SOP 502F: Humanitarian Use Devices

1. POLICY

The IRB shall review all submissions for Humanitarian Use Devices (HUDs). Before using a HUD, the investigator must obtain IRB approval, unless an emergency situation exists. HUDs are subject to continuing review by the IRB.

As defined in the Federal Food, Drug, and Cosmetic Act, a HUD is a device that is “intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.”

Specific Policies

1.1 HUD

Humanitarian use of investigational devices must be prospectively reviewed by the IRB. 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.

1.2 A HUD project is subject to continuing review requirements. HUD projects are not considered research. Generally, a HIPAA authorization form for research is not required unless the use of the HUD is clinical and is used for obtaining safety or efficacy data.

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

1.4 Consent of the Patient

The investigator shall obtain informed consent from the patient or the patient’s legally authorized representative as permissible. 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.

1.5 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. The physician must, within five working days after the use of the device, provide written notification to the IRB that includes the identification of the patient involved, the date on which the device was used, and the reason for the use. See SOP 502G: Emergency Use of FDA Regulated Products.

2. SCOPE
This SOP applies to all HUDs submitted to the IRB.

3. RESPONSIBILITY
3.1 The IRB administrative staff is responsible for facilitate 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
SOP 302: Administrative Review and Distribution of Materials
SOP 403: Initial Review – Criteria for IRB Approval
SOP 502G: Emergency Use of FDA Regulated Products
SOP 801: Investigator Qualifications and Responsibilities

6. ATTACHMENTS

203-A      HSC Reviewer Checklist
203-A-1    NC Reviewer Checklist

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, 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 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 institutional committees have completed their review and the contract is signed, if applicable.

APPROVED BY: ___________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016