



Humanitarian Use Devices (HUDs)

Using Humanitarian Use Devices (HUDs)

Humanitarian use devices (HUDs) are a special class of device approved by the FDA for use in a rare condition (manifesting in fewer than 4,000 persons per year). The FDA allows the manufacture and use of HUDs without the same efficacy data for other FDA approved devices due to the small number of individuals impacted. A Humanitarian Device Exemption (HDE) is issued by the FDA, and an approved HDE authorizes the marketing of a HUD.

A device that has received HUD designation is eligible for FDA 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 or alternative forms of treatment.

The FDA requires that HUDs receive approval and ongoing monitoring from an IRB.

Sometimes a research protocol may be designed to collect safety and effectiveness related to a HUD or the requested use is for a new indication. IRB approval for the investigational study must be obtained before any research may begin and all applicable parts of the Investigational Device Exemption (IDE) regulation must be followed.

For more information on HUDs, the IRB's role and investigator requirements, please reference [FDA guidance](#) on this topic.

Submission Requirements

Physicians are required to submit an application and receive IRB approval to use the HUD at the institution. Effective July 2016, any NEW request for use of a HUD at Banner-University Medical Centers requires IRB oversight from Banner Health IRB.

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The information below provides GENERAL instruction on FDA requirements for Humanitarian Use Device responsibilities.

Physician Responsibilities



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- Obtain IRB approval and institutional clearances prior to first use of the HUD and maintain IRB approval (renewal at length of time designated by the IRB) as long as the HUD continues to be used in the institution (**see exceptions in emergency situations**)
- Ensure that patients receive the labeling information prepared by the HDE holder or, when safety and effectiveness data is being collected for a PMA, informed consent is obtained (21 CFR 50)
- Ensure that the device is used only by designated individuals in designated facilities approved for HUD use (i.e., individuals and facilities listed in the IRB approved protocol for HUD use);
- Ensure that the HUD is used within the scope of its labeling (i.e., indication listed in the Directions for Use)
- Report to the HDE holder/FDA and to the IRB whenever a 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 (21 CFR 814.126(a))

IRB Responsibilities

- Conduct initial (full board) as well as continuing review (full board or expedited) of the HUD
- Ensure that health care providers are qualified through training and expertise to use the device as required in the HDE Approval Order
- Ensure that patients receive the labeling information prepared by the HDE holder or, when safety and effectiveness data is being collected for a PMA, informed consent is obtained (21 CFR 50)
- Ensure that physicians submit reports to the HDE holder and to the IRB whenever a 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 (21 CFR 814.126(a))

HDE Holder Responsibilities

- Ensure that the HUD is used only in facilities with IRB approval
- Maintain records of the names and addresses of the facilities to which the HUD is shipped; correspondence with reviewing IRBs; and any other information required by a reviewing IRB or FDA (21 CFR 814.126(b)(2))
- Submit a report to FDA and to the IRB of record whenever a 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 (21 CFR 814.126(a))
- Provide the FDA with updated information on a periodic basis demonstrating that the HUD designation is still valid, based on the most current and authoritative information available (21 CFR 814.126(b)) and provide FDA with information on the number of devices shipped or sold since initial marketing approval, the clinical experience with the device and a summary of any changes made to the device (see 21 CFR 814.126(b)(1))
- Register HDE clinical trial information on CT.gov



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Emergency Use Situations

There are two types of emergencies:

- A) The HUD has already been approved use by the IRB at the institution. The patient has a life-threatening condition that needs immediate treatment and there are no acceptable alternative treatments available for the condition. In these situations the HUD may be used without any further IRB involvement, so long as it is being used for clinical purposes to treat a patient and not for research. The physician has reporting requirements to the HDE holder as with any use of a HUD.

Whenever possible, physicians should follow certain patient protection measures (i.e. obtain informed consent and devise a schedule to monitor the patient).

- B) The HUD has NOT been approved for use by the IRB at the institution. When a physician in an emergency situation determines that IRB approval for the use of a 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 to treat the patient. Emergency use situations are those in which:

- The patient has a life-threatening condition that needs immediate treatment;
- No generally acceptable alternative treatment for the condition exists; and
- Because of the immediate need to use the device, there is no time to use existing FDA approval procedures for the use.

Whenever possible, physicians should follow certain patient protection measures (i.e., concurrence of the IRB chairperson, informed consent, independent assessment by an uninvolved physician) prior to the emergency use. Physicians must obtain authorization of the HDE holder. When time is limited, the physician may contact an IRB chairperson by phone to discuss the emergency situation.

The physician must report the emergency use within five (5) days to the IRB. The notification must include the identification of the patient involved, the date of the use, and the reason for use.

References

Federal Food, Drug, and Cosmetic Act, Section 510(m)(2)

21 CFR 814 - Premarket Approval of Medical Devices

21 CFR 50 - Protection of Human Subjects

21 CFR 56 - Institutional Review Boards

U.S. Food and Drug Administration Guidance for HDE holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device

Exemption (HDE) Regulation: Questions and Answers, issued July 8, 2010