

Phoebe Putney Health System, Inc.

POLICY TITLE: HUMANITARIAN USE DEVICES (HUD)

ENTITY: PPMH

Approved by: IRB CHAIR

Review Period: 3 Years

Contact Information: IRB COORDINATOR

Effective Date: 5-25-2016

Review Date: 5-22-2019

Scope: The Humanitarian Use Devices (HUD) policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To establish procedures for the review, approval, and continuing review of humanitarian Use devices (HUDs) under an FDA-approved Humanitarian Device Exemption (HDE) within Phoebe Putney Memorial Hospital (PPMH).

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. A HUD is approved for marketing through a humanitarian device exemption (HDE) application.

Humanitarian Device Exemption (HDE) is basically a premarket approval application (PMA) that is NOT required to contain clinical data demonstrating that the HUD is effective for its intended use, but is required to contain all other information ordinarily required of a PMA. In addition, an HDE application must include the following specific information to satisfy the HUD statutory requirements:

- a. That 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. That the device would not otherwise be available unless an HDE application was approved;
- c. That no comparable device (other than another HUD approved device or a device being studied under an IDE) is available to treat or diagnose the disease or condition; and
- d. That 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 (21 CFR part 56), 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 in 21 CFR 56.110, 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 a facility 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 Applicant 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. However, unless an exemption applies, the PPMH IRB requires that a clinical informed consent form for 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 with PPMH must be reviewed and approved by a convened meeting of the PPMH IRB. Applicants must submit the following to the IRB Coordinator or the Director of Clinical Research according to the timeframe set by the IRB Administrator.
 - a. The PPMH 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 4,000 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 and continuing review form from the IRB Coordinator. The form is to be completed and returned to the IRB office as noted in the letter. Continuing review of approved HDE applications can be conducted by expedited review or by full Board review. The Board 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 device 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
- 21 CFR 56.109, 56.110

REVISION HISTORY

Revision Number	Description of Changes	Approvals	Date
N/A	Initial release of Policy for PPHS Policy Management System (Compliance 360 Program). This policy replaces all previous versions.	IRB Committee	5-25-2016
1	Changed "fewer than 4,000" to "not more than 8,000" because of change on December 13, 2016 to Section 3052 of the 21 st Century Cures Act (Pub. L. No. 114-255)	IRB Committee	05-22-2019