Humanitarian Device – HUD

Modified: January 2017

Background:

As defined in 21 CFR 814.3(n), and updated by the 21st Century Cures Act, a humanitarian use device (HUD) is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.” The FDA makes its determination when a request a HUD designation is submitted.

Q: What are some of the differences between a humanitarian device exemption (HDE) and an investigational device exemption (IDE)? They both use “device exemption” in their titles and can thus be confusing to IRBs.

FDA approval of an HDE authorizes an applicant to market a HUD in accordance with approved labeling and indication(s) for use, subject to certain profit and use restrictions set forth in section 520(m) of the FD&C Act. If a HUD meets the HDE standards for approval, it is exempt from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the FD&C Act. See section 520(m)(2) of the FD&C Act.

A device being used under an approved IDE is a device that has not been cleared or approved by the FDA for marketing but has been authorized for investigational use in an FDA-regulated clinical investigation (i.e., an IDE is an investigational exemption). With this exemption, the investigational device can be shipped lawfully for the purposes of conducting clinical investigations of the device without complying with certain other requirements of the FD&C Act that would apply to devices in commercial distribution. See 21 CFR Part 812.

Q: Is the use of an HUD considered research?

A (HUD) is commercially approved under the HDE. (See, 21 CFR 814 Subpart H – Humanitarian Use Devices.) The HUD is not considered “investigational” nor is the use of the device considered “research.” However, the federal regulations require IRB review and approval before a HUD is used at the institution.

HUDs can be used in two different ways:
- For treatment purposes only (i.e., not to answer a research question or to collect any information for publication purposes); OR
- As part of a research protocol.

Q: Do HUD’s for clinical use only have to be submitted to the IRB?

Yes. The PI is required to submit a myIRB application in order for the IRB to review and approve the use a HUD. The smart forms will prompt the submitter on the items that are needed.
Q: What are the typical submission requirements for a “HUD” being used in clinical care situations only?

Typically, the submission will include:

- An informed consent. The one provided by the manufacturer can be used, or a UF template consent can be found on the IRB website.
- An informational brochure, provided by the manufacturer.
- Any training certificates, if training with the device is required by the manufacturer.
- Proof, typically from the manufacturer, that the device has been FDA approved as an HUD.

Q: What type of IRB review is required for an HUD submission?

The initial approval of an HUD must occur during a Full Board meeting. Continuing reviewers are required each year, and can be approved via an Executive Review (outside of Full Board).

Q: Does an IRB have to make the determination of a significant risk (SR) or non-significant risk (NSR) device (21 CFR 812.66) when it reviews a HUD?

No. When an IRB is deciding whether to approve the use of a HUD at a facility, its review does not include an SR/NSR determination. As noted above, use of a legally marketed HUD within its HDE-approved indication at a facility to treat or diagnose patients is not a clinical investigation.

However, if an application for an investigational study of the HUD for a different indication than the HDE-approved indication, then this type of clinical investigation is subject to the IDE regulations at 21 CFR Part 812.

Q: Can an HUD be used off-label?

Yes. Unless it is an emergency, before an HUD is used off-label, the FDA recommends that the HDE holder obtain FDA approval of the use following the expanded access policy for unapproved devices. If FDA approves the expanded access request, the physician should ensure that the patient protection measures are addressed before the device is used and should devise an appropriate schedule for monitoring the patient.

Q: Can an HUD be used in an emergent situation?

If the HUD is to be used in an emergency situation and the PI does not have time to obtain IRB approval before the use of the HUD, the PI is required to submit a myIRB application for IRB review within 5 days after the emergent use of the HUD. The PI must include an explanation as to why prior IRB approval was not obtained.
Consent for the use of a HUD (with prior IRB approval or in an emergency situation) must be obtained from the participant or LAR using the standard hospital consent form, and does not require the use of a research consent form.

Q: What type of IRB submission is needed if the HUD is to be used in a research project?

In the event that you are using a HUD as part of a research protocol you must submit Full Board paperwork (since this would be considered greater than minimal risk). Otherwise, if you only wish to use the HUD for treatment purposes, the IRB has special paperwork for submission. Of note – you must seek initial and continuing (usually annual) approval to use the HUD.