Policy

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: XI.D
Section: Investigational Drugs, Biologics, and Devices
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: November 1, 2003
Revision Dates: March 7, 2008; July 1, 2015

Subject: Humanitarian Use Devices

Definitions:
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.
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.
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.

Policy:
It is the policy of the Human Research Protections Program (HRPP) to review and approve the use of all Humanitarian Use Devices.

I. IRB Review of HUD Use.
A. In order for a HUD to be used in treatment, diagnosis, or research, the IRB and the FDA must approve it and a Humanitarian Device Exemption (HDE) issued.
   1. 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.
   2. The IRB may impose more stringent restrictions for use of the HUD as a means of additional protections, as deemed necessary.
B. 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 for subsequent continuing reviews the IRB may use expedited review procedures.
C. The physician utilizing the HUD for treatment, diagnosis or research must use the HUD only in accordance with the labeling of the device, intended purpose, and in the designated population for which the FDA approved its use.
   1. Only the holder of the HDE may authorize the use of the HUD; and
   2. Informed consent is required from a patient prior to the use of a HUD when:
      (a) The HUD is the subject of a clinical investigation; or
      (b) The IRB requires use of informed consent.

II. Considerations for Prompt Reporting.
A. 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 7 calendar days after the Investigator first learns of the effect or
problem (See HRPP Policy III.L). This reporting is in addition to, not a substitute for, FDA and/or manufacturer reporting requirements in accordance with 21 CFR 803.30.

B. The physician or health care provider 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 HRPP policy for amendments.

References:
21 CFR 56.110
21 CFR 814, 803.30