



Requirements for Humanitarian Use Device (HUD)

1. Definition of Humanitarian Use Device - The definition of 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.

2. Physician Responsibilities for the Use of a HUD

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 UCI IRB generally requires that treating physicians obtain informed consent.

3. The IRB's Role in HUD Review and Approval

Pursuant to 21 CFR 814.124(a), the FDA requires IRB review and approval before a HUD is used, as well as continuing review of the use of the HUD. 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 does not constitute research unless the physician or health care provider intends to collect data from its use.

4. Initial IRB Approval. The HUD and its proposed use must be submitted to the IRB for review and approval by a convened IRB committee. Thirty-five copies of the following materials should be provided for review:

- 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.

5. 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.

6. Continuing Review

- 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.

7. Reporting Adverse Events to the IRB

- Investigators are required to submit adverse events as they would on a research study using the IRB Adverse Event Report form.

8. 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 can not 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:
 - a. 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.
 - b. Obtain *clinical* informed consent for the “off-label” use of the HUD.
 - c. 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.
 - d. 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.

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

APPLICABLE REGULATIONS AND GUIDELINES

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

21 CFR 814, Premarket Approval of Medical Devices

21 CFR 814, Subpart H, Humanitarian Use Devices

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>)

SAMPLE INFORMED CONSENT

CLINICAL CONSENT FOR THE USE OF A HUMANITARIAN USE DEVICE

Title: Humanitarian Use Device: [Add Device Name] HDE# [Include #]

Primary Physician: Name
Address
Telephone Number

Secondary Physician: Names of all secondary physicians authorized to use the device
Department
Address
Telephone

What is a Humanitarian Use Device?

A Humanitarian Use Device 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 U.S. Food and Drug Administration (FDA) approves the use of Humanitarian Use Devices 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 risk of its use. Note that the Humanitarian Use Device, [*name of device*], for [*name of disease or condition*] is approved by the FDA. The use of [*name of device*] will be limited to the indication listed in the protocol labeling by the FDA. Its use does not involve research.

[Insert a paragraph addressing a description of the HDE and how it will be used].

What will be involved with the use of this device?

During your surgical procedure your physician would like to use the Humanitarian Use Device, [*name of device*], to aid in the repair of your [*state the disease or indication of use*]. Your doctor has told you that you have [*name of the disease or condition*] and because of this he/she would like to use the Humanitarian Use Device.

What are the possible risks, side effects and discomforts associated with the use of this device?

Based on the results of prior research studies on this device and experience with its approved use, the possibility of adverse events or side effects from the [*name of the device*] are the following:

Provide quantitative information (using percentages AND number of people out of 100) on the frequency of adverse events.

What are the possible benefits associated with the use of this device?

It is felt that the use of this [*name of device*] during your [*add name of procedure*] may benefit you in terms of [*list all benefits of the device*].

What alternative treatments or procedures are available?

If you decide not to take part in the treatment protocol, you may choose to have [*list alternatives*].

Will my insurance provider or I be charged for the costs of this device or any procedures associated with its clinical use?

You or your insurance provider will be responsible for any costs or charges associated with the use of the [*add the name of device*] and the surgical procedures needed to insert the device. All other costs relating to your normal care will be billed in the usual manner.

VOLUNTARY CONSENT

All of the above as been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this treatment protocol and the physicians listed on the first page of this form will answer future questions.

Patient's signature

Date

PHYSICIAN'S CERTIFICATION

I certify that the nature and purpose, the potential benefits and possible risks associated with the [*name of device*] and its proposed clinical use have been explained to the above individual and that any questions about this information have been answered.

Physician's signature

Date