Humanitarian Use Devices

Policy

This policy indicates that based on FDA regulatory requirements, it is the policy of the Boston Children's Hospital Institutional Review Board to review and approve the use of Humanitarian Use Devices.

Procedure

Humanitarian Use Device (HUD): A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.

Humanitarian Device Exemption (HDE): A Food & Drug Administration (FDA) approval for a physician to use an HUD in clinical treatment or in clinical investigation. An approved HDE authorizes marketing of an HUD. An HUD may only be used in facilities that have established a local institutional review board (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.

IRB Review of HUD Use Within it Labeled Indication

For a HUD to be used in treatment, diagnosis, or research, the IRB and the FDA must approve it and a Humanitarian Device Exemption (HDE) must be issued by the FDA.

While the effectiveness of the device does not have to be demonstrated, the IRB will consider the HDE brochure and the information provided about risks and benefits.

The IRB approval must verify 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. The device's labeling must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been proven or demonstrated.

The initial review of a HUD is to be completed by the convened IRB. A separate application has been developed for HUD submissions and they include asking for the following information:

- The generic and trade name of the device;
- The FDA HDE number;
- The date of HUD designation;
- The indication(s) for use of the device;
- A description of the device;
- Contraindications, warnings, and precautions for use of the device;
- Adverse effects of the device on health;
- Alternative practices and procedures;
- The HUD brochure;

- Marketing history; and
- A summary of studies using the device.

The investigator using the HUD must use the HUD only in accordance with the labeling of the device, intended purpose, and in the designated population for which the FDA approved its use. If the investigator plans to collect data for a new use of the device, then the IDE regulations must be followed.

The IRB may approve use of the HUD without any further restrictions, or under a protocol, or on a case-by-case basis.

Informed Consent

The IRB requires that documented informed consent is obtained from a patient prior to the use of an HUD. The consent is to describe the status of the device and the intended use. In addition if an investigator proposes to collect prospective data when the device is used, this data collection should be addressed in the consent. The consent also needs to indicate that the effectiveness of the device for a specific indication has not been demonstrated. The document should not use the term "research" to refer to the use of the device. It is also suggested that the investigator provide the HUD brochure (prepared by the manufacturer, if available) to the patient, and review it with the patient prior to use.

Continuing Review

Continuing IRB review is required and may occur using expedited procedures if the HUD is not being used in the course of a research study. At the time of continuing review, the investigator must report the HUD activities for the previous year.

Unanticipated Event Reporting

Adverse events and unanticipated problems that results from the use of a humanitarian device are subject to "Unanticipated problem" reporting requirements.

FDA regulations require that if a physician or health care provider receives or otherwise becomes aware of information, from any source, that reasonably suggests that a HUD has or may have caused or contributed to the death or serious injury of a patient, the physician or health care provider must report such findings to the FDA **as soon as possible, but no later than 10 working days** after the Investigator first learns of the effect or problem. This reporting is in addition to, not a substitute for, FDA and/or manufacturer reporting requirements in accordance with 21 CFR 803.30.

Using HUD in Emergency Use Situations or Use of HUD When There Are No Alternatives in Non-Emergency Situations

Using HUD in Emergency Use Situations

If a physician in an emergency situation determines that approval from an IRB 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.

In such an emergency situation, within 5-days after the use of the device, the physician must provide written notification to the chairman of the IRB of such use. The written notification

should include the identification of the patient involved, the date on which the device was used, and the reason for the use.

If a physician in an emergency situation determines the use of an HUD outside of the approved indicated use represents an opportunity to prevent serious harm or death to a patient, a HUD may be used in accordance with the emergency exemption procedures (see emergency exemption policies) This use would need to be reported to the sponsor and the investigator is responsible for all reporting as consistent with emergency use procedures.

Use of HUD When There Are No Alternatives in Non-Emergency Situations

If an investigator wants to use a HUD outside its approved indication(s) but it is not an emergency situation, the investigator should contact the IRB office for guidance. Investigators will likely need to submit the same information required for an emergency exemption and will also be required to contact the HDE holder prior to use.

Related Content

Federal Guidance

FDA 21 CFR 814, 21 CFR 803.30

Draft Guidance: ***HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers; August 5, 2008***

Document Attributes

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