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MHRI IRB Quick Guidance for Humanitarian Use Device (HUD)

As defined in 21 CFR 814.3(n), 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 fewer than 4,000 individuals in the United States per year."

HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in emergencies where the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient.

HUDs may have a Humanitarian Device Exemption (HDE) for a particular indication. An HDE is an application similar to PreMarket Approval (PMA) issued by the FDA, however, exempt of the effectiveness data requirement (requires safety data). An HDE allows it's holder to market the device for sale, with certain restrictions.

Although the use of a HUD within its approved labeling does not constitute research, the FDA requires IRB approval be obtained before a HUD can be used in a facility. The responsibilities of physicians and IRBs are listed below.

Physician Responsibilities

- Obtain IRB approval and institutional clearances ***prior*** to first use of the HUD and maintain IRB approval (continuing review) as long as the HUD continues to be used in the institution
- Ensure that patients receive the labeling information prepared by the HDE holder, or, when safety and effectiveness data is being collected for PMA, informed consent is obtained (21 CFR 50) **Premarket approval** (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices
- 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 application for HUD use)
- Ensure that the HUD is used within the scope of its labeling (i.e., indication listed in the Directions for Use or Instructions 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))

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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 are 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))

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 Industry and FDA Staff - Humanitarian Device Exemption (HDE)

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What is a 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.

Is a HUD-approved by the FDA?

HUDs have an approved Humanitarian Device Exemption (HDE). An HDE is an application that is exempt from the effectiveness requirements that must be demonstrated before a typical device approval. The approval of the HDE allows the device manufacturer to market the HUD.

Can the HUD be used for other indications?

The HUD should only be used according to the approved labeling and indication(s). Investigational use of the device cannot be approved as a HUD. If the HUD is being studied for a use other than its approved indications, an IDE may be required and the investigation would require IRB approval.

Does the IRB have to make a risk determination when considering the use of a HUD at the facility?

No. The IRB does not need to make any type of risk determination for the use of the HUD.

If the HUD requires IRB approval prior to use, is it research?

No. The use of a HUD for the approved indication is not research. However, the FDA regulations require that the IRB review the use at the facility.

If it is not research, what should the IRB consider?

The FDA recommends following the approval criteria found at 21 CFR 56.111 as much as possible. For example, you should review the risks to patients, ensure risks are minimized and evaluate whether the risks are reasonable in relation to the proposed use of the device.

What type of material should the IRB review?

The IRB should review: the HDE approval; a description of the device; the product labeling; the patient information packet; a sample consent form if required by the IRB; a summary of how the physician proposes to use the device.

Should the IRB review each use of the HUD at a facility?

No. The IRB is not required to review and approve each use.

Is a consent form required?

No. The regulations do not require a consent form, but the IRB may require one. There will most likely be a patient information brochure that addresses information that patients should know about the HUD. This should be distributed to patients if available.

Can the HUD be used without prior IRB approval?

If there is an emergency situation and the physician determines that the IRB approval for use of the HUD at the facility cannot be obtained in time to prevent serious harm or death to a patient, the HUD may be used without prior IRB approval. The physician must report the use within 5 days and provide written notification of the use to the IRB.

Does the physician using the HUD need to report "adverse events" to the IRB?

No. The IRB is not responsible for monitoring of a HUD in the same way they monitor a clinical research investigation. The physician using the HUD **does** need to report whenever a HUD may have caused or contributed to a death or caused or contributed to a serious injury. **Note:** The physician using the HUD must also report this to the manufacturer.

Humanitarian Device Exemption (HDE) Regulation: Questions and Answers, issued July 8, 2010
21 CFR 814