Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 501: Humanitarian Use Devices (HUDS)

POLICY

An HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. The manufacturer or other sponsor of an HUD ("HDE Holder") is required to obtain FDA approval to use an HUD for a specific indication by submitting an application for Humanitarian Device Exemption ("HDE"). FDA approval of an HUD for a specific indication is a prerequisite to the HUD being considered for use at DMH by the IRB. Use of an HUD is not considered part of an investigational study and is, therefore, subject to different requirements under federal laws and regulations. It is the intent of DMH to comply with applicable federal laws and regulations governing the use of HUDs.

Any physician who wants to use an HUD at DMH ("Physician User") must obtain the prior written approval of the IRB, as set forth in this Policy, subject to the special procedures for Emergency Use and Compassionate Use set forth in this Policy. The IRB is responsible for approving the use of any HUD at DMH, and thereafter continually monitoring the use of the HUD after initial approval, in accordance with applicable federal laws and regulations. The Physician User is responsible for using the HUD only as approved by the IRB and in accordance with applicable federal laws and regulations.

PROCEDURES

A. Physician User Responsibilities

1. The Physician User must submit the following documents to the IRB for initial approval:

    a. An application for use of the HUD, including a Physician User Signed Statement of Responsibilities and a Project Summary.

    b. Documentation verifying the HDE Holder has been granted an FDA-approved HDE for use of this device. This should include:

        i. A copy of the original request to the FDA for designation as an HUD.

        ii. A copy of the HDE application.

        iii. The package inserts and patient information leaflets or brochures, along with other information provided by the HDE Holder and/or its detail-men.

        iv. A copy of the FDA approval of the HDE and the FDA's Summary of Safety and Probable Benefit.

    c. A copy of the HUD informed consent form, as necessary.

2. Following IRB approval of the use of an HUD, the Physician User shall:

    a. File all post-approval documents and information with the FDA in accordance with federal regulations.

    b. Retain any and all documentation pertaining to the use of the HUD, including, but not limited to, information and documentation provided to the Physician User by the HDE Holder, correspondence with the HDE Holder and the FDA, the initial Project Summary and subsequent Continuing Review Applications, and copies of signed consent forms from all patients, as necessary, for whom the HUD was used. This responsibility commences upon IRB approval of the use of the HUD and does not end until three (3) years after such IRB approval has been withdrawn, even if the Physician User leaves DMH or is otherwise replaced by another Physician User with IRB approval.

c. Obtain informed consent from any patient who is a candidate for use of the HUD, as necessary.
d. Provide the patient with an HUD information packet and provide an explanation that the HUD is designed to diagnose or treat a disease or condition described in the HDE labeling, that no comparable device is available to treat the disease or condition, and that the effectiveness of this device has not been demonstrated.

e. Within five (5) days of each use of the HUD, notify the IRB of the HUD use, whether or not on an emergency basis, and provide a follow-up report that includes reasons for using the device and outcome of the procedure.

f. Report any unanticipated problems (i.e. serious adverse events or protocol deviations) occurring in connection with the use of the HUD within 48 hours. The Physician Users are also responsible for submitting a UPIRSO Submission Form and all necessary paperwork to the IRB in accordance with the IRB's Unanticipated Problems Involving Risks to Subjects and Others Policy.

g. Submit the appropriate Continuing Review Form each year or as requested by the IRB if the use of the HUD is expected to continue past the IRB approval expiration date.

3. The Physician User will not initiate or implement changes from the approved use of the HUD without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to human patients in accordance with the special procedures for Emergency Use set forth in this Policy. In order to obtain IRB review of any such change, the Physician User must submit an Amendment Form to the IRB.

4. The Physician User will not allow the off-label use of the HUD, except in accordance with the special procedures for Emergency Use and Compassionate Use set forth in this Policy.

B. IRB Responsibilities

1. Review of an initial application for approval of the use of an HUD will be undertaken by the full IRB at a convened meeting.

2. The IRB is free to establish its own criteria for IRB approval and monitoring of an HUD, but issues to be considered include, but are not limited to, the following:

    a. The generic or trade name of the device.

    b. The FDA HDE number (six-digit number preceded by an H).

    c. The date of HUD designation.

    d. Indications for use of the device.

    e. A description of the device.

    f. Contraindications, warnings, and precautions for use of the device.

    g. Adverse effects of the device on health.

    h. Alternative practices and procedures.

    i. Marketing history.

    j. Summary of studies using the device.

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.

4. The IRB will monitor the HUD usage and provide the appropriate continuing review, conducted according to a time frame established by the IRB, at least annually, utilizing the same guidelines governing research projects, as articulated in the Continuing Review Policy. The IRB will track the use of the HUD in the Physician User's Continuing Review Form. In addition, the IRB will review any of the following items provided by the Physician User:

    a. Any amendments or supplements to the HDE;

    b. Annual reports and monitoring or accountability reports from the HDE Holder;

    c. Any reports of adverse events or unanticipated problems;

    d. Increases in the incidence of anticipated adverse events;

    e. Reports of device failures necessitating labeling, manufacturing, or device modification; and

    f. Any further results of clinical testing.

5. Upon receipt of an Amendment Form or other protocol change to the use of the HUD, the IRB Co-Chair or his/her designee will determine if the revision meets the criteria for minimal risk. If the change represents more than minimal risk to patients, it must be reviewed and approved by the full IRB at a convened meeting. Minor changes, involving no more than minimal risk to the patient, will be reviewed in accordance with the Expedited Review Policy.

6. The IRB Co-Chair and/or designee will provide the DMH Administration with a copy of all internal MDR forms received concerning an HUD to determine whether the event is reportable under the FDA's user facility medical device reporting requirements. The IRB Co-Chair will inform the FDA of any serious issues of physician noncompliance or significant safety concerns surrounding the HUD.

C. Off-Label Use of an HUD in an Emergency Situation

1. 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 User adheres to certain procedures governing the "Emergency Use" of an unapproved device.

2. The Physician User is responsible for compliance to ensure that all other physicians who desire to use the HUD are pre-approved by the IRB and use the device according to its approved labeling.

3. Before the Physician User may use an HUD for an Emergency Use, each of the following must exist:

    a. HDE approval from the FDA for the HUD already exists;

    b. The patient is in a life-threatening condition that needs immediate treatment;

    c. There is no generally acceptable alternative treatment for the patients; and

    d. Because of the immediate need to use the device, there is no time to use existing IRB procedures in order to obtain approval for the use.

4. Every effort should be made by the Physician User to obtain the IRB Co-Chair's concurrence, informed consent from the patient or his/her legally authorized representative, an independent assessment by an uninvolved (i.e., not referring) physician, and administrative clearance from DMH, depending on the immanency of the emergency.

5. After the emergency use occurs, the Physician User should submit a follow-up report on the patient's condition and information regarding patient protection measures to the HDE Holder. The Physician User is required to submit these reports to the IRB as well.

D. Compassionate Use of an HUD in a Non-Emergency Situation

1. The FDA also allows for "Compassionate Use" of an HUD, for an indication not otherwise addressed by the HDE approved by the FDA for the particular device, in a situation that is not an emergency, when the Physician User determines there is no alternative device for the patient's condition.

2. As in the case of Emergency Use, the Physician User shall ensure that the patient protection measures set forth in paragraph 4 of Section II(C) of this Policy are addressed before the device is used. The Physician User should first obtain FDA approval for Compassionate Use.

3. A Physician User who wishes to use an HDE-approved device for compassionate use shall provide the IRB and the HDE Holder with:

    a. A description of the patient's condition;

    b. The circumstances necessitating use of the device;

    c. A discussion of why alternative therapies or diagnostics are unsatisfactory; and

    d. Information to address the patient protection measures.

Applicable Regulations and Guidance:

21 CFR 56.110
21 CFR 814.24
21 CFR 814.124
21 CFR 814.126
21 CFR 803.32
45 CFR 46.110

Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm
Humanitarian Use Devices List:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm

SCOPE
This SOP applies to all Physician Users, all IRB members, and the IRB administrator.