LSU Health NEW ORLEANS Human Research Protection Program	HUMANITARIAN USE DEVICE FOR CLINICAL TREATMENT OR DIAGNOSIS			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	4.09	06.06.2020	4.09	02.08.2020

1.0 Introduction

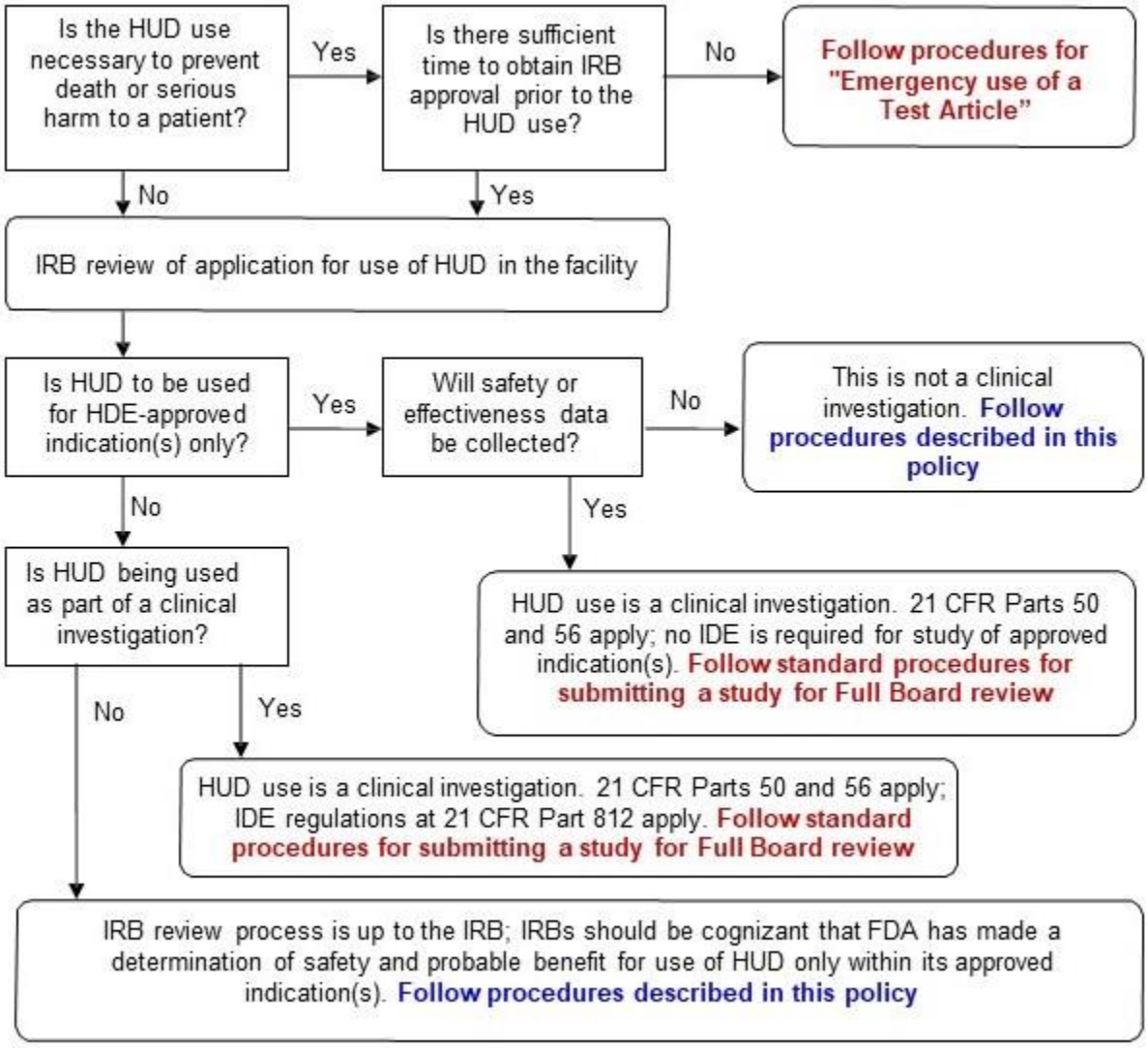
A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. FDA regulations (21 CFR 814.124) provide for the submission of a Humanitarian Device Exemption (HDE) in which the manufacturer is not required to provide the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose prior to marketing. This regulation was developed to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

A physician may use an HUD in the course of routine clinical care to treat or diagnose patients. Or, he/she may use the device in a clinical investigation (research). In both circumstances, use of the HUD requires prospective IRB review and approval by the Full Committee. **This policy pertains only to the use of an HUD for non-emergency, clinical treatment and diagnosis.** For use of an HUD in a clinical investigation, please follow the standard procedures for submitting a (greater than minimal risk) research protocol for Full Board review. For use of an HUD in an emergency situation, please follow the procedures for *Emergency Use of a Test Article*.

2.0 Policy Statements

- The LSUHSC Human Research Protection Program requires that physicians comply with all applicable regulations pertaining to HUDs.
- Generally, a Humanitarian Use Device (HUD) that has been granted a Humanitarian Device Exemption (HDE) by the FDA may be administered only if such use has been approved by the institution's IRB of record.
- Once IRB approval is granted, use of the HUD within the approved indication(s), as well as other clinical uses that are intended solely to address the specific needs of an individual patient, is allowed.
- All uses of the HUD for clinical treatment and diagnosis at an institution are to be reported to the IRB at the time of continuing review.
- If a physician in an emergency situation determines that IRB approval cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB. Reporting of the emergency use of the HUD to the IRB is required as per the policy and procedures for ***"Emergency Use of a Test Article."***

3.0 Decision Tree



4.0 Procedures

4.1 Physician Responsibilities

- Complete the "***Humanitarian Use Device"*** application using the IRB electronic system. Some of the information requested in the application include:
    - a description of the device
    - a summary of how the clinician proposes to use the device, including a description of any screening procedures, the HUD procedure, potential risks, available alternatives and a plan for care of patients, including follow-up visits, tests or procedures.
    - A list of all physicians that will use the HUD

- Electronically submit the "***Humanitarian Use Device"*** application along with the required documents. These documents include:
    - the FDA Humanitarian Device Exemption approval order,
    - the HUD manufacturer's product labeling,
    - the Patient Information brochure, and
    - a sample HUD Treatment consent form
- Confirm initial LSUHSC IRB approval for clinical use of the HUD at the indicated institution/facility.
- Obtain and document informed consent using the *HUD Treatment Consent Form*.
- Provide patient information packets (when available) to patients prior to their receiving the HUD. If no packet is available, the patient should be provided with the following information:
    - Labeling information prepared by the HDE holder.
    - An explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition.
    - Information reflecting the HUD status of the device including that the effectiveness of the device for this use has not been demonstrated.
- Comply with requirements for **continuing review** at the intervals determined by the IRB.
- Complete an **Amend submission** using the IRB electronic system whenever there are modifications to the HUD or proposed changes to the clinical use of the device. As applicable, the form should be accompanied by 1) the FDA's approval of the modification; 2) the HDE holder's amendments to the HUD product labeling, HUD brochure and/or other pertinent materials corresponding to the requested modifications.
- Promptly complete a **Reportable Event submission** using the IRB electronic system whenever the HUD may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. In this context, serious injury means an illness or injury 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.

4.2 IRB Responsibilities

- Conduct the initial review of the "***Humanitarian Use Device"*** application at a convened IRB meeting. The IRB will have among its members (or consultants) the appropriate experience and expertise to review the proposed use of the HUD.
- Apply the review criteria at 21 CFR 56.111 and elsewhere in Part 56, as applicable, when reviewing the HUD clinical use application.

- The IRB may use its discretion to determine how to approve use of a HUD. An IRB may specify limitations on the use of the device based upon one or more measure of disease progression, prior use and failure of any alternative treatment modalities, and reporting requirements to the IRB.

- Ensure that health care providers listed on the application are qualified through training and expertise to use the device.
    - Each Physician wishing to use an HUD must be individually documented as having IRB approval to use such devices. IRB approval for one physician on the facility medical staff does not mean that another member of either the physician's group or facility's medical staff also has approval to use such devices.

- The IRB may refer the continuing review of the HUD clinical use application to expedited review procedures because the HDE-approved HUD is a legally marketed device and no safety and effectiveness information is being systematically collected. Expedited review procedures are appropriate when use of an HUD is within its approved labeling and does not constitute research.

5.0 Definitions

Humanitarian Use Device (HUD): A medical device that is intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in not more than 8,000 individuals in the United States per year. HUD designations are issued by the FDA.

Humanitarian Device Exemption (HDE): A Food and Drug Administration (FDA) premarket approval application (granted to the manufacturer) that allows marketing of a product that is exempt from effectiveness requirements. FDA approval of an HDE authorizes an applicant to market a Humanitarian Use Device (HUD), subject to certain profit and use restrictions.

Use/Clinical Use: The use of a HUD according to its approved labeling and indication(s) to treat or diagnose patients.

Clinical Investigation: FDA has defined "clinical investigation" to be synonymous with "research". As such, "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. In the context of using an HUD, the activity is a clinical investigation if it involves collection of safety and effectiveness data.

6.0 References and Regulations

FDA References

- Humanitarian Device Exemption (HDE) Regulation: Questions and Answers, Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff (July 8, 2010).
- Humanitarian Device Exemption (HDE) Program, Guidance for Industry and Food and Drug Administration Staff (Content current as of: 09/05, 2019)

- Humanitarian Device Exemption (Content current as of: 09/05, 2019)
- Humanitarian Device Exemption (HDE) Postmarket Activities (Content current as of: 09/05, 2019)
- HDE Approvals (Content current as of: 08/24/2018)

FDA Regulations

- Humanitarian Use Devices 21 CFR 814 (Subpart H)
- Medical Device Reporting 21 CFR 803

Version Number	Revision Date	Summary of Changes
2.0	06.06.2020	Specified policy is for clinical treatment, not clinical investigation, with HUD. Inserted decision tree. Linked newly created HUD Treatment consent template.
1.1	02.08.2020	Converted to a web version policy from original Guidebook
1.0	03.25.2019	N/A