

 <p>West Virginia University</p> <p>HRPP POLICIES AND PROCEDURES</p> <p>Office of Research Integrity and Compliance Human Research Protections Institutional Review Board</p>	<p>Policy #: 3C.008</p> <p>Title: Humanitarian Use Device (HUD), Humanitarian Device Exemption Policy, & Cover Letter</p> <p>Section: <i>Protocol Submission & Training (3C – Protocol)</i></p> <p>Date: May 18, 2010</p> <p>Page: Page 122 of 246</p>
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Humanitarian Use Device (HUD), HUD Exemption Policy, and Cover Letter

1.0 Definitions

- 1.1 **Food and Drug Administration (FDA):** The FDA is the federal oversight agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.
- 1.2 **Humanitarian Use Device (HUD):** A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.
- 1.3 **Humanitarian Use Device Exemption (HDE):** A Federal Drug Administration (FDA) approval for a physician to use a HUD in clinical treatment or as the subject of a clinical investigation.

2.0 Policy

It is the policy of the West Virginia (WVU) Institutional Review Board (IRB) to review and approve the use of all Humanitarian Use Devices (HUD) only after it is established that the physician has received adequate training about federal and local policies related to the use of HUDs and HDEs.

3.0 IRB Review of HUD Use

In order for a HUD to be used in treatment, diagnosis, or research at WVU, the IRB and the FDA must approve it and a Humanitarian Device Exemption (HDE) must be issued.

- The IRB approval must verify that the use of the HUD, as proposed, is congruent with current labeling of the device and does not exceed the scope of the FDA approved indication.
- The IRB may impose more stringent restrictions for use of the HUD as a means of additional protection, as deemed necessary.

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 meet expedited criteria.

The physician utilizing the HUD for treatment or diagnosis must use the HUD only in accordance with the labeling of the device for its intended purpose, and in the designated population for which the FDA approved its use.

- Only the holder of the HUD agreement with the FDA must use the HUD; AND
- The IRB will not require informed consent since the use of an HUD is not considered research.

The IRB must be confident that the physician understands all relevant federal and local policies and procedures related to the use of Humanitarian Use Devices.

4.0 Considerations for Prompt Reporting

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 10 working days after the Investigator first learns of the effect or problem. This reporting is in addition to, not a substitute for, FDA and/or manufacturer reporting requirements in accordance with 21 CFR §803.30.

The physician or health care provider shall promptly report any FDA action(s) regarding the HUD to the IRB.

Modifications to the HUD or the clinical use of the HUD are to be promptly reported to the WVU IRB in accordance with the IRB policy for amendments.

It is the responsibility of the physician to notify the patient of any new information that is received concerning the use and safety of the HUD.

The IRB will review each protocol separately, but in most cases, the IRB will request that the physician submit a continuing protocol at three-month intervals in which he/she discusses fully the number of times the HUD has been used, any problems associated with its use, any information received by the sponsor or the FDA concerning the use of the HUD at any other sites. The IRB may, at its discretion, decide after reviewing one or more continuing requests, decide that an interval different from once every three months

(i.e., annually, semiannually, monthly, etc) would be more appropriate for a particular protocol.

5.0 Humanitarian Use Device Cover Letter

The WVU IRB has decided to no longer require a formal signed consent form when a HUD is employed. However, the IRB decided that a cover letter containing the following items be given to the patient and/or patients legally authorized representative as soon as possible after the decision to use a HUD is made.

The format that is chosen is up to the physician, but it must contain the following information:

1. A statement that the device is approved by the FDA under a special designation, and that it has been tested for safety but not efficacy. In other words, the risks associated with the device are known, but it is not known if it works or not for the specific problem for which it is being offered as treatment. This is because the device is intended to be used infrequently--fewer than 4,000 times per year in the United States--and is therefore less thoroughly tested than a device that would be used more often.
2. A listing of the risks associated with the use of the device.
3. A statement that the device is approved only for use according to its label, and that the patient to whom it is being offered meets the conditions of its intended use. For instance, if the FDA said it should be offered only after A, B and C have been tried and failed (or are inappropriate or inapplicable to the patient), then in fact A, B and C "have" been tried or are inappropriate/inapplicable.
4. A statement that the cost of the device will be charged to the patient. The patient should be encouraged to check with his/her insurance company to see if the company will pay.

(Source: FDA Guidance for Industry and FDA Staff-Humanitarian Device Exemption (HDE) Regulation: Questions and Answers, July 18, 2006)