George Washington University  
Committee on Human Research  
Institutional Review Board  

Humanitarian Use Device Policy

I. Background

In 1996, the Food and Drug Administration (FDA) issued a final rule to carry out the provisions of the Safe Medical Devices Act of 1990 regarding humanitarian use devices (HUDs). A HUD is a medical device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. A HUD is approved for marketing through a humanitarian device exemption (HDE) application. Marketing approval of an HDE is valid for only 18 months, after which the HUD device may no longer be marketed unless the HDE holder has sought and obtained an extension.

An HDE application is basically a premarket approval application (PMA) that is NOT required to contain clinical data demonstrating that the HUD is effective for its intended use, but is required to contain all other information ordinarily required of a PMA. In addition, an HDE application must include the following specific information to satisfy the HUD statutory requirements:

1. That the device is to be used to treat or diagnose a disease or condition that affects or is manifested in less than 4,000 individuals in the U.S. per year;
2. That the device would not otherwise be available unless an HDE application was approved;
3. That no comparable device (other than another HUD approved device or a device being studied under an IDE) is available to treat or diagnose the disease or condition; and
4. That the device will not expose patients to an unreasonable or significant risk of illness/injury, and the probable benefit to health from using the device 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.

II. The Committee on Human Research (CHR)/Institutional Review Board (IRB) Policy Regarding HUD Use at GWU

A. Initial And Continuing Review of A HUD

A HUD may only be used in facilities that have established IRBs constituted and acting in accordance with FDA’s regulations governing IRBs (21 CFR part 56), including responsibility for continuing review of use of the device. For initial review of a HUD, full committee review is required. For continuing review, however, an IRB may use the

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1 All GWU CHR/IRB correspondence regarding HUD Use is to be forwarded to the Office of Human Research, 712 Ross Hall.
expedited review procedures in 21 CFR 56.110, unless the IRB determines that full committee review is necessary. The GWU CHR/IRB has determined that full committee review is necessary for HUD continuing reviews.

B. **IRB Approval of HUD Use**

A HUD may only be administered to, or implanted in, a patient located at a facility if such use has been approved by the IRB at the facility. IRB approval of the use of a HUD can not exceed the scope of the FDA approved indication(s), but may limit the scope of the FDA approved indications if the IRB feels such limitation is appropriate. The GWU CHR/IRB reserves the right to limit such FDA approved indications when appropriate. For example, the GWU CHR/IRB may limit use of the HUD to a particular medical specialty, prior use and failure of any alternative treatment modalities, and/or reporting requirements to the IRB or IRB chair.

C. **IRB Review/Approval of Each Individual Use of a HUD**

The GWU CHR/IRB does not require review/approval of each individual use of a HUD as long as the use of the HUD falls within the FDA approved indication and IRB limitation(s), if applicable. HUD uses, which fall within FDA approved indication(s) and IRB limitation(s) (if applicable), must be reported to the GWU CHR/IRB at the next continuing review of the HUD. Alternatively, HUD uses which fall outside the FDA approved indications and IRB limitation(s), if applicable, must be reported to the GWU CHR/IRB in accordance with the procedures outlined in Section V or VI, as appropriate, of the attached document entitled “Procedures for Review, Approval, and Continuing Review of HUD Use at GWU.”

D. **Clinical Informed Consent for use of a HUD**

IRB approval of informed consent is not required before a HUD is used because an HDE, which provides for temporary marketing approval, does not constitute research. Nevertheless, the GWU CHR/IRB requires that a clinical informed consent form for HUD use be signed by the patient prior to use of the HUD at GWU, when practicable. See attached document for guidance regarding contents of a Clinical Informed Consent Form for HUD Use.

Please become familiar with the procedures set out in the attached document entitled “Procedures for Review, Approval, and Continuing Review of HUD Use at GWU” before initiating clinical use of a HUD at GWU.
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Procedures for Review, Approval, and Continuing Review of HUD Use at GWU

I. Initial IRB Review/Approval. A HUD must be reviewed and approved by the full GWU CHR/IRB prior to initial use at GWU. The physician/health care provider requesting initial use of a HUD at GWU must submit 15 copies of the following:

A. The HUD product labelling, clinical brochure, and/or other pertinent manufacturer informational materials;

B. The FDA HDE approval letter;

C. Written clinical use statement(s) from the GWU physician/health care provider specifying how the HUD will be used at GWU (i.e., who will be administering/implanting the HUD, for what clinical indication(s), etc). The(se) statement(s) must specify that the use of the HUD will be limited to the clinical indication(s) listed in the FDA- approved product labelling; and

D. HUD Clinical Consent Form. This consent form shall address the proposed clinical use of the HUD. The HUD clinical consent forms should be modelled after other clinical consent forms to include, at a minimum, the following information:

1. A description of the HDE/HUD approval process, e.g. “Your medical care will involve the use of (specify device), which has been approved by the Food and Drug Administration (FDA) as a Humanitarian Use Device (HUD) for (specify the intended use). A HUD is a medical device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. FDA approved the use of (specify device) based on evidence indicating that the device will not expose the patient (i.e., you) to a significant risk of illness or injury and that the probable benefit to the patient’s health (i.e., your health) outweighs the risk from its use. FDA did not necessarily approve the use of (specify device) based on evidence indicating that the HUD will be effective for its intended use. FDA, nevertheless, approved the use of the device because there is no other comparable device available to treat or diagnose your (specify disease or condition) at this time.”

2. A description of the HUD and how the HUD will be used in the clinical setting. This information can be obtained from the FDA HDE Approval Letter and/or the HUD device labelling, clinical brochure, and/or other manufacturer informational materials, and GWU, CHR, IRB
limitations, if any. Based on this description, it should be clear to the patient why he/she is a candidate for the use of the device.
3. A discussion of possible risks, side effects, and/or adverse events associated with the HUD and its proposed clinical use;
4. A discussion of the possible benefits associated with the clinical use of the HUD;
5. A discussion of any alternative treatments or procedures (if any) that the patient may wish to consider in lieu of clinical use of the HUD;
6. Voluntary consent statement(s) with patient signature and date of signature; and
7. Physician/health care provider certification statement with physician/health care provider signature and date of signature.

II. Continuing IRB Review/Approval. Renewal of IRB approval of a HUD is semi-annual in order to coincide with temporary marketing approval of the HUD, which is 18 months. A physician/health care provider requesting continuing use of a HUD at GWU must submit 15 copies of the following:

A. A cover letter signed by the responsible physician/healthcare provider requesting continuation of IRB approval of the HUD. The cover letter should identify the HUD, specify the clinical use statement(s) of the HUD, and, if applicable, summarize any known FDA action(s) taken regarding the HUD since last initial or continuing review;

B. Summary of all correspondence received from the holder of the humanitarian device exemption (HDE) since last initial or continuing review, if applicable;

C. A copy of the current FDA-approved product labelling for the HUD;

D. A copy of the current clinical informed consent form;

E. For each patient in whom the HUD has been used during the previous 6 months provide a summary of:

1. The clinical indications for the use of the HUD;
2. Any adverse events felt to be related or possibly related to the use of the HUD; and
3. The clinical outcome of the use of the HUD.

III. Prompt Medical Device Reporting. Whenever the physician/health care provider who requested use of the HUD at GWU 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 the serious injury of a patient, the physician/health care provider shall:
A. Submit a completed FDA form 3500A to the GWU CHR/IRB as soon as practicable, but not later than 10 work days after becoming aware of the information; and

B. Notify the GWU Hospital Medical Director in accordance with the GWU Hospital Medical Device Reporting Policy. This notification to the GWU Hospital Medical Director is the responsibility of the physician/health care provider who requested use of the HUD.

Please note that the above referenced reporting is an addition to, not a substitute for, FDA and/or manufacturer reporting as outlined in 21 CFR 803.30. Please refer to that section for additional medical device reporting standards associated with the use of a HUD.

IV. Prompt Reporting of FDA Action(s) on the HUD. The physician/health care provider who requested use of the HUD at GWU must promptly report to the GWU CHR/IRB any FDA action(s) taken regarding the HUD for which he/she has become aware. This report, which shall be in the form of a memorandum to the Chair of the GWU CHR/IRB, shall be forwarded to the Chair within 10 days of receiving knowledge of such FDA action. Depending on the FDA action taken, the Chair may elect to initiate an immediate IRB action (e.g., withdraw IRB approval of use of the HUD because FDA rescinded the HDE due to the availability of a comparable device) or await action until the full IRB has discussed the FDA action taken on the HUD (e.g., modifying the clinical use of the HUD because FDA has done so). Any immediate action taken by the Chair of the IRB will be discussed and voted on at the next IRB meeting.

V. Modifications to the HUD or the Clinical Use of the HUD. GWU CHR/IRB approval is required for any modifications of the HUD and/or of the proposed clinical use(s) of the HUD. A physician/health care provider requesting modification to either the HUD or the clinical use(s) of the HUD must submit one copy of the following:

A. A cover letter signed by the responsible physician/healthcare provider, describing the modification to the HUD and/or the proposed clinical use(s) of the HUD and the rational for such modification(s);

B. A copy of the HUD manufacturer’s amendment to the HUD product labelling, clinical brochure, and/or the pertinent manufacturer informational materials corresponding to the requested modification(s);

C. A copy of any FDA HDE amendment/supplement approval letters; and

D. A copy of the revised clinical use statement(s) and clinical consent form with the modifications highlighted.

VI. Emergency Use of a HUD
A. A HUD may be used off-label (outside its approved indications for use) in an emergency situation, i.e., to save the life or protect the physical well being of a patient.

B. The treating GWU physician/health care provider should ensure that the following patient protection measures are followed before and after the emergency use occurs:

1. **Before the HUD emergency use occurs.** If possible, the physician should obtain the following:
   a) Concurrence of the GWU CHR/IRB chairperson;
   b) Informed consent from the patient or his/her legal representative;
   c) An independent assessment by an uninvolved physician; and
   d) Authorization from the HDE holder before emergency use of the HUD.

2. **After the HUD emergency use occurs.** The treating GWU physician/health care provider shall submit a follow-up report on the patient’s condition and information regarding the patient protection measures that were followed to both the GWU CHR/IRB and the HDE holder.

C. Please note that the above referenced emergency use reporting to the GWU CHR/IRB is an addition to, not a substitute for, the GWU Hospital Emergency Use Reporting Policy. Emergency Use Reporting of a HUD to the GWU Hospital is the responsibility of the physician/health care provider who requested use of the HUD.

**D.** For further guidance on emergency use of a HUD, please see ‘Emergency Use of Unapproved Medical Devices’ within Chapter III, Expanded Access to Unapproved Devices of the “IDE Policies and Procedures Guidance” at: [www.fda.gov/cdrh/ode/idepolicy.html](http://www.fda.gov/cdrh/ode/idepolicy.html).

**VII. Compassionate Use of a HUD**

A. A HUD may be used off-label for compassionate use, i.e., when a HUD is the only option available for a patient(s) faced with a serious, non-life threatening condition.

B. Before compassionate use of a HUD occurs, the treating GWU physician/health care provider shall:

1. 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 addressing the applicable patient protection measures outlined in section VI.B. above. The HDE holder should, in turn, submit this information in an HDE amendment for FDA approval before the use occurs.

2. Ensure that FDA approval of compassionate use of the HUD is obtained prior to its use.

3. Obtain GWU Hospital Administration Approval for compassionate use of the HUD.

C. If FDA approves the HUD compassionate use request, the physician/health care provider shall devise an appropriate schedule for monitoring the patient, taking into consideration the limited information available regarding the potential risks and benefits of the device and the specific needs of the patient.