

St. John Hospital and Medical Center
Institutional Review Board
Standard Operating Procedures

This portion of the SJH&MC IRB Standard Operating Procedures has been approved for immediate implementation by the IRB on 7/16/09. This version supersedes all previous versions.

HUMANITARIAN USE DEVICE - HUD / HDE

1. POLICY

The FDA requires the IRB to approve the use of a Humanitarian Use Device (HUD) to treat or diagnose a medical condition as specified in the sponsor- or manufacturer-secured FDA granted Humanitarian Device Exemption (HDE). This policy sets forth the requirements for IRB approval, monitoring, and continued reporting responsibilities, as well as procedures for physicians seeking to use an HUD at St. John Hospital and Medical Center.

Specific Policies

1.1 Physician (reported physician) Responsibilities

- 1.1.1. Physicians wishing to use an HUD at St. John Hospital and Medical Center facilities must provide the IRB an application for initial approval along with documentation verifying the device/product sponsor has been granted an FDA-approved Humanitarian Device Exemption (HDE) for use of this device. IRB approval must be obtained prior to use of an HUD to treat or diagnose a specified medical condition.

Once IRB approval has been granted, the physician is required to provide the IRB with the following reports:

- Notification within 24 hours of each use of an HUD (Initial Report) with a follow-up report (HUD Use Follow-up Report) of the event within five (5) days of the HUD use.
 - Report of any serious or unexpected adverse event(s) or problems occurring with this HUD use within 48 hours (Clinical Unanticipated Problems Forms).
- 1.1.2. Continuing review by the IRB is required. Physicians will need to submit the appropriate continuing review application form if the use of the HUD is expected to continue past the IRB approval expiration date.
 - 1.1.3. Changes in the approved HUD project, during the period for which IRB approval has already been given, may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

The physician or HDE holder (sponsor) must submit requests for changes to the IRB in writing (Application for Revision).

- 1.1.4. The physician will promptly inform the IRB of any off-label use of the HUD device.
- 1.1.5. Emergency and Compassionate Use of an HUD. The FDA allows for **emergency, off-label use** of an HUD to save the life or protect the physical well-being of a patient, provided the physician follow procedures governing emergency use of an unapproved device. The reported physician is responsible to assure compliance if the HUD is used by a non-reported physician. If possible, the physician should obtain the IRB Chairperson's concurrence,

informed consent from the patient or his/her legal representative, an independent assessment by an uninvolved (i.e., not referring) physician, and institutional clearance. In addition the physician should obtain authorization from the HDE holder before the emergency use of the HUD. After the emergency use occurs, the physician should submit a follow-up report on the patient's condition and information regarding the patient protection measures to the HDE holder, who would then submit this information as a HDE report to the FDA. The physician is required to submit these reports to the IRB as well (see section 1.1.1. above).

The FDA also allows for **compassionate use** of an HUD in a situation that is not an emergency, but the physician determines there is no alternative device for the patient's condition. As in the case of emergency use, the FDA recommends that the physician ensure that patient protection measures discussed above are addressed before the device is used. Additionally, the FDA recommends the physician first obtain FDA approval for compassionate use.

The FDA believes that a physician who wishes to use a HDE-approved device for compassionate use should provide the HDE holder with:

- a description of the patient's condition and
- the circumstances necessitating use of the device,
- a discussion of why alternative therapies or diagnostics are unsatisfactory
- information to address the patient protection measures. For detailed information on FDA Guidance on IDE Policies and Procedures for patient protection measures, use the following link <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm>.

1.2 IRB Responsibilities

1.2.1. The FDA requires an IRB to approve and monitor the activity of an HUD although an HUD is not defined as research under the federal regulations. The IRB is free to establish its own criteria for IRB approval, but regulatory requirements and issues to be considered are, but not limited to, the following:

- FDA regulations require IRB approval before use of an HUD.
- The holder of the HDE (usually the sponsor) is responsible for ensuring the HUD is used only at facilities that have established an IRB that operates in compliance with FDA regulations.
- The generic or trade name of the device.
- The FDA HDE number (six-digit number preceded by an H).
- The date of HUD designation.
- Indications for use of the device.
- A description of the device.
- Contraindications, warnings, and precautions for use of the device.
- Adverse effects of the device on health.
- Alternative practices and procedures.
- Marketing history.
- Summary of studies using the device.
- There is no time limit on the FDA approval of an HDE.

- 1.2.3. The IRB does not have to approve each individual use of an HUD. The IRB has the discretion to determine the conditions of HUD use. The IRB may approve the use of the device in general, in a specific number of patients, only under certain circumstances, etc. The IRB may limit the use of the HUD based on any criteria that it deems appropriate.
- 1.2.4. Review of an initial application for approval of the use of an HUD requires full IRB review. The only exception to the requirement for full IRB review of an HUD is found under the federal regulations describing studies which meet the criteria for Expedited status, category #1.b(ii) - If the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling, then the project would qualify for expedited review conducted by the IRB Chairperson or his/her designee.
- 1.2.5. The IRB will monitor the HUD usage and provide the appropriate continuing review, at least annually, utilizing the same guidelines governing research projects (See policy Continuing Review – Ongoing). As part of the continuing review, the IRB will require copies of the sponsor's monitoring reports and accountability reports.
- 1.2.6. Upon receipt of a protocol change to the HUD project, the IRB Chairperson or his/her designee, with assistance of the Consultant to the IRB and/or IRB Coordinator, will determine if the revision meets the criteria for minimal risk. If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB. Minor changes, involving no more than minimal risk to the subject, will be reviewed by the expedited review procedure (See Policy Expedited Review).
- 1.2.7. The Consultant to the IRB and/or IRB Coordinator in conjunction with the IRB Chairperson and/or designee will provide the [Office of Risk Management] with a copy of all internal adverse event reports received concerning an HUD. The [Office of Risk Management] will determine whether the event is reportable under the FDA's user facility medical device reporting requirements.
- 1.2.8. The IRB Chairperson or his/her designee in conjunction with the Consultant to the IRB and/or IRB Coordinator will inform the FDA of any serious issues of physician noncompliance or significant safety concerns surrounding the HUD.

2. SCOPE

These policies and procedures apply to all HUD/HDE projects submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.110

21 CFR 814.126

21 CFR 803.32

45 CFR 46.110

FDA Information Sheets, 1998

OHRP IRB Guidelines

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.