HUMANITARIAN USE DEVICES (HUD)

Description

A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease that affects fewer than 4,000 individuals in the United States per year. To be considered for HUD status, a device sponsor must complete a humanitarian device exemption (HDE) application with the FDA.

An approved HDE application authorizes the applicant to market the HUD. The labeling for the HUD must state that the device is an HUD and that the effectiveness of the device has not been demonstrated.

An HUD is the only situation where federal regulations require the IRB to approve and monitor an activity that is clearly not research. Research is not required for the use of an HUD, and each IRB is free to establish its own criteria for IRB approval. The IRB review of HUDs can be particularly challenging, given that there is no research objective or design, no investigational device, no subjects, no study harm, or benefits. The primary reason for this requirement may be to give notice to the institution that the HUD will be used.

Issues to Consider:

1. FDA regulations require local IRB approval before use of an HUD.
2. A local IRB may defer to another IRB that has agreed to assume responsibility for reviewing the use of the HUD in the setting in question. All inter-IRB agreements must be documented in writing.
3. The holder of the HDE is responsible for ensuring that the HUD is used only at facilities that have established an IRB that operates in compliance with FDA regulations.
4. The IRB has the discretion to determine the conditions of HUD use. The IRB may approve the use of the device in general, in a specific number of patients, only under specific circumstances, etc.
5. The regulations require that an IRB conduct both initial and continuing review of an HUD.
6. The regulations do not require informed consent to use an HUD outside the setting of a research protocol. However, the IRB may require informed consent be obtained in any situation it deems appropriate.
7. The IRB will specifically ask for a statement from the local user that the HUD is not being used as a part of a research project or clinical investigation designed to collect data to support an FDA pre-market approval application.

Points to Address

New Study Application:

1. Section 4.2b, Use of a Medical Device: Please answer “Yes.”
2. Section 4.2h, Humanitarian Device Exemption (HDE): Please answer “Yes” (if applicable) and attach a copy of the letter from the FDA granting the HDE to the Documents and Attachments page.

Consent Document:

1. Template: Use the template specifically designed by the IRB for use with HUD device applications. Contact the IRB office for assistance.
2. Background: Include a description of the HUD and describe why it is being used. Describe why current therapies are not satisfactory and why an alternative treatment or approach will be used. Include a statement that the FDA has approved the device for humanitarian use.
3. Risks: State that the HUD has not been proven effective for this use.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.
4. **Research-Related Injury Statement**: Include this section verbatim from the HUD template.
5. **Number of Participants**: Include the following statement verbatim, “A humanitarian use device is one which is used for conditions or diseases which typically affect fewer than 4000 people in the United States per year.”

**References & Links**

*FDA HUD Page*  