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Owner	Dawn Benson: SVP, General Counsel
Area	Institutional Review Board (IRB)
Applicability	Phoebe Putney Memorial Hospital
Reference Tags	Policy

Humanitarian Use Devices (HUD)

Scope:

This policy describes the responsibilities of clinicians and the Phoebe Putney Memorial HOspital INstitutional Review Board ("IRB") related to use of humanitarian use devices in clinical treatment or diagnosis, i.e., use that does not constitute human subject research.

Purpose:

The IRB requires that clinicians comply with all applicable regulations pertaining to humanitarian use devices, and that all uses of humanitarian use devices be reviewed and approved by the IRB as defined by Federal regulations.

Definitions:

Humanitarian Use Device (HUD) is a medical device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. HUD designations are issued by the FDA.

Institutional Review Board (IRB) is the institutional review board of record for Phoebe Putney Memorial Hospital, Inc.

PPMH is Phoebe Putney Memorial Hospital

Humanitarian Device Exemption (HDE) is a Food and Drug Administration ("FDA") premarket approval

application that allows marketing of a product that is exempt from effectiveness requirements. FDA approval of a HDE authorizes an applicant to market a HUD, subject to certain profit and use restrictions. An HDE application must include the following specific information to satisfy the HUD statutory requirements:

a. The device is to be used to treat or diagnose a disease or condition that affects or is manifested in not more than 8,000 individuals in the U.S. per year;

b. The device would not otherwise be available to a person with the disease or condition in question without the HDE, and no comparable device, other than another device or a device approved under am HDE or an IDE is available to treat or diagnose the disease or condition; and

c. The device will not expose patients to an unreasonable or significant risk of illness/injury, and the probable benefit to health from using 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.

Policy:

1. A HUD may only be used in facilities that have an established IRB constituted and acting in accordance with FDA's regulations governing IRBs, including responsibility for continuing review of use of the device. For initial review of a HUD, full IRB committee review is required. For continuing review, however, an IRB may use the expedited review procedures, unless the IRB determines that full Board review is necessary.
2. A HUD may only be administered to, or implanted in, a patient located at PPMH if such use has been approved by the IRB for the facility. IRB approval of the use of a HUD cannot exceed the scope of the FDA approved indication(s), but may limit the scope of the FDA approved indications if the IRB feels such limitation is appropriate. IRB approval of each use of the HUD is not required as long as the use of the HUD falls within the approved FDA indication and any IRB limitations.
3. HUD uses must be reported on a continuing review basis by the clinician to the IRB on the form provided by the IRB for this purpose. Continuing review will be conducted, at a minimum, annually for all applicants holding HDE approvals from the IRB.
4. FDA does not require IRB approval of informed consent before a HUD is used because a HDE, which provides for temporary marketing approval, does not constitute research. Unless an exemption applies, the IRB requires that a clinical informed consent form for a HUD must be signed by the patient prior to use of the HUD at a PPMH facility when practicable.

Procedure:

1. Initial IRB Approval – The HUD and its proposed use must be reviewed and approved by a convened meeting of the IRB. Applicants must submit the following to the IRB Coordinator according to the time frame set by the IRB Administrator.
    a. The IRB Application for Humanitarian Use Device Under a Humanitarian Device Exemption (HDE)
    b. The HUD manufacturer's product labeling, patient package insert, and/or other

pertinent manufacturer informational materials.

c. The FDA HDE approval letter.

d. Proposed Patient Clinical Consent form, or rationale for exemption from the form. This form shall incorporate the following:

i. A description of an HDE/HUD approval process; e.g., "Your medical care will involve the use of (specify device), which has been approved by the U.S. Food and Drug Administration (FDA) as a Humanitarian Use Device (HUD). A HUD is a device used to diagnose or treat a disease or condition that affects fewer than 8,000 individuals in the United States per year and for which no comparable device is available. The FDA approves the clinical use of a HUD based primarily on evidence that it does not pose a significant risk of injury to the patient and that the potential benefit of the device to the health of the patient outweighs the risks of its use. The FDA approval of a HUD is based on limited data documenting its effectiveness in humans."

ii. A description of the HUD and how this device will be used in the clinical setting. Based on this description, it should be clear to the patient why he/she is a candidate for the use of the device.

iii. A discussion of possible risks, side effects, and/or adverse events associated with the HUD and its proposed clinical use.

iv. A discussion of the possible benefits associated with the clinical use of the HUD.

v. A discussion of any alternative treatments or procedures (if any) that the patient may wish to consider in lieu of clinical application of the HUD.

vi. A statement that the patient has read the package insert and/or patient information sheet for the HUD.

vii. Voluntary Consent statement(s) with patient signature and date lines.

viii. Physician Certification statement with physician signature and date lines.

2. Continuation of IRB Approval: The IRB is responsible for determining the period for conducting continuing review. Such reviews occur, at a minimum, annually. Each applicant with an approved HDE will receive a letter from the IRB Coordinator. Continuing review of approved HDE applications can be conducted by expedited review or by full Board review. The IRB will determine which process to use at the time of the initial review and approval.

3. Manufacturer modifications to the HUD or device labeling.

a. IRB approval is required for any modifications of the HUD and/or proposed clinical use of the device. Applicants should submit the following information to the IRB as soon as possible:

i. A cover letter, signed by the physician applicant, describing the modifications to the device and/or the proposed clinical use of the device and the rationale for such modifications.

ii. A copy of the HUD manufacturer's amendments to the HUD product

labeling, clinical brochure, and/or other pertinent manufacturer informational materials corresponding to the requested modifications.

iii. A copy of the revised clinical use statement and clinical consent form with the modifications highlighted.

4. Off-Label use of a HUD in emergency or compassionate situations: It is recognized that there may be circumstances in which "off label" use of a HUD may be necessary to save the life or protect the well-being of a given patient. Under either of these situations, the investigator must follow the emergency use procedures outlined in the PPMH policy "Emergency Use of Drugs, Biologics, and Devices."

References:

- 21 CFR 814.124
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Approval Signatures

Step Description	Approver	Date
Chief Operating Officer	Deborah Angerami: CEO	12/12/2025
Owner/Legal Approval	Dawn Benson: SVP, General Counsel	10/22/2025

Applicability

Phoebe Putney Memorial Hospital

History

Sent for re-approval by Pardue, Sharon: Paralegal on 10/22/2025, 2:03PM EDT

> No Changes needed to the policy at this time. Reviewed and approved by the Phoebe IRB Committee on October 22, 2025.

Last Approved by Benson, Dawn: SVP, General Counsel on 10/22/2025, 2:45PM EDT

Approval flow updated in place by Williams, Mary: Paralegal on 12/4/2025, 5:27PM EST

Last Approved by Angerami, Deborah: President/CEO PPMH on 12/12/2025, 3:04PM EST

Activated on 12/12/2025, 3:04PM EST