not possible, both the investigator and a physician who is not otherwise participating in the treatment or care of the patient shall certify in writing all of the following:

a. The patient is confronted by a life-threatening situation necessitating the use of the HUD;

b. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the patient;

c. Time is not sufficient to obtain consent from the patient’s legally authorized representative; and

d. No alternative method of approved or generally recognized therapy is available that provides and equal or greater likelihood of saving the life of the patient.
1.3 Emergency Situations

If a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, the investigator may use a HUD without prior approval by the IRB. Within five University business days after the use of the device, the physician must provide written notification to the IRB that includes:

- The identification of the patient involved;
- The date the device was used; and
- The reason for the use.

See SOP 502G: Emergency Use of FDA Regulated Products for more information.

2. SCOPE

This SOP applies to all HUDs submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB administrative staff is responsible for facilitating the review of the HUD.

3.2 The IRB Administrator is responsible for assigning the submission to the next available IRB meeting and for providing the Reviewer Checklist in the IRB’s electronic information system.

3.3 The HRPP Director or designee is responsible for maintaining up-to-date review tools for review of HUD submissions.

3.4 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.5 The IRB Reviewer is responsible for conducting appropriate review of HUD submissions planned for this category in consultation with appropriate experts and resources.

3.6 The IRB is responsible for conducting a thorough discussion of this type of research project to verify that all regulations have been followed.

3.7 The investigator is responsible for notifying the HDE holder upon the IRB’s suspension or termination of the HUD project. See SOP 801 Investigator Qualifications and Responsibilities for additional guidance.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 814 Subpart H, Humanitarian Use Devices

FDA Information Sheets, Guidance for IRBs and Clinical Investigators, 1998 Update

FDA Humanitarian Device Exemptions; Final Guidance

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
7. PROCESS OVERVIEW

7.1 Processing a HUD submission is similar to processing other submissions for research involving human research participants. The IRB Administrator shall process new submissions and revisions to currently approved HUDs and continuing review of HUDs per SOP 301: Research Submission Requirements, and SOP 403: Initial Review – Criteria for IRB Approval)

7.2 The investigator submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.3 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403 – Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members.

7.4 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as required, including documentation of the HDE, package insert, or device information. The IRB Administrator also verifies if additional University committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any addition information and/or reviews.

7.5 The IRB Administrator assigns the submission to an appropriate Board agenda and follows the process as detailed in SOP #403: Initial Review – Criteria for IRB Review.

7.6 The IRB Reviewers review the HUD submission to verify that it falls within the criteria stated in the regulations

7.7 Modifications may be required before final approval. When the modifications are received by the IRB, the IRB Administrator verifies all changes are made before assigning the submission to the IRB Chair or IRB designee for final review.

7.8 When IRB review is completed, the IRB Administrator generates the appropriate letter to notify the investigator of the results of the review and reports the final approval by posting to the next IRB agenda.

7.9 Enrollment may not commence until all required University committees have completed their review and the contract is signed, if applicable.

APPROVED BY: ____________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020