Humanitarian Use Devices for Clinical Treatment or Diagnosis

Content Applies To

Mayo Clinic Human Research Protection Program

Relying Organizations for which Mayo Clinic IRB is the IRB of Record

Purpose

This document describes the responsibilities of clinicians and the Mayo Clinic Institutional Review Board (IRB) related to use of Humanitarian Use Devices in clinical treatment or diagnosis, i.e., use that does not constitute human subject research.

Key Terms

Clinical Investigation: Collection of safety and effectiveness data pertaining to a Humanitarian Use Device (HUD). Note: Clinical investigations are not the focus of this document, however, and are subject to Mayo Clinic IRB and institutional policies applicable to human subject research.

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.

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 fewer than 4,000 individuals in the United States per year. HUD designations are issued by the FDA.

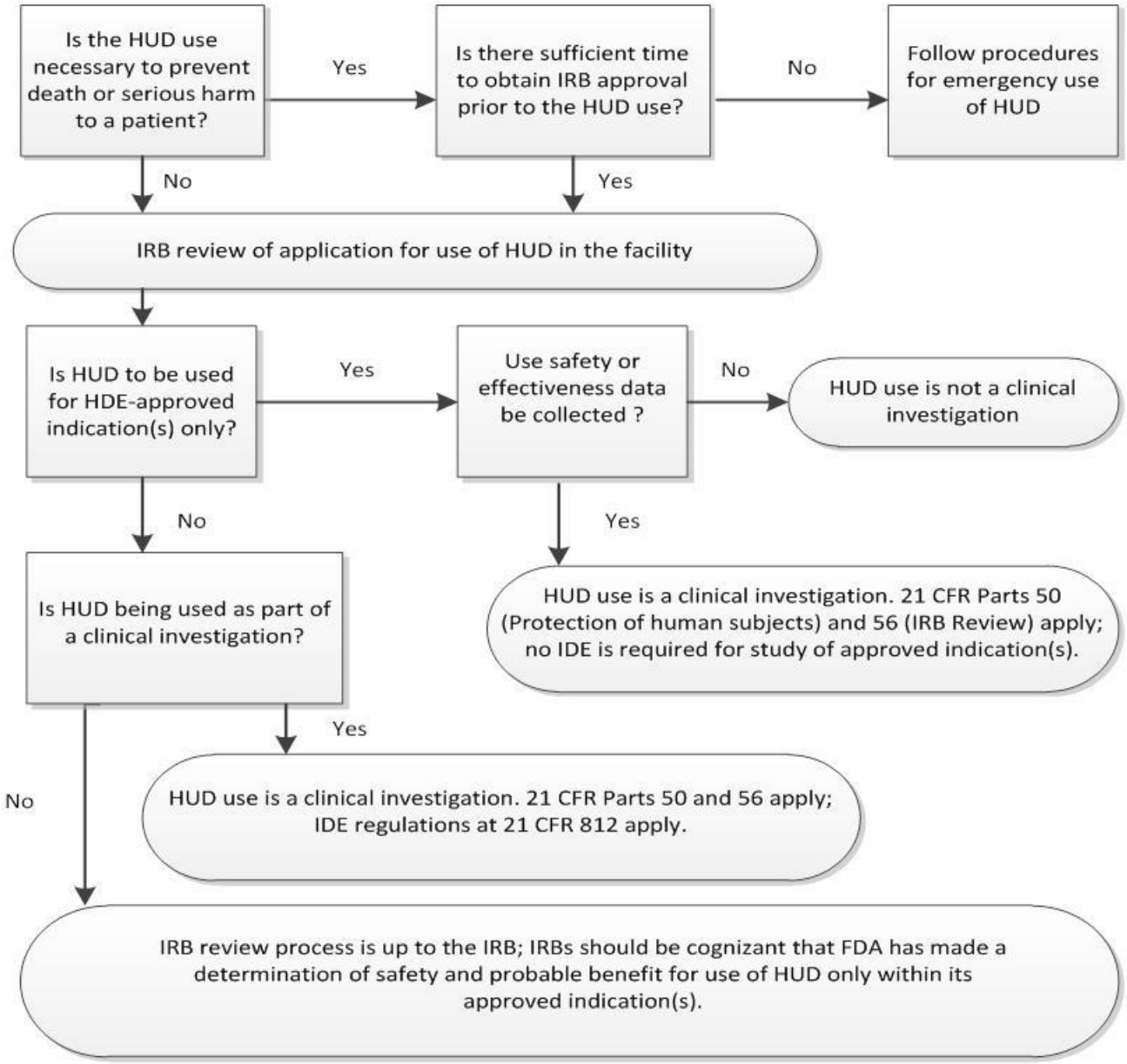
Use/Clinical Use: The use of a HUD according to its approved labeling and indication(s) to treat or diagnose patients.

Policy

The Mayo Clinic Office for Human Research Protection - Institutional Review Board (IRB) requires that clinicians comply with all applicable regulations pertaining to humanitarian use devices, and that all uses of humanitarian use devices be reviewed and approved by the IRB as defined by Federal regulations.

1. 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.
2. If a clinician 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. Refer to the Mayo Clinic IRB policy, "Emergency Single-Case Use of an Investigational Device, Drug or Biologic Product" for further information and instruction.

Decision Tree



Procedure

Clinician Responsibilities

- Complete and submit a Greater than Minimal Risk application using the IRB electronic system. Include the following information about the proposed HUD clinical use:
    - The FDA HDE (Humanitarian Device Exemption) number and approval order (obtainable from the HDE-holder or the FDA's website)
    - A description of the device
    - The product labeling
    - Patient information packet that may accompany the HUD
    - A summary of how the clinician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

- Confirm initial Mayo Clinic IRB approval for clinical use of the HUD at the institution.
- Obtain and document clinical informed consent as required by the institution at which the HUD will be used. (When the use of a HUD is for clinical diagnosis or treatment, i.e. not associated with human subject research activity, research informed consent and HIPAA regulations for research do not apply).
- 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:
    - 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.
    - A description of any ancillary procedures associated with the use of the HUD.
    - A description of the use of the HUD.
    - All known risks or discomforts.
    - Information reflecting the HUD status of the device including a statement indicating 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 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. Refer to the IRB policy "Submitting a Reportable Event to the IRB".

IRB Responsibilities

- Conduct the initial review of the HUD clinical use application at a convened IRB meeting. The IRB will have among its members (or consultants) the appropriate experience and expertise to perform a complete and adequate review of the 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.
- Ensure that health care providers listed on the application are qualified through training and expertise to use the device.
- 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.

Related Documents

Emergency Single-Case Use of an Investigational Device, Drug, or Biologic Product

References

FDA Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers issued on July 8, 2010

Effective Date

July 6, 2015