Standard Operating Procedure (SOP)

SOP number: SOP CW AHC 236	**SOP Name:** Humanitarian Use Device (HUD)
Location: *Company-Wide Policies	**Responsible Department:** Research Services
SOP Owner/Executive Owner: Executive Director Research Services	**Original Creation Date (If applicable):** 01/18/2022
Effective Date: 08/16/2023	**Review Date:** 08/16/2023

I. SCOPE: This standard operating procedure (SOP) applies to all physicians using Humanitarian Use Devices (HUD) for the treatment or diagnosis of patients at AdventHealth.

II. PURPOSE: The purpose of this SOP is to describe the requirements and responsibilities for all physicians using a HUD for treatment purposes, which must be overseen by AdventHealth's Institutional Review Board (IRB). Although use of a HUD for the treatment or diagnosis of a patient is not considered research, the Food and Drug Administration (FDA) regulations governing the use of medical devices requires an IRB to review and oversee HUD use at their local or designated facilities.

III. QUALIFIED PERSONNEL: IRB Executive Chair, IRB members, IRB staff members, physicians and other personnel involved in obtaining an IRB specific consent for a HUD.

IV. TRAINING: Cerner HUD Module,(or Epic, whichever is applicable); AdventHealth IRB HUD training; Training required by the FDA approval order for Humanitarian Device Exemptions (HDEs)

V. SUPPLIES & EQUIPMENT: Not Applicable

VI. PROCESS/PROCEDURE:

A. HUD Training Requirements

1. IRB Required Training:
   a) All physicians using the HUD must complete AdventHealth IRB HUD training.
2. FDA Training Requirements:
   a) Personnel involved in the use of a HUD should review the FDA approval order to determine training requirements set forth by the FDA.
   b) The FDA approval orders of HDEs can be found by entering the HDE number at the following website: https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/hde-approvals

B. AdventHealth HUD Application Requirements

1. Research Review Application – submit to the Office of Sponsored Programs (OSP)
2. Submit IRB Initial Review Application including all applicable documents as listed in the application form.

C. Consent Requirements

1. Routine clinical treatment consent processes must be followed to treat for clinical care according to all relevant hospital policies.
2. The IRB may require an additional informed consent to be obtained for the use of the HUD in addition to the usual treatment consent. This requirement will be communicated to the applicable personnel at the time of IRB review and will be included in the IRB approval letter.
3. In the event the IRB requires informed consent, the HUD user or designee will be responsible for:
   a) Providing an informed consent form to the IRB for review utilizing the HRP-506 – TEMPLATE Consent for HUD or a consent form provided by the HDE holder.
   b) Ensuring that informed consent is obtained for all patients receiving the HUD. The signed, original informed consent document should be maintained with the HUD records, a copy placed in the patient's medical record and a copy given to the patient.

D. Management of HUD Utilization at AdventHealth

1. Obtain IRB approval and OSP clearance PRIOR to first use of the HUD and maintain IRB approval as long as the HUD continues to be used in the institution. This includes but is not limited to modifications when appropriate and annual renewals.
2. It is a federal requirement to provide all HUD patients with the labeling and patient materials (such as a patient information brochure) prepared by the HDE holder prior to the patient receiving the HUD whenever feasible.
3. Ensure the HUD device is used ONLY by designated individuals in designated facilities approved for HUD use (listed in the documents submitted to the IRB and HDE holder).
4. HUD user or designee is responsible for keeping proper control of the device. Use the applicable HUD form/interface to track the use of HUDs within AdventHealth's electronic medical record (EMR). The AdventHealth IRB recommends HUD standard documentation in the patient's EMR. Please contact Research Information Systems (ResIS) at AIT.ResIS@AdventHealth.com for HUD set up and training.
5. The following responsibilities are included in keeping proper control of the device:
   a) Only the designated physician(s) or health care provider(s) use the device (as listed in the IRB submission, unless IRB determines a list of personnel is not required).
   b) The device is kept in a secure place with limited access ensuring only IRB approved HUD users have access to the device.
   c) HUD user or designee will be accountable for receiving the devices, using or implanting the devices, and maintaining the following documentation: quantity received, dates of receipt, recording unique identifiers if applicable, i.e. serial #s, expiration dates if applicable, date of use or implant, patients, medical record numbers (MRNs), Date of Birth (DOB), etc.

d) Ensure the HUD is used within the scope of its labeling (indication listed in the directions for use). The HUD user or designee must make sure that only eligible patients that meet the criteria as described in the documents submitted to the IRB receive the device.

6. Research departments that are utilizing Florence eRegulatory binder system may store HUD records in that system.

E. HUD Reporting Requirements

1. Annual review by the IRB is required as long as the HUD continues to be used in the institution.
2. HUD user or designee must prepare and submit medical device reports (MDR) to the FDA, IRB, and HUD device manufacturer in accordance with 21 CFR 803 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=803) in the following events:
   a) When a HUD may have caused or contributed to a death.
   b) When a HUD may have caused or contributed to a Serious Injury.
   c) When a HUD has malfunctioned and would be likely to cause or contribute to a death or Serious Injury if the malfunction were to recur (21 CFR 814.126(a)).

F. Special Circumstances (off-Label and Emergency Use)

1. Off-label use
   a) If the HUD has AdventHealth IRB approval: report off-label uses at the time of annual review.
   b) If the HUD does not have AdventHealth IRB approval: follow the process for Compassionate Use of devices according to HRP-826 INVESTIGATOR GUIDANCE – Emergent & Non-Emergent Use of Test Articles.

2. Emergency Use

   a) If a physician in an emergency situation determines that IRB approval for the use of a HUD cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used within the scope of its labeling or off-label without prior IRB approval.
   b) The emergency use of a HUD must be reported to the IRB according to HRP-826 INVESTIGATOR GUIDANCE – Emergent & Non-Emergent Use of Test Articles and HRP-222 FORM – Emergent Use Report – Devices.

VII. <u>DEFINITION(S)</u>: For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in

Research.

VIII. EXCEPTION(S): See CW AHC 101 Research Oversight

IX. REFERENCE(S):

21 CFR 803
FDA 21 CFR Part 814.124
FDA 21 CFR 814.3(n)
21 CFR 814.126

X. RELATED DOCUMENT(S) / ATTACHMENT(S):

- Definitions in Human Research
- Designations in Research
- Abbreviations in Research
- Research Oversight
- Human Research Protection Program
- FORMS and TEMPLATES are located in the IRB electronic submission system.
- WORKSHEETS and INVESTIGATOR GUIDANCE are located on the AdventHealth Research Institute website
  - HRP-450 WORKSHEET – Criteria for Approval HUD
  - HRP-826 INVESTIGATOR GUIDANCE – Emergent & Non-Emergent Use of Test Articles