

The Carle Foundation

IRB Policy 411

Subject	Humanitarian Use Device		
Approval	May 2009	Review	Sep 2010
Purpose	To provide guidance for the use of Humanitarian Use Device (HUD) for research or treatment.		

Statement of Policy

1. A Humanitarian Use Device (HUD) will be used only after the Institutional Review Board (IRB) reviews and approves its use, as required by the FDA. [21 CFR 814 Subpart H]
2. The IRB will provide oversight of the use of HUDs in compliance with the Common Rule and applicable FDA regulations, as well as applicable policies of Carle Foundation Hospital and the Carle IRB. Failure to comply with this or any Carle IRB policy can result in termination of research privileges; see [IRB General Administration Policy 101 Compliance with Policies and Procedures Mandate](#).

Specific Policies

1. Applicable to both treatment and research use of a HUD

- a. A HUD is a device that is 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.
- b. In order to obtain approval for use of a HUD, the applicant must first obtain designation of the device as a HUD from the FDA's Office of Orphan Products Development. If the FDA approves the device as a HUD, the applicant must then submit a Humanitarian Device Exemption (HDE) application to the FDA, including a reference to the FDA's determination that the device qualifies as a HUD. An approved HDE authorizes marketing of the HUD.
- c. The labeling for a HUD must state that the device is a HUD and that, although the device's use is authorized by federal law, the effectiveness of the device for the specific indication has not been demonstrated.
- d. The FDA mandates that HUDs be used only for the purposes of treatment and research within the scope of the indication approved* in the HDE, and monitored by the institution's IRB (see 21 CFR 814.124(a)).
 - *Exception: Use of a HUD for an indication that is NOT specified in the respective product labeling must comply with the provisions for the Emergency Use of Unapproved Drugs or Devices (see IRB Policy 409) or, if a new indication is being investigated, an investigational device exemption (IDE) must be filed with the FDA and a research application submitted to the Carle Scientific Review Committee and the Carle IRB.
- e. Initial IRB review must be undertaken by full committee. Continuing review will be conducted according to a time frame established by the IRB, but at least annually. The IRB will track the use of the HUD in the applicant's report at continuing review. In addition, the applicant will provide to the IRB the following:
 - Any amendments or supplements to the HDE
 - Annual reports from the Sponsor
 - Unanticipated adverse effects
 - Increases in the incidence of anticipated adverse effects
 - Reports of device failures necessitating labeling, manufacturing or device modification
 - Any further results of animal/ laboratory or clinical testing
- f. If at any time IRB approval is withdrawn, the FDA must be notified within 5 working days. [21 CFR 814.24]
- g. HUD users are required to promptly report to the IRB, the HDE holder or the FDA or both, whenever the device may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Such reports must be made as soon as practicable but no more than 10 work days after the day that the HUD user became aware of information. In addition, HUD users must promptly report to the IRB any unanticipated problems involving risks to patients, subjects or others.
- h. If safety and effectiveness data will be collected, the activity will be deemed to be research, rather than treatment, and additional oversight will be required, including approval by the Carle Scientific Review Committee and the Carle IRB.

Specific Policies (cont.)

2. IRB Review of a HUD for treatment purposes only

- a. An applicant wishing to use a HUD for treatment purpose (not for research) must complete and submit a HUD Submission Form to the Carle IRB for review and approval before the HUD is used. The submission will include sufficient information to permit the IRB to understand the HUD, its status, proposed use, risks, benefits, alternatives and information to be provided to the patient(s).
- b. IRBs are responsible for initial as well as continuing review of the HUD. For initial review of a HUD, IRBs are required to undertake a full committee review. Unlike a research submission, however, the HUD application will not require review and approval by the Carle Scientific Review Committee before it is submitted to the IRB.
- c. Continuing review may be conducted using expedited procedures unless the Carle IRB determines that full committee review is required.
- d. Consent
While the federal regulations [21 CFR 814, Subpart H] do not require that the physician obtain informed consent for the use of the HUD but leave this decision to the IRB, the Carle IRB requires informed consent via a separate HUD consent form. This consent is in addition to the manufacturer's patient information brochure being offered to the patient, and any applicable surgical consent form. The consent must explain that the device is a HUD whose efficacy has not been proven and the potential risks and benefits of the HUD. A sample consent form is provided in Appendix 2.

3. IRB Review of a HUD for research purposes

- a. An investigator wishing to use a HUD for research purposes must complete and submit an IRB application to the Carle Scientific Review Committee. After approval has been obtained from the Carle Scientific Review Committee, the submission will be forwarded to the Carle IRB for full committee review. Review and approval must occur before the HUD is used.
- b. Informed consent will be required unless consent is waived by the IRB under the regulations governing human subject protection in research and the IRB policies. The consent must clearly state that the effectiveness of the HUD for the specific indication has not been demonstrated.
- c. All State and Federal regulations, IRB policies, and institutional policies governing research with human subjects will apply.

Reference

HUD guidance for industry and FDA staff: <http://www.fda.gov/cdrh/ode/guidance/1381.html>

Humanitarian Use Devices list: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm>

Investigator reporting obligations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=803&showFR=1&subpartNode=21:8.0.1.1.3.3>

Appendix 1: IRB Guidelines for Humanitarian Use Devices (HUDs)

Appendix 2: HUD Consent Form (sample)

21 CFR 814

Approval On File

*Approved by IRB Board Aug 2010

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