**Institutional Review Board**

# HUD/HDE IRB REQUIRMENTS

**DEFINITIONS:**

Humanitarian Use Device (HUD): a medical device intended to benefit patients in the treatment and diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

Humanitarian Use Device Exemption (HDE): a premarket approval application submitted to the FDA seeking a Humanitarian Device Exemption from the safety and effectiveness requirements of sections 514 and 515 of the Food, Drug, and Cosmetic Act. The HDE allows a physician to use an HUD in clinical treatment or in clinical investigation. An approved HDE authorizes marketing of an HUD.

HDE holder: the individual who obtains the Humanitarian Device Exemption (HDE) from the FDA.

Investigational Device Exemption (IDE): allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the FDA.

Research: In this context, research refers to the physicians' intent to collect safety and effectiveness data about a device for a ***new*** use.

**RESPONSIBILITIES:**

## HUD User

Research and non-research HUD use:

1. Ensure that the HDE exists for the use of the HUD.
2. Obtain permission from HDE holder for use of HUD.
3. Ensure HUD use meets HDE requirements.
4. Verify that the HUD will be used for treatment, diagnosis, or research in accordance with the labeling of the device, intended purpose, and the designated population for which the FDA approved its use.
5. Submit a plan/protocol for use of the HDE to the PHCIRB.
6. Obtain PHCIRB approval for use prior to use.
7. Submit documentation to PHCIRB for continuing review of HDE. This will entail a summary of the clinical indications for use of the HUD in each patient, adverse events or unanticipated problems involving risk to participants or others that are possibly or probably related, the clinical outcomes of each participant, if known, and any Medical Device Reports per 21 CFR 803.

Emergency HUD use:

1. Ensure and provide documentation to PHCIRB attesting that the criteria for emergency use are met:
    a. No alternative treatment
    b. Life-threatening or serious disease or condition
    c. No time to obtain FDA approval.
2. Obtain concurrence of IRB chair for HUD use, if possible.
3. Obtain an independent assessment of HUD use from a physician uninvolved in the study, if possible prior to use. Assessment must be forwarded to the PHCIRB within the (5) business day post emergency use reporting window.
4. Obtain HDE holder permission and patient informed consent, if possible prior to use. HDE holder permission must be forwarded to the PHCIRB within the (5) business day post emergency use reporting window.
5. After emergency use, within 5 business days, send report to IRB (via IRBNet) and HDE holder regarding use. Submissions to the IRB must be accompanied by either a telephone call to 404.605.3638 or email to madeline.peyton@piedmont.org.

Compassionate/ Off-label HUD use:

1. Ensure criteria for compassionate use are met:
    a. No alternative treatment
    b. Serious disease or condition
    c. Obtain FDA approval prior to use.
2. Submit documentation to HDE holder supporting use.
3. Obtain FDA correspondence regarding amendment to HDE (from HDE holder). This information will be submitted to the IRB.
4. Obtain PHCIRB approval.
5. Obtain IDE for ***research*** on uses of HUD not covered by HDE.
6. Submit documentation to PHCIRB for continuing review of HDE. This will entail a summary of the clinical indications for use of the HUD in each patient, adverse events or unanticipated problems involving risk to participants or others that are possibly or probably related, the clinical outcomes of each participant, if known, and any Medical Device Reports per 21 CFR 803.

**HDE Holder:**

Research and non-research HUD use:

1. Complete HDE application to FDA satisfaction. This includes establishment that no comparable device is available for proposed use.
2. Provide permission letters to HUD users for submission to the local IRB.
3. Hold both HUD and HDE prior to shipment of a device to a facility with an established Institutional Review Board that operates in compliance with FDA regulations.
4. Ensure initial and continuing IRB review and approval.
5. Report clinical experience to FDA via annual reporting.
6. Maintain IRB correspondence.

Compassionate HUD use:

1. Submit HDE amendment to FDA for approval, obtain approval and forward to HUD User for submission to IRB.