Humanitarian Use Device

OHSU Policy

I. Policy

A. Initial and continuing review by the OHSU IRB is required for the use of HUDs even if there is no intent to collect data.

B. Use of a HUD within its approved labeling does not constitute research by the Common Rule definition.

C. All proposed uses of HUDs at OHSU must be reviewed by the OHSU IRB at a convened meeting of the full board prior to any provision of patient care or treatment with the HUD. There is an exception to this rule in emergency situations. See policy.

D. Continuing review will be on an annual basis using expedited review procedures as long as use of the HUD within its approved labeling continues. The regulations do allow the IRB to require shorter reviews intervals or full board review at each review and the IRB will do so at its discretion.

E. Clinical Investigation of a HUD beyond its FDA approved indication requires an approved Investigational Device Exemption (IDE) and the OHSU IRB cannot approve it otherwise.

F. An HDE holder may collect safety and effectiveness data to support a PMA for the HDE-approved indication without an IDE. However, compliance with 21 CFR part 50 is required.

G. Informed Consent
   i. The IRB will require prospective informed consent unless it determines that obtaining consent is impracticable.
   ii. The informed consent document must be reviewed and approved by the IRB.

H. Reporting Requirements
   i. Under 21 CFR Part 803 the PI is required to submit a report to the FDA whenever:
      a. A device with an approved HDE may have caused or contributed to a death or serious injury; or
      b. A device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

I. As provided by 21 CFR 814.82(a)(9), in order to provide continued reasonable assurance of the safety and probable benefit of the device, the holder shall submit adverse reaction or device defect reports to the IRB.

J. The IRB does not require review and approval of each individual use of a HUD as long as each use of the HUD is within the FDA approved indication and has been approved by the IRB. The regulations do allow the IRB to restrict its approval; therefore the IRB may approve use of the HUD without any further restrictions, use of the device under a protocol, or use of the device on a case-by-case basis.

Effective: 4/21/2008