

<b>Humanitarian Use Device (HUD)</b>	Effective Date	
	Revisions Date	11.19.20

**1.0 Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for what qualifies as a HUD and the regulatory requirements in terms of IRB submission and review.

**2.0 Persons Affected:**

- 2.1 Individuals involved in the use of a HUD
- 2.2 University & Medical Center Institutional Review Board (UMCIRB) Chairperson (or designees) and members
- 2.3 UMCIRB office staff and administrators

**3.0 SOP:** This SOP is to ensure the use of a HUD meets the requirements of federal regulations. The UMCIRB utilizes the same review procedures and processes for approving a HUD as other human research, with two exceptions:

- 3.1 UMCIRB may waive a consent document for the participant, and
- 3.2 Continuing review may be conducted using an expedited review process.

These exceptions apply when the HUD is being used in accordance with its approved labeling. However, the UMCIRB requires that patients either receive information related to the device or an informed consent document.

Unless it is an emergency, off-label use of a HUD should only be used after the Humanitarian Device Exemption (HDE) holder requests and receives approval for this use from the Food and Drug Administration (FDA). When the HUD is being used under a research protocol designed to collect safety and effectiveness data within the approved labeling, informed consent should be obtained. If the research protocol is proposing a new use of the HUD, Investigational Device Exemption (IDE) regulations for medical device clinical investigations would be followed and informed consent should be obtained.

**4.0 Definitions:**

- 4.1 **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 no more than 8000 individuals in the United States per year.
  - 4.1.1 The Office of Orphan Products Development (OOPD) determines if a device meets specific requirements, including scientific rationale and population prevalence, for designation as a HUD.
- 4.2 **Humanitarian Device Exemption (HDE):** To obtain approval for a HUD, a HDE application must be submitted to the FDA. An approved HDE authorizes marketing of the HUD. However, a HUD may only be used in facilities that have established a local IRB to supervise clinical testing of devices and after an IRB has approved the use of the device to treat or diagnose the specific disease.

**5.0 Responsibilities:**

- 5.1 **Investigators/Study team members** are responsible for:

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- 5.1.1 Including documentation that the investigator/sponsor has obtained a Humanitarian Device Exemption (HDE) from the FDA.
- 5.1.2 Providing the informative material that will be given to patients that receive the HUD (patient education pamphlets, information booklets, etc.).
- 5.2 **UMCIRB office staff** are responsible for:
  - 5.2.1 Verifying HUD status and the inclusion of patient information material within the IRB application.
- 5.3 **UMCIRB** is responsible for:
  - 5.3.1 Initial review of request for HUD use.
    - 5.3.1.1 May approve the protocol without any restrictions or on a case-by-case basis.
    - 5.3.1.2 May approve the use of the HUD for a period of time not to exceed 1 year.
    - 5.3.1.3 May allow the continuing review to be conducted under expedited procedures provided:
      - 5.3.1.3.1. Initial use of the HUD was approved without any further restrictions, and the continuing review period was not less than 1 year, and
      - 5.3.1.3.2. There have been no complaints from individuals on whom the device was used, and no additional risks have been identified.
  - 5.3.2 Verifying that the HUD does not pose an unreasonable risk of illness or injury to the recipient, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.
  - 5.3.3 Verifying that the use of the HUD, as proposed, is consistent with current labeling of the device and does not exceed the scope of the FDA approved indication.
- 5.4. **UMCIRB Chairperson (or designee)** is responsible for:
  - 5.4.1 Reviewing and approving the continuing review of an HUD under an expedited procedure in those cases where the UMCIRB allowed for this at the time of initial review.

**Revision History:**

Date	Change	Reference Section(s)
5.14.14	Updated to stand-alone document.	All
1.27.2016	Clarification of when research using a HUD would fall under IDE regulations	3.0
6.8.2017	Updated definition of HUD per FDA regulatory amendment	4.1
11.19.2020	Updated office name	2.0, 5.2

**References:**

FDA 21CFR814:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=814&showfr=1>

Frequently Asked Questions About Medical Devices:

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>

FDA Humanitarian Use Devices; 21st Century Cures Act: [Technical Amendment](#)