SOP: 502F
HUMANITARIAN USE DEVICES

1. POLICY

The IRB shall review all applications for Humanitarian Use Devices (HUDs). Before using a HUD, the investigator must obtain IRB review and approval. 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 application 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; therefore, research authorization forms are not required.

1.3 Consent of the Participant

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 participant.

1.4 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 including the identification of the patient involved, the date on which the device was used, and the reason for the use.

2. SCOPE

This policy and these procedures apply to all HUDs submitted to the IRB.

3. RESPONSIBILITY

The IRB administrative staff is responsible to facilitate the review of the HUD.

The IRB Administrator is responsible for posting the protocol to the next available IRB meeting and providing appropriate checklist/review sheets to the IRB Chair/Reviewers.

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

The IRB Chair or 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 designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation to obtain that expertise.

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

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

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.

6. ATTACHMENTS

203-A New Study Reviewer Checklist – Full Board

203-E Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates
203-F Reviewer Checklist for Research Involving Prisoners
203-G Reviewer Checklist for Research Involving Children

7. PROCESS OVERVIEW

7.1 A HUD submission is a process similar to other research involving human research participants. The IRB Administrator shall process new research projects, revisions to currently approved research, and continuing review of research documents per SOP 301, Research Submission Requirements; and SOP 302, Administrative Review and Distribution of Materials.

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

7.3 The IRB review is conducted per SOP 403, Initial Review – Criteria for IRB Approval.

APPROVED BY:_____ **DATE: 09/01/2009**

NEXT ESTABLISHED REVIEW DATE: MAY 2012