Issuing Department: Human Subjects Protection Program
Policy Number: 2011-020.0
Policy Title: Humanitarian Use Device

Purpose

The purpose of this policy is to set forth requirements for review, approval and use of a Humanitarian Use Device.

Definitions

See Policy 2011-007.0 for the definitions of:

Humanitarian Device Exemption	Humanitarian Use Device	Informed Consent
IRB Approval	Legally Authorized Representative	

Policy

A clinician must obtain review and approval by the convened Institutional Review Board (IRB) prior to use of a Humanitarian Use Device (HUD). The IRB approval will be for use in accordance with the FDA approved indication. However the IRB reserves the right to impose additional limitations on the scope of the FDA approved use of the device. For example, the IRB may limit use to a specific medical specialty.

Continuing review may be conducted by the expedited review process if the use of the HUD falls within one of the categories published in the federal register. However the Chair reserves the right to require full board review.

The clinician must submit a consent form that is specific to the use of the HUD, apart from the clinical consent form. The clinician must use the HUD consent form in addition to the clinical consent form when obtaining consent.

An HUD may be used in an emergency situation to save the life or protect the physical well being of a patient when there is not time to obtain prospective IRB review and approval. The clinician must obtain authorization from the Humanitarian Device Exemption holder for emergency use and if possible concurrence from the IRB Chair an independent physician and consent of the patient or the patient's legally authorized representative. The emergency use must be reported to the HDE holder and IRB within 5 days. The HDE holder is then obligated to submit the report as an amendment to the HDE. The reporting of an emergency use to the IRB is in addition to any hospital requirements for reporting emergency use.

Procedure

Standard Use:

The clinician must submit to the IRB the material listed on the HUD application form for initial and continuing review.

- The clinician must request continuing review for use of the HUD at least annually.

The IRB will conduct the initial and continuing review of the material using a primary reviewer system, or if after initial review the use of the HUD is eligible for expedited review, in accordance with expedited review procedures.

- For full board reviews, the IRB Regulatory Specialist will document the review in the IRB minutes.
- For expedited reviews, the board will be informed of the activity at the next regularly scheduled meeting for which the submission deadline has not passed.

The IRB staff will send the notification letter (e.g. approval letter, deferral letter) to the clinician.

- The approval letter sent to the clinician by the IRB staff will indicate the date by which continuing review must occur.
- The material that must be submitted for continuing review is noted on the HUD request for continuation form.

Once approved for use, the clinician must use the HUD consent form in addition to the clinical consent form when obtaining consent.

Emergency Use Procedures:

When there is not time to obtain prospective IRB approval, the clinician must obtain authorization from the HDE holder for emergency use. In addition to the authorization from the HDE holder, the physician should obtain, if possible:

- the IRB Chair's concurrence
- the informed consent from the patient or his/her legally authorized representative
- an independent assessment by an uninvolved physician.

Within 5 business days after the use the physician must submit a follow-up report on the patient's condition and information regarding the patient protection measures taken to the HDE holder and to the IRB.

Related Policies

2011-007.0 – Definitions Applied to Policy
2011-009.3 – Institutional Review Board – Expedited Review
2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

21 CFR 814 Sub-part H

Document Attributes

Date Created: 8/17/2017

Replaced Version: 7/8/2011

Reviewed and Approved By: *Richard H. Simon* **Date:** *17 August 2017*
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