Humanitarian Use Devices

Definitions

Humanitarian Use Device (HUD): a medical device intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 8,000 individuals in the United States per year.

Humanitarian Device Exemption (HDE): an exemption from FDA that indicates that the device is approved for marketing, but the approval is based on evidence of safety and probable benefit (rather than assurance of effectiveness).

Initial IRB Review Requirements

A HUD may be utilized at this site only if WHF IRB has agreed to oversee the HUD use. FDA guidance allows for the use of an "appropriate local committee" in place of an IRB for local review, but at Woman's the IRB review will be used to fulfill this obligation. The physician is responsible for obtaining IRB approval before the HUD is administered to or implanted in a patient; however, HUDs are allowed for use in emergency situations without IRB approval. The IRB should be notified within five working days of any HUD used in an emergency situation.

The IRB is required to perform a full IRB review for initial approval. Any serious adverse events or unanticipated problems with the HUD should be reported to the IRB immediately, and no later than two business days following awareness of the event.

FDA also recommends that the IRB or appropriate local committee review the following materials, as applicable, during initial review of a request to use a HUD:

- A copy of the HDE approval order;
- A description of the device;
- The product labeling;
- The patient information packet that may accompany the HUD;
- A sample consent form for the use of the HUD in clinical care, if required by the IRB or appropriate local committee or by facility policy; and
- A summary of how the physician proposes to use the device, including any use off-label and a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Continuing IRB Review Requirements

Continuing review of the HUD will continue until the device receives pre-market approval (PMA), is terminated by the sponsor, or the investigator no longer chooses to use the device. If the use of the HUD does not exceed the scope of the FDA-approved indication, it may be reviewed through expedited continuing review procedures (unless the IRB determines that full IRB review should be performed). The IRB may opt to conduct the first continuing review using the full board and then require expedited review procedures for subsequent annual review.

Informed consent

If the HUD is the subject of a clinical investigation (one in which safety and effectiveness is being collected to support a PMA), IRB approval and informed consent is required before use. If the HUD is being used according to the labeled indication, the FDA and HDE regulations do not require informed consent. This exemption from requirements is because a Humanitarian Device Exemption (HDE) provides for marketing approval, and use of the HUD for the labeled indication does not constitute research or an investigation (which would normally require informed consent). The IRB, however, may require that the physician or HDE holder provide information to the patient that incorporates a discussion of the potential risks and benefits, any procedures associated with the use of the device, and a statement that the device is a humanitarian use device for which effectiveness for the labeled indication has not been demonstrated.

Off-label Use of a HUD

If a physician wants to use a HUD outside its approved indication(s), FDA recommends that the physician follow the IRB or appropriate local committee's requirements for use of a HUD at that facility, which may include separate approval requirements for use outside the approved indication(s). The IRB may ask for additional review from consultants with the appropriate expertise.

Withdrawal of IRB approval

The physician is responsible for notifying the HDE holder of any withdrawal of approval upon notification. The HDE holder is required to notify the FDA of any withdrawal of approval for the use of a HUD by a reviewing IRB within five working days after being notified of the approval withdrawal.

Further information:

A HUD guidance document is available from FDA at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program