Although use of a HUD for the treatment or diagnosis of a patient is not considered research, the FDA regulations governing the use of medical devices requires an Institutional Review Board (IRB) to review and oversee HUD use at their local or designated facilities. (FDA 21 CFR Part 814.124)

At Florida Hospital, HUDs must receive FH IRB approval and OSP institutional clearance.

DEFINITIONS:

Humanitarian Use Device (HUD): A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year (FDA 21 CFR 814.3(n)).

Humanitarian Device Exemption (HDE): An HDE application is a marketing application that is similar to a premarket approval (PMA) application in that the applicant must demonstrate a reasonable assurance of safety, but in an HDE application, the applicant seeks an exemption from the PMA requirement of demonstrating a reasonable assurance of effectiveness. A device that has received HUD designation is eligible for HDE approval if, among other criteria, the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices and alternative forms of treatment.

HUD REQUIREMENTS AND RESPONSIBILITIES:

1) **IRB Training Requirements:**
    a. Complete the Humanitarian Use Devices (HUDs) module that is part of the CITI Basic Biomedical course. Refer to https://drupal02.floridahospital.org/irb/content/requirements for more information.
    b. This module must be completed by all persons listed on ***HRP-201 FORM: Research Personnel***.
        i. Form should include all health care providers that may potentially use the HUD in the diagnosis or treatment of patients at FH or anyone designated to assist in the administration of this process.

2) **FDA Training Requirements:**
    a. In the event the FDA requires training, the HUD user and all other health care providers that may potentially use the HUD device at FH must receive training by the HDE holder.
    b. The FDA approval orders of HDEs are available for review on their website, at (just select the HDE number): http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm#2

3) **FH HUD Application Requirements:** The HUD user or designee must complete and submit the following documents:
   a. ***HRP-200 FORM: Initial Review Application*** – submit to the IRB along with additional information listed in the Submission Requirements section of the form.
   b. ***Research Review Application*** – submit to OSP.

   The HUD user/designee should review the HRP-450 WORKSHEET – Criteria for Approval HUD and use as a guide for preparing an IRB submission.

4) **Consent Requirements:**
   a. **The IRB *may require* informed consent to be obtained for the use of the HUD in addition to the usual treatment consent.** This requirement will be communicated to you at the time of IRB Preliminary Review and will be included in the IRB Approval letter.
      i. In the event the IRB requires informed consent, the HUD user or designee will be responsible for
         1. providing an informed consent to the IRB for review utilizing the ***HRP-506 HUD Consent Template*** or a consent form provided by the HDE holder and
         2. ensuring that informed consent is obtained for all patients receiving the HUD. The signed, original informed consent document should be maintained with the HUD records, a copy placed in the patient's medical record and a copy given to the patient.
   b. **If the IRB does not require an additional IRB approved informed consent**, routine procedures must be followed to obtain the usual consent to treat necessary for clinical care according to all related hospital policies.

5) **Management of HUD Utilization at FH:**
   a. Obtain **IRB approval and OSP clearance** PRIOR to first use of the HUD and maintain IRB approval as long as the HUD continues to be used in the institution. This includes but is not limited to modifications when appropriate and renewals.
   b. It is a federal requirement to **provide all HUD patients with the labeling and patient materials** (such as a patient information brochure) prepared by the HDE holder prior to the patient receiving the HUD whenever feasible.
   c. Ensure the HUD device is **used ONLY by designated individuals** in **designated facilities** approved for HUD use (listed in the documents submitted to the IRB and HDE holder).
   d. HUD user or designee is responsible for **keeping proper control of the device**. There is a Cerner PowerChart HUD application provided to track the use of HUDs at FH. **The FH IRB recommends HUD standard documentation in the patient's Electronic**

Medical Record (EMR). Please contact Research Information Systems (ReSIS) at FH.MIS.ReSIS@flhosp.org for HUD set up. The following responsibilities are included in keeping proper control of the device:

i. Only the designated physician(s) or health care provider(s) use the device (as listed on ***HRP-201 FORM: Research Personnel Log***.)
ii. It is kept in a secure place with limited access ensuring only IRB approved HUD users have access to the device
iii. HUD user or designee will be accountable for receiving the devices and using or implanting the devices (quantity received, dates of receipt, recording unique identifiers if applicable, i.e. serial #s, expiration dates if applicable, date of use or implant, patients, MRNs, DOB, etc.)
iv. Ensure the HUD is used within the scope of its labeling (indication listed in the Directions for Use). The HUD user or designee must make sure that only eligible patients that meet the criteria as described in the documents submitted to the IRB receive the device.

6) HUD Reporting Requirements:

a. Submission of annual Progress Reports is required for Continuing IRB Review as long as the HUD continues to be used in the institution.
b. HUD user or designee must prepare and submit Medical Device Reports (MDR) to the FDA and IRB and HUD device manufacturer in the following events:
   i. When an HUD may have caused or contributed to a death
   ii. When an HUD may have caused or contributed to a serious injury. Serious Injury means an injury or illness that (1) is life-threatening, (2) results in permanent impairment of a bodily function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a body structure.
   iii. When an HUD has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (21 CFR 814.126(a)).
   iv. The specific requirements for this reporting are set forth in the Medical Device Reporting (MDR) Regulation, at 21 CFR Part 803, found here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=803

7) Special Circumstances (Off-Label and Emergency Use):

a. Off-label Use
   i. If the HUD has FH IRB approval: report off-label uses at the time of continuing review.

ii. If the HUD does **not** have FH IRB approval: follow the process for Compassionate Use of Devices according to ***HRP-826 INVESTIGATOR GUIDANCE: Emergent & Non-Emergent Use of Test Articles***

b. Emergency Use – If a physician in an emergency situation determines that IRB approval for the use of an HUD cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used within the scope of its labeling or off-label without prior IRB approval

i. The emergency use of a HUD must be reported to the IRB according to ***HRP-826 INVESTIGATOR GUIDANCE: Emergent & Non-Emergent Use of Test Articles*** and ***HRP-222 FORM: Emergent Use Report***

RESOURCES:

Link to informational video on HUDs provided by the FDA (20 minutes):
http://fda.yorkcast.com/webcast/Viewer/?peid=679dff2747964a5c90c7274a7313255f

FDA 21 CFR Part 814 Subpart H-Humanitarian Use Devices;
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814&showFR=1&subpartNode=21:8.0.1.1.11.7

Humanitarian Device Exemption (HDE): Questions and Answers, Draft Guidance for HDE Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff, dated March 18, 2014;
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm389275.pdf

Guidance for HDE Holders, Institutional Review Board (IRBs), Clinical Investigators, and Food and Drug Administration Staff/Humanitarian Device Exemption (HDE) Regulation: Questions and Answers, dated July 8, 2010;
http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm110194.htm

Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Frequently Asked Questions about Medical Devices http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf