Community Healthcare System

The Review

Community Healthcare System Central IRB (CHS CIRB)
Website: www.drcomhs.org

Volume 1 No. 5 *December 2018*

HUDs, Emergence Use, Compassionate Use; Let's Review

A Humanitarian Use Device or HUD is a device intended to benefit patients by treating or diagnosing a disease that affects fewer than 8,000 individuals in the United States per year. To be considered for HUD status, a device manufacturer must complete a humanitarian device exemption (HDE) application to the FDA. The application must contain sufficient information for the FDA to determine that the device does not present an unreasonable risk of illness or injury and the probable benefit from its use justifies the potential risks. An approved HDE application authorizes the applicant to market the HUD. The labeling for the HUD must state that the device is a HUD and the effectiveness of the device has not been demonstrated. An approved HDE application is valid for as long as the use of the device continues to meet the conditions of the HDE application.

What impact does this have on the CHS CIRB and the physician/investigator?

This is the only situation where federal regulations require the IRB to approve and monitor an activity that is clearly not research.

The regulations require that an IRB conduct both initial and continuing review of a HUD. The IRB does not have to approve each individual use of an HUD. That is, the IRB may approve use of the HUD for its FDA approved indication(s) without any further restrictions or use of the device on a case-by-case basis. The CHS CIRB will approve the use of the HUD for more than one physician/investigator, i.e., all of the interventional cardiologists. However, there must be one physician/investigator who is willing to assume the responsibility for the conduct of the other physician/investigators.

The regulations do not require a consent form to document consent during the consent discussion. The local IRB may require the use of a consent form or may determine that the product labeling developed by the HDE holder incorporates enough information to assist a patient in making an informed decision about the use of the device.

Compassionate Use of a HUD

A previously CHS CIRB approved HUD may be used off-label in certain life threatening situations necessitating the use of the test article. The physician/investigator and an independent physician must conclude that there is no generally recognized standard acceptable treatment or therapy available for use. Prior to use, the physician/investigator should;

1. Notify the sponsor holding the HDE that a patient has been identified for a planned off label use of the device; and
2. Complete and submit the Application/Report for the Emergency/Compassionate Use of a Test Article to the CHS CIRB along with any documentation submitted to the sponsor.

Emergent Use of a HUD

"Emergent Use" is defined as the use of a test article (e.g., investigational drug, biologic, or

device) on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for use. The Federal Regulations requires that 3 conditions be met to qualify for an emergency exemption;

1. The subject has a life threatening condition necessitating use of the test article.
2. No standard acceptable treatment is available.
3. There is not sufficient time to obtain full IRB approval.

"Life threatening" is any disease or condition where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes and where the end point of the clinical trial analysis is survival. The criteria do not require the condition to be immediately life threatening or to immediately result in death. Rather, the subject must be in a situation requiring intervention before review at a convened meeting of the IRB is feasible.

In emergent situations, an investigator is required to obtain informed consent unless he can certify in writing that;

1. The subject is confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent could not be obtained because of an inability to communicate with, or obtain legally effective consent from the subject.
3. Time was not sufficient to obtain consent from the subject's legally authorized representative.
4. No alternative method of approved or generally recognized therapy is available that provides and equal or greater likelihood of saving the subject's life.

Within 5 working days following the emergent use of the test article, the physician/investigator should submit an "Application/Report for the Emergency Use of a Test Article" to the CHS CIRB.

Research Involving a HUD

If the HUD is being used as part of a research project or clinical investigation designed to collect data to support an FDA pre-market approval, the IRB must comply with all of the FDA regulations related to IRB review of research.

Related Policies and Forms

IRB 16: Emergency or Compassionate/ Humanitarian Use of a Test Article

Application/Report for the Emergency/Compassionate Use of a Test Article

IRB 17: Humanitarian Use Device (HUD) Humanitarian Device Exemption (HDE)

CHS CIRB Contact Information

Jana L. Lacera, RN, MSA, CDM
901 MacArthur Blvd.
Munster, IN 46321
Phone: 219-703-1546
E-mail: jlacera@comhs.org