

Policy Number: 46

Title: Humanitarian Use Devices

Date of Last Revision: 08/10/2005; 07/22/2010; 05/01/16; 11/21/19

Policy

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to review and approve the use of all Humanitarian Use Devices.

I. IRB Review of Humanitarian Use Device (HUD) Use

- A. On December 13, 2016, Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255) changed the population estimate required to qualify for Humanitarian Use Device (HUD) designation from "fewer than 4,000" to "not more than 8,000." Accordingly, a HUD is defined as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.
- B. In order for a HUD to be used in treatment, diagnosis, or research at UCI, the IRB must approve it and the FDA must issue a Humanitarian Device Exemption (HDE).
 - 1. The IRB approval must verify that the use of the HUD, as proposed, is in accord with current labeling of the device and does not exceed the scope of the FDA approved indication.
 - 2. The IRB may impose more stringent restrictions for use of the HUD as a means of additional protections, as deemed necessary.
- C. The initial review of a HUD is to be completed by the full IRB Committee. The full Committee may make the determination at initial review that subsequent continuing reviews may go through the expedited review process. Expedited review procedures are appropriate for continuing review since the initial review would have been performed by the full board and use of the HUD within its approved labeling does not constitute research. Accordingly, an expedited review category does not need to be assigned.
- D. The physician utilizing the HUD for treatment, diagnosis or research must use the HUD only in accordance with the labeling of the device, intended purpose, and in the designated population for which the FDA approved its use.
 - 1. Only the holder of the HUD agreement with the FDA must use the HUD; and
 - 2. Informed consent is required from a patient prior to the use of a HUD when:
 - a) The HUD is the subject of a clinical investigation; or
 - b) The IRB requires use of informed consent.

II. Considerations for Prompt Reporting

- A. Whenever the physician or health care provider receives or otherwise becomes aware of information, from any source, that reasonably suggests that a HUD has or may have caused or contributed to the death or serious injury of a

patient, the physician or health care provider must report such findings to the FDA, and the IRB as soon as possible, but no later than 5 working days after the Investigator first learns of the effect or problem via the electronic Unanticipated Problems (UP) reporting process (See HRP Policy # 19) This reporting is in addition to, not a substitute for, FDA and/or manufacturer reporting requirements in accordance with 21 CFR 803.30.

- B. The physician or health care provider shall promptly report any FDA action(s) regarding the HUD to the IRB.
 - C. Modifications to the HUD or the clinical use of the HUD are to be promptly reported to the UCI IRB in accordance with the IRB policy for modifications.
- III. A HUD may be used off-label in an emergency situation to save the life or protect the physical well-being of a patient. The FDA recommends that the physician and HDE holder follow the same emergency use procedures that govern the use of unapproved devices. Off-label use of a HUD in an emergency situation that cannot wait for IRB review and approval may be handled under the Emergency Use of an Unapproved Drug, Biologic or Device provision provided that the situation meets the FDA criteria under 21 CFR 56.104 (d) and the HUD is not used outside its approved labeling (See IRB Policy 45).

References:

FDA 21 CFR 814, 803.30

U.S. Food and Drug Administration Device Exemptions Regulation: Questions and Answers; Final Guidance for Industry, July 12, 2001.

U.S. Food and Drug Administration Device Regulations, June 26, 1996.

HDE Program Guidance for Industry and FDA Staff Information Sheet, September 6, 2019

The full text of the 21st Century Cures Act is available

at:<https://www.congress.gov/114/bills/hr34/BILLS-114hr34eah.pdf>.

A list of approved HDE applications may be found at <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/hde-approvals>.

Procedure Number: 46.A**Title: Procedure for Using Humanitarian Use Devices****Procedure:**

This procedure outlines the process for review and approval for use of a Humanitarian Use Device (HUD).

I. Physician Responsibilities

- A. The Investigator will provide all applicable information regarding the use of a HUD in the IRB Application.
- B. A HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health 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. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.
- C. The FDA also recommends that the IRB or appropriate local committee (this is the IRB at UCI) review the following materials, as applicable, during initial review of a request to use a HUD:
 1. A copy of the HDE approval order;
 2. A description of the device;
 3. The product labeling;
 4. The patient information packet that may accompany the HUD;
 5. A sample consent form for the use of the HUD in clinical care, if required by the IRB or appropriate local committee or by facility policy; and
 6. A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.
 7. A list of approved HDE applications may be found at <https://www.fda.gov/medicaldevices/device-approvals-denials-and-clearances/hde-approvals>. The approval order, labeling, and patient information may be found by selecting the submission number of the appropriate HDE application.
- D. An informed consent document will be written, using the IRB consent template, and submitted, when applicable.
- E. The HUD brochure prepared by the manufacturer is to be provided and reviewed with the patient prior to use.
- F. The Physician will fulfill continuing review requirements at the designated IRB intervals. In addition, at each continuing review, a summary of any individual use of the HUD for the previous six (6) months at other sites. This summary should be available from the sponsor and will include the following:

1. The clinical indications for the use of the HUD in each patient;
 2. Adverse events or unanticipated problems to participants or others that are possibly related to the use of the HUD; and
 3. Clinical outcomes of each participant, if known.
- G. Modifications, serious adverse events or unanticipated problems to participants or others, and continuing reviews are to be reported according to IRB policies and procedures. In addition, these occurrences are to be reported to the FDA and/or manufacturer as outlined in 21 CFR 803.30.
- H. When the use of a HUD is for diagnosis or treatment, and not associated with research or data collection, HIPAA regulations for research are not applicable. However, HIPAA regulations for hospital medical records per Institutional policy are applicable.

II. IRB Committee Responsibilities

- A. The full IRB Committee will conduct all HUD reviews and approvals, including a review of the HDE documents.
- B. The assigned reviewers of the HUD will verify that the provided documents for use of the HUD are congruent with the manufacturing labeling and the approved use under the HDE. The labeling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.
- C. Based on the information above, the Committee will determine if the HUD request meets the FDA criteria.
- D. Submission of modifications, serious adverse events or unanticipated problems to participants or others, and continuing review will be reviewed at the level for which criteria is met.

III. IRB Administrator Responsibilities

- A. The Administrator will pre-review and request any necessary revisions for submitted documents for the use of the HUD as outlined for new IRB Applications.
- B. The Administrator will verify that a copy of the FDA's Investigator Agreement and any supplemental information regarding the HUD supplied by the manufacturer have been submitted with the initial application as required.
- C. Once the required documentation and revisions are received from the Investigator, the Administrator will place the new study on the next available Committee agenda, assign reviewers, and prepare the reviewer and Committee member packets.
- D. The Administrator will assist reviewers in obtaining additional information that may be requested regarding the HUD from the Investigator.
- E. The Administrator will notify the Physician in writing of the IRB Committee's determinations.
- F. The HRP staff will process all requests for modifications, serious adverse events or unanticipated problems to participants or others, and continuing reviews per corresponding IRB policies and procedures.
- G. Appropriate HPS database entries are to be completed.