Humanitarian Use Devices

Effective Date: March 20, 2023
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Scope

This policy indicates that based on U.S. Food & Drug Administration (FDA) regulatory requirements, it is the policy of the Boston Children's Hospital Institutional Review Board (IRB) to review and approve the use of Humanitarian Use Devices.

Definitions

Humanitarian Use Device (HUD): A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 8,000 individuals in the United States per year.

Humanitarian Device Exemption (HDE): A U.S. Food & Drug Administration (FDA) approval for a physician to use a Humanitarian Use Device (HUD) in clinical treatment or in clinical investigation. An approved Humanitarian Device Exemption (HED) authorizes marketing of a HUD. A 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.

Humanitarian Device Exemption Holder (HDE Holder): The person or company who obtains the approval of a Humanitarian Device. Exemption (HDE) from FDA.

Policy Statements

IRB Review of Humanitarian Use Device (HUD) Use Within its Labeled Indication

For a **Humanitarian Use Device (HUD)** to be used in treatment, diagnosis, or research:

1. The Institutional Review Board (IRB) and the FDA must approve it and
2. 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:

1. The HDE brochure and
2. The information provided about risks and benefits.
3. The IRB relies on the Departmental Review process which occurs prior to IRB submission to assess the provider's qualifications through training and expertise with use of the device.

The initial review of a HUD is to be completed by the convened IRB.

1. 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.
    a. The device's labeling must state that the device is a HUD 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 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 Investigational New Device (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 a HUD and has developed HUD informed consent templates available on the IRB website. In some circumstances, the IRB may also accept use of the HDE holder developed patient information packets that generally contain a discussion of the potential risks and benefits of the HUD and any procedures associated with its use.

1. The consent is to describe the status of the device and the intended use.
2. If an investigator proposes to collect prospective data when the device is used, this data collection should be addressed in the consent.
3. The consent also needs to indicate that the effectiveness of the device for a specific indication has not been demonstrated.
4. The document should not use the term "research" to refer to the use of the device.
5. 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

IRB Continuing Review is required and may occur using expedited procedures.

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.

1. 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.
2. 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 IRB Chair of such use. The written notification should include:

1. The identification of the patient involved
2. The date on which the device was used
3. The reason for the use

If a physician in an emergency situation determines the use of a 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 administrative office for guidance. The IRB has developed a process to review non-emergency off label clinical uses which may involve either

- Submission of a HUD application specific to an off label use for a distinct population or for a specific disease or disorder.
- Submission of a Protocol Exception for individual patient off label clinical use.

Investigators will need to address additional questions about risks/benefits and may need to provide documentation that the off label clinical use is approved by the HDE holder. The IRB has also developed an Informed Consent Template for off label clinical uses which must be used.

Procedures

A separate IRB application has been developed for HUD submissions and asks for the following information:

1. The generic and trade name of the device;
2. The FDA HDE number;
3. The date of HUD designation;
4. The indication(s) for use of the device;
5. A description of the device;
6. Contraindications, warnings, and precautions for use of the device;
7. Adverse effects of the device on health;
8. Alternative practices and procedures;
9. The HUD brochure;
10. Marketing history; and
11. A summary of studies using the device.

Related Content

- U.S. Food & Drug Administration CFR – Code of Federal Regulations
    - 21 CFR 814: Premarket Approval of Medical Devices
    - 21 CFR 803.30: Medical Device Reporting
- U.S. Food & Drug Administration Guidance
    - ***Humanitarian Device Exemption (HDE) Program: Guidance for Industry and Food and Drug Administration Staff***