

Humanitarian Device Exemption (HDE)

Definitions:

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

Humanitarian Device Exemption (HDE) - application that is similar to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of sections 514 and 515 of the Food, Drug, and Cosmetic Act (the Act). FDA approval of an HDE authorizes an applicant to market a Humanitarian Use Device (HUD)

Overview:

On June 26, 1996, the FDA issued a final rule (21 CFR Part 814) to carry out the provisions of the Safe Medical Devices Act of 1990 regarding humanitarian use devices (HUDs). Since a device manufacturer's research and development costs could exceed its market return for diseases or conditions affecting such small patient populations, the FDA promulgated this regulation to provide an incentive for the development of devices for such humanitarian use.

The regulation provides for the FDA submission of a humanitarian device exemption (HDE) application, which is similar in both form and content to a premarket approval (PMA) application. However, unlike a PMA application, an 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 HDE application must, however, 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. This determination should take into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the HDE applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that the device could not otherwise be brought to market unless it is granted HUD status.

An approved HDE authorizes marketing of the HUD for clinical use; **however clinical use of the device is limited to the indication specified in the product labeling**. Also, a HUD may only be used in facilities that have established a local institutional review board (IRB) to oversee the clinical introduction and use of the device within that institution. The labeling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized for clinical use by Federal law, the effectiveness of the device for the specific clinical indication for which it is approved has not been demonstrated.

Submission Requirements:

Initial IRB Approval: The HUD and its proposed use within the UPMC HS must be reviewed and approved by a convened IRB committee. Submit 1 copy of the following to the IRB office or email pdf files to askirb@pitt.edu:

1. The signed IRB Cover Sheet for a Humanitarian Use Device with “New Project” checked
2. The HUD manufacturer’s product labeling, clinical brochure, and/or other pertinent manufacturer informational materials
3. The FDA HDE approval letter
4. A letter signed by the responsible UPMC physician specifying for what clinical indication(s), where, and by whom the HUD will be used within the UPMC HS environment. The letter must specify that use of the HUD will be limited to the clinical indication(s) listed in the FDA-approved product labeling
5. Clinical Consent Form - The Commonwealth of Pennsylvania requires written informed consent for all invasive clinical procedures. Thus, there should be a consent form to address the proposed clinical use of the HUD. Since the HUD is approved for clinical use by the FDA, words such as “research” or “study” should be avoided in this clinical consent form. The HUD clinical consent form must include the following:
 - a. A description of an HDE/HUD approval process
 - b. A description of the HUD and how this device will be used in the clinical setting. Based on this description, it should be clear to the patient why s/he is a candidate for the use of this device
 - c. A discussion of possible risks, side effects, and/or adverse events associated with the HUD and its proposed clinical use
 - d. A discussion of the possible benefits associated with the clinical use of the HUD
 - e. A discussion of any alternative treatments or procedures (if any) that the patient may wish to consider in lieu of clinical application of the HUD
 - f. Voluntary Consent statement(s) with patient signature and date lines
 - g. Physician Certification statement with physician signature and date lines

Note that UPMC fiscal review and approval for clinical use of the HUD must be secured prior to use of the device in in the UPMC HS environment. All patients must be given a copy of the manufacturer’s patient information sheet in addition to signing the consent form.

Refer to the sample consent form below for additional guidance.

Continuation of IRB Approval: Renewal of IRB approval is required annually. Submit 1 copy of the following information to the IRB office or email pdf files to askirb@pitt.edu:

1. The signed IRB Cover Sheet for a Humanitarian Use Device with “Renewal” checked
2. A cover letter signed by the responsible physician requesting continuation of IRB approval of the HUD. The cover letter should identify the HUD and describe for what clinical indication(s), where, and by whom it was used within the UPMC environment

3. A copy of the current FDA-approved product labeling for the HUD
4. A copy of the current IRB-approved consent form and manufacturer's patient information sheet and an attestation that each patient received the documents
5. A summary of the following information for each patient in whom the HUD has been used during the previous year:
 - a. The clinical indication for the use of the HUD
 - b. Any adverse events felt to be related or possibly related to the use of the HUD; and
 - c. The clinical outcome of the use of the HUD

Modifications to the Device or the Clinical Use of the Device: IRB approval is required for any modifications of the device and/or the proposed clinical use of the device. Submit 1 copy of the following information to the IRB office or email pdf files to askirb@pitt.edu:

1. The signed IRB Cover Sheet for a Humanitarian Use Device with "Modification" checked
2. A cover letter signed by the responsible physician describing the modifications to the device and/or the proposed clinical use of the device and the rationale for such modification(s)
3. A copy of the HUD manufacturer's amendment to the HUD product labeling, clinical brochure, and/or other pertinent manufacturer informational materials corresponding to the requested modification(s)
4. A copy of the revised clinical use statement and clinical consent form with the modifications highlighted

Additional Requirements:

Refer to the following website for more information on the HDE process:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm#8>

Sample Consent Document:

(Division, Department or School Letterhead)

Institutional Review Board
University of Pittsburgh
IRB Number:
Consent Form Approved:
Renewal Date:

CLINICAL CONSENT FOR USE OF A HUMANITARIAN USE DEVICE

TITLE: Humanitarian Use Device: **[Add Device Name]**

HDE#: **[Include #]**

PRIMARY PHYSICIAN:

Name
Department
Address
Telephone Number with Area Code

SECONDARY PHYSICIAN:

Names of all secondary physicians authorized to use the device
Department
Address
Telephone Number with Area Code

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 risks of its use.

Note that the use of 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 Humanitarian Use Device 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 for use]. Your doctor has told you that you have [name 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?

There may be adverse events or side effects that are currently unknown and it is possible that certain of these unknown risks could be permanent, serious or life threatening.

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:

It is recommended that language such as Common, Infrequent, or Other Risks be used instead of percentages when describing risks. In addition, we suggest that the risks are listed within the three categories in order of severity (i.e., death would be listed before hives).

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 the 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 this treatment protocol, you may choose to have **[add list of alternatives]**.

Will my insurance provider or I be charged for the costs of this device or any procedure 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 the 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.

Who will have access to my identifiable information related to the use of this device?

In addition to the physicians listed on the first page of this authorization (consent) form and their clinical staff, the following individuals will or may have access to your identifiable information:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable information related to the use of the device.

Authorized representatives of the manufacturer of the device, **[insert manufacturer's name]**, will review and/or obtain your identifiable information for the purpose of monitoring the accuracy and completeness of the data and for performing required scientific analyses. Authorized representatives of the manufacturer may also be present during the use or placement of the device. While the manufacturer understands the importance of maintaining the confidentiality of your identifiable medical information, UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the device manufacturer.

