



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 1004
Humanitarian Use Device (HUD)

Purpose

This document describes the responsibilities of clinicians and the USA Institutional Review Board (IRB) and processes related to use and review of Humanitarian Use Devices (HUD) including clinical, emergency, compassionate and investigational use.

Scope

This Standard Operating Procedures (SOP) applies to the following situations involving HUDs:

- Clinical use of a HUD as a legally marketed device, or
- Emergency or compassionate use of a HUD based on a healthcare provider request that meets IRB criteria, or
- Investigational use for research purposes either consistent with approved labeling or off-label

Applicability

This SOP applies to IRB administrative staff, IRB members, and healthcare providers.

Definitions

Clinical Investigation: Collection of safety and effectiveness data pertaining to a Humanitarian Use Device (HUD). Note: Clinical investigations are not the focus of this document, however, and are subject to Mayo Clinic IRB and institutional policies applicable to human subject research.

Humanitarian Device Exemption (HDE): a limited approval for the marketing of a device without any claims of effectiveness and with certain restrictions on its profit and use. This

limited marketing approval is only available for devices that have been designated a humanitarian use device (HUD). FDA approval of an HDE authorizes an applicant to market a Humanitarian Use Device (HUD), subject to certain profit and use restrictions.

Humanitarian Use Device (HUD): A HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year.

Use/Clinical Use: The use of a HUD according to its approved labeling and indication(s) to treat or diagnose patients.

Policy

The USA 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.

Generally, a Humanitarian Use Device (HUD) that has been granted a Humanitarian Device Exemption (HDE) by the FDA may be administered only if such use has been approved by the institution's IRB of record. Once IRB approval is granted, use of the HUD within the approved indication(s), as well as other clinical uses that are intended solely to address the specific needs of an individual patient is allowed. All uses of the HUD for clinical treatment and diagnosis at an institution are to be reported to the IRB at the time of continuing review.

If a clinician in an emergency situation determines that IRB approval cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB. Reporting of the emergency use of the HUD to the IRB is required. Refer to the *SOP: Emergency Use: Investigational Drugs, Biologics, and Devices*.

Procedures

1.0 Physician Responsibilities

1.1 A physician may utilize a HUD when agreeing to the following:

- The HUD will be utilized for treatment, diagnosis, or research in accordance with the labeling of the device, intended purpose, and in the designated population for which the FDA approved its use;
- The patient must be informed that the HUD is a device authorized under Federal law for use; however, the effectiveness of the device for a specific indication has not been demonstrated; and
- The informed consent of the patient or the patient's legally authorized representative will be obtained when the use of the HUD involves research or

when required by the IRB. The IRB generally requires that treating physicians obtain informed consent.

- 1.2 Confirm initial IRB approval for clinical use of the HUD at the institution.
- 1.3 Obtain and document clinical informed consent as required by the University of South Alabama Health Systems. (When the use of a HUD is for clinical diagnosis or treatment, i.e. not associated with human subject research activity, research informed consent and HIPAA regulations for research do not apply).
- 1.4 Provide patient information packets (when available) to patients prior to their receiving the HUD. If no packet is available, the patient should be provided with the following information:
 - An explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition.
 - A description of any ancillary procedures associated with the use of the HUD.
 - A description of the use of the HUD.
 - All known risks or discomforts.
 - Information reflecting the HUD status of the device including a statement indicating that the effectiveness of the device for this use has not been demonstrated.
- 1.5 Federal regulations require that an annual review be submitted to the IRB. The annual review can be reviewed in an expedited manner. A renewal report should be submitted to the IRB to include the total number of patients who have received the device in the previous year, a copy of the current FDA approved product labeling for the HUD, a copy of the current IRB approved consent document.
- 1.6 Investigators are required to submit adverse events as they would on a research study using the IRB Adverse Event Report form.

2.0 The IRB's Role in HUD Review

Pursuant to 21 CFR 814.124(a), the FDA requires IRB initial as well as continuing review approval before a HUD is used within its marketed approval. The IRB must ensure that the proposed use is within the FDA-approved indication and that the use of the device does not exceed the scope of the FDA's approval.

The use of a HUD within its market approval only is not research; rather, it is the use of a legally marketed device. The use of a HUD outside its market approval for treatment only

is also not research. It is the use of a legally marketed device in the practice of medicine. The use of a HUD does not constitute research unless the physician or health care provider intends to collect data from its use. The IRB may choose to prohibit off label uses as part of its initial approval.

The use of a HUD within its market approval in conjunction with efforts to collect data regarding safety and effectiveness is the use of a legally marketed device **and** an exempted clinical investigation. The FDA regulations for the protection of human subjects (**21 CFR Part 50**) and IRB review (**21 CFR Part 56**) will apply, but the regulations for the use of an investigational device (**21 CFR Part 812**) will not.

The HUD and its proposed use must be submitted to the IRB for review and approval by a convened IRB committee.

- The HUD manufacturer’s product labeling, clinical brochure and/or other pertinent manufacturer information materials
- The FDA HDE approval letter
- Written statement from the principal investigator specifying how (ie, for what clinical indication(s), where and by whom the HUD will be used within the clinical setting. The clinical indication should be limited to what is specified in the FDA-approved product labeling.

The **IRB Review Checklist: Criteria for Approval and Considerations for HUD** should be used to facilitate IRB review and approval.

3.0 Clinical Consent Form

All invasive clinical procedures require written informed consent. Therefore, there should be a consent form addressing the proposed **clinical** use of the HUD. Because the HUD is approved for clinical use, terms such as “research” should be avoided in the consent document. Although the FDA regulations do not require a consent form, it is up to the institution to determine whether one should be used. Historically, the University’s IRB has requested that consent be obtained and that the proposed consent form be reviewed by the IRB. Please submit a copy with your IRB application or provide [justification for waiver of consent](#). The consent form should be modeled after other clinical consent forms for invasive procedures. A HUD informed consent template has been developed for your use.

4.0 Off-Label Use of a HUD in Emergency or Compassionate Situation

In special instances an HUD can be used on an emergent basis. If an HUD is used under emergency circumstance, it cannot be used again until a complete IRB application has been submitted and approved. Emergency use is defined as necessary to save the life or

protect the well-being of a given patient. Under these circumstances, the physician should, on a case by case basis:

- 4.1 Before the device is used, if at all possible, notify the IRB Chair or Vice Chair of the planned “off-label” use of the HUD. The IRB Chair or Vice-Chair will provide an independent assessment as to whether the proposed use constitutes an emergency or compassionate situation.
- 4.2 Obtain *clinical* informed consent for the “off-label” use of the HUD.
- 4.3 FDA approval for “off-label” use of the HUD should be obtained by the device manufacturer (HDE holder) prior to the device for the emergency/compassionate use procedure. Please remember that use of an HUD in an off-label manner is a violation of federal laws. The IRB has been mandated to monitor HUD uses so that off-label uses are reported to the FDA.
- 4.4 After the emergency use occurs, the physician should submit a follow-up report on the patient’s condition and information regarding the patient protection measures to the HDE holder, who then submit this report as an amendment to the HDE.

5.0 Compassionate Use of a HUD in a Non-Emergency Situation

The IRB may approve compassionate use of a HUD if the physician determines that there is no emergency, but there is no alternative device for the patient’s condition. The physician who wishes to use the HUD should provide the HDE holder with the following:

- a description of the patient’s condition and the circumstances necessitating treatment with the device
- a discussion of why alternative therapies are unsatisfactory, and
- information to address patient protection measures.

Regulated Documents

[21 CFR 814, Premarket Approval of Medical Devices](#)

[21 CFR 814, Subpart H, Humanitarian Use Devices](#)

Related Documents

[HUD Informed Consent Template](#)

Related Forms:

IRB Reviewer Checklist: Criteria for Approval and Considerations for HUD (IRBNet Forms and Templates)

Guidance Documents

[FDA, Humanitarian Device Exemption \(HDE\) Regulation: Questions and Answers; Final Guidance for Industry, July 12, 2001](#)

[Humanitarian Use Devices, A brief guide for clinicians, investigators, and IRB members, Dale E. Hammerschmidt, M.D., University of Minnesota, October, 2001](#)
(<http://www.research.umn.edu/irb/members/education/HUDs.pdf>)

History:

Effective Date:

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Responsible Office:

Office of Research Compliance and Assurance