IRB REVIEW OF HUMANITARIAN USE DEVICE

DESCRIPTION

In order for a Humanitarian Use Device (HUD) to be used in treatment, diagnosis, or research at the University of Cincinnati (UC), the HUD must be approved by the FDA and IRB and a Humanitarian Device Exemption (HDE) must be issued.

RESPONSIBILITY

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 labeling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for specific indication has not been demonstrated. The IRB may impose more stringent restrictions for use of the HUD as a means of additional protections, as deemed necessary.

PROCESS

1. Initial Review
   a. The initial review of a HUD is to be completed by the full IRB Committee. The Board will review the HDE documents, Investigator Agreement, and any supplemental information supplied by the manufacturer and verify that the provided documents are congruent with the labeling and the approved use under the HDE.
   b. A HUD may only be administered if the FDA approved use has been approved by the IRB. If IRB approval cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB. In such an emergency situation, the HDE holder shall, within 5 days after the use of the device, provide written notification to the IRB Chair of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.
   c. Informed consent is required from a patient prior to the use of a HUD when the HUD is the subject of a clinical investigation or the IRB requires use of informed consent. A specific informed consent document can be created for the HUD use.
   d. The Board may make the determination at initial review that subsequent reviews meet expedited criteria.

2. Reporting Requirements
Human Research Protection Program Institutional Review Board Procedure

a. Whenever the HDE holder 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 HDE holder must report such findings to the FDA and the IRB as soon as possible, but no later than 10 business days after the Investigator first learns of the effect or problem. The VAMC requires a report to the IRB within 5 business days of the Investigator learning of the effect or problem. Events resulting in temporary or permanent interruption of the investigation in order to avoid potential harm to the patient should be reported within 48 hours.

b. The HDE holder shall promptly report any FDA action(s) regarding the HUD to the IRB.

c. Modifications to the HUD or the clinical use of the HUD are to be promptly reported to the IRB in accordance with the Human Research Protections Policies and IRB procedures.

d. The HDE holder shall notify the FDA of any withdrawal of approval for the use of a HUD by the IRB within 5 working days after being notified of the withdrawal of approval.

Applicable Regulations, Document(s):
21 CFR 814.124
21 CFR 803.30
UC HRPP Policy II.02
VHA Handbook 1058.01

| Adoption Date: 07/2007 | Created by: M. Linke | Date of Revision: 6/2014 | Revised By: K. Mills | Summary of Revision: Streamlining and clarifying procedure |

Date June 2014 Signature signed copy on file