

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy & Procedure Title: Humanitarian Use Devices Category: IRB Review Process	

## I. Policy Statement

While remaining consistent with the protection of public health and safety, and with ethical standards, PH IRB will review submissions regarding a Humanitarian Use Device in order to encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year.

## II. Definition of Terms

**Humanitarian Use Device (HUD):** A device used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals annually in the United States. A HUD is an approved device whose use must comply with [21 CFR 814, Subpart H “Humanitarian Use Devices,”](#) and [21 CFR Part 803, “Medical Device Reporting”](#).

**Humanitarian Device Exemption (HDE):** An FDA approved application for a HUD is similar to a pre-market approval application (PMA), but is exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a HUD.

**HUD Adverse Device Effect(s) (HUD ADE):** An event that reasonably suggests that a device has or 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.

- **Serious injury:** An injury or illness that (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

## III. Procedure

- A. Once a device has received a HUD designation from the FDA, whether for treatment, diagnosis, or research, the use of a HUD must be initially reviewed at a convened PH IRB Meeting and approved before the device may be used.

To request PH IRB review, a Physician must submit the following documentation:

1. The FDA HDE approval letter;
2. The HUD manufacturer’s (HDE Holder) product labeling, clinical brochure, and/or other pertinent manufacturer informational materials;
3. Patient Information Packet (if available from HDE Holder);
4. A statement that specifies the use of the HUD will be limited to the clinical indication(s) listed in the FDA-approved product labeling;

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5. PH institutional approval for this use (letter from PH signed by the President/CEO, Service Line Director or designee);
  6. If applicable, information describing the Physician's clinical experience or any training required/completed as required by the HDE Holder;
  7. PH IRB HUD Submission Form.
- B. PH IRB approval for the use of a HUD is limited to those physicians, or physician groups, and locations specifically listed on the initial PH IRB HUD Submission Form or as designated by PH IRB. The approved physicians, or physician groups, and locations will be listed on the HUD Review Certificate. If additional users or locations are required, a PH IRB HUD Amendment Form must be submitted to PH IRB for review and approval.
- C. A "Responsible Physician" must be designated on the PH IRB HUD Submission Form. The Responsible Physician accepts responsibility for all reporting requirements for all uses of the HUD, including the uses by all PH IRB-approved physicians at all locations listed on the HUD Review Certificate.
- D. Clinical Consent Form.
1. Consent for the use of a HUD is not required.
  2. However, if an HDE Holder decides to collect safety and effectiveness data, or the HUD is used in an emergency situation, informed consent of the patient must be obtained. (See PH IRB P&P Emergency Use of a Drug, Biologic, or Medical Device)
- D. Continuing Responsibilities for the Use of a HUD. Continuing review of the use of a HUD must occur within the appropriate timeframe as specified by the PH IRB or the use of the HUD must cease until such time that it can be reviewed. PH IRB Office will provide the Responsible Physician with a PH IRB HUD Continuing Review Form at the appropriate time for completion.
1. The Responsible Physician should track and/or be prepared to report the following at the time of Continuing Review on the PH IRB HUD Continuing Review Form:
    - a. The number of patients who received the HUD for all physicians listed on the HUD Review Certificate since original approval, and since the last review.
    - b. HUD ADE must be submitted to PH IRB and to the HDE Holder who will submit to the FDA no later than 10 work days after the day the Responsible Physician becomes aware of information. A brief summary of all HUD ADE must be submitted at Continuing Review.
    - c. A copy of the HDE Holder's most recent Annual Report to the FDA, unless previously submitted in the past year.

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- E. Modifications to the HUD, HDE and/or Device Labeling. After the FDA has granted approval for use of the HUD for additional clinical indications, PH IRB approval is required before the HUD can be used for these additional indications. The Responsible Physician should submit the following documentation to PH IRB for review of a HUD modification:
1. A PH IRB HUD Amendment Form describing the modifications to the device, the proposed clinical use of the device, and the rationale for such modification(s);
  2. A copy of the FDA's approval of the modification;
  3. A copy of the HUD manufacturer's modifications to the HUD product labeling, clinical brochure, and/or other pertinent manufacturer information materials corresponding to the requested modification(s);
  4. A copy of the revised clinical use statement;
  5. A copy of the revised Patient Information Packet, if available.
  6. A copy of the revised Consent Form, if applicable.
- F. Off-Label Use of a HUD in an Emergency or Compassionate Situation. It is recognized that there may be circumstances in which "off-label" use of a HUD may be necessary to save the life of a patient, or to protect the well-being of a patient when there are no acceptable alternative devices or therapies for the patient's condition. When these situations arise, the Responsible Physician should:
1. Determine if the situation meets the requirements for a one-time Emergency Use. To make this determination and for additional information on how to proceed, follow the procedures outlined in the PH IRB P&P: Emergency Use of Drugs, Devices or Biologics.
  2. If the off-label use does not qualify for the one-time emergency procedure, submit a PH IRB HUD Amendment Form to PH IRB, prior to the use of the HUD, following the procedures previously outlined in this policy (see Section III E of this policy).
- G. Other Amendments
- a. Change of Responsible Physician, other physicians, locations of use.
  - b. Any other change(s) to the HUD use.

#### IV. References

- A. [FDA, Humanitarian Device Exemption \(HDE\) Regulation: Questions and Answers; Final Guidance for Industry, July 18, 2006](#)
- B. [FDA: Draft Guidance for HDE Holders, Institutional Review Boards \(IRBs\), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption \(HDE\) Regulation: Questions and Answers August 5, 2008](#)
- C. [Humanitarian Use Device Regulations](#)

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- D. [Humanitarian Use Devices, A brief guide for clinicians, investigators, and IRB members, Dale E. Hammerschmidt, M.D., University of Minnesota, October, 2001](#)
- E. [21 CFR 814, Premarket Approval of Medical Devices](#)
- F. [21 CFR 814, Subpart H, Humanitarian Use Devices](#)
- G. [21 CFR 803, Medical Device Reporting](#)
- H. [PH IRB Policy and Procedure for Emergency Use of Drugs, Devices and Biologics](#)

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