

# **ST. LUKE'S UNIVERSITY HEALTH NETWORK**

## **IRB POLICIES AND PROCEDURES MANUAL**

### **500 Reviews Requiring Special Consideration (SC)**

#### **Policy SC 503: Review and Approval of a Humanitarian Device Exemption**

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#### **1. PURPOSE**

To delineate the policy and procedure for IRB review, approval, and supervision of a proposal involving a Humanitarian Device Exemption (HDE).

#### **2. INTRODUCTION**

The provisions of the FDA Safe Medical Devices Act of 1990 regarding Humanitarian Use Devices (HUDs) became effective on October 26, 1996. HUDs are devices that are intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. The Office of Orphan Products Development (OOPD) determines if a device meets specific requirements including scientific rationale and population prevalence, for designation as a HUD. The manufacturer's research and development costs for bringing such a device to market could exceed its market returns for diseases or conditions affecting small populations. The FDA developed and published this regulation to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

To be considered for HUD status the sponsor must complete a Humanitarian Device Exemption (HDE). An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. Because of the impractical cost of conducting large-scale clinical trials for devices designed for potentially small user populations, the HDE application is not considered research and thus the applicant is not required to present the results of scientifically valid clinical investigations that demonstrate that the device is effective for its intended purpose. The application must, however, contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of illness or injury from its use. Additionally, the applicant must demonstrate that no comparable devices are available for that purpose and that they could not otherwise bring the device to market without receiving HUD status.

If a HUD is being used in a clinical investigation (e.g. if collection of safety and effectiveness data is performed), regardless if the HUD is being used for its HDE-approved indication(s) or for a different indication, then this would be considered investigational use and would be subject to the same requirements that apply to all FDA-regulated clinical studies, including 21 CFR Parts 50 and 56. Additionally, if the HUD is being studied for a use other than its approved indication(s), the Investigation Device Exemption (IDE) regulations (21 CFR Part 812) apply, and if the device is a significant risk device, an FDA-approved IDE is required.

#### **3. RESPONSIBILITY FOR EXECUTING THE POLICY**

Institutional Review Board Leadership, including the Medical Director, Chair, and Vice-Chair

#### **4. POLICY STATEMENT**

An approved HDE authorizes marketing of the HUD pending IRB approval and supervision of the clinical testing of the HUD. The labeling for the HUD must state that the device is a HUD and that, although federal law authorizes the device, the effectiveness of the device for the specific indication has not been demonstrated. HDE applications must demonstrate that no comparable device, other than another HUD-approved under the HDE regulation or a device being studied under an approved IDE, is available to treat and/or diagnose the disease or condition. HDE applications do not have to be renewed and are valid as long as the use of the device continues to meet the conditions of the HDE application. An IRB-approved HUD protocol does, however, require periodic continuing review for the duration of its use at the institution.

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### 5. PROCEDURES

#### 5.1: General IRB Responsibilities

The IRB has a unique role in the HUD setting. All IRB regulations and guidance documents are written from the point of regulation of human subjects research. In approving an HDE application, the IRB must operate without guidance from a federal system designed to regulate only human subjects research. This is the only situation where federal regulations require the IRB to approve and monitor an activity that clearly is not research. An HDE application approved by the FDA and an IRB authorizes marketing of the HUD.

Consequently, when evaluating a request to use such a device for medical treatment or diagnosis, the IRB is left to its own discretion to establish criteria for IRB approval of the device.

This policy requires the IRBs, when evaluating a request to use a HUD, to consider the following items that are generally included in the HDE application:

- The generic and trade name of the device
- The FDA HDE number (6 digits)
- The date of the HUD designation
- Indications for the use of the device
- Description of the device
- Consideration of whether the sponsor has determined the device does not pose an unreasonable or significant risk of illness or injury and that the probable benefit to health outweighs the risk of illness or injury from its use.
- Demonstration that no comparable devices are available for the specific purpose/indication being requested and that they could not otherwise bring the device to market without receiving HUD status.
- Any contraindications, warnings, and precautions for the use of the device
- Adverse effects (known and possible) of the device on health
- Alternative practices and procedures
- Marketing history
- Summary of studies using the device

The IRB must conduct both initial and continuing review of the HUD and monitor adverse events. Approval may be granted for a maximum one year or less depending on the perceived risk levels. There is no time limit on the FDA approval of an HDE.

#### 5.2: Initial Review

Initial IRB approval of the HDE application must be performed at a convened meeting of the IRB. The IRB need not approve individual uses of an HUD, but rather may approve the use of the device without any restrictions, use of the device under protocol, or use of the device on a case-by-case basis on a protocol basis. The use of the device should, however, not exceed the scope of the FDA-approved indication.

While the regulations do not require a consent form as the device will be used outside a research setting, the IRB will make a determination as to whether it would be prudent to require a consent form, particularly to indicate the unproven status of the device. Alternatively, the IRB may require that both the investigator and the subject sign the Device Brochure to indicate that the subject and the investigator have had a discussion about the HUD and that the subject has understood what the device is and why an IRB is required to monitor its use.

Items to be submitted and reviewed by the convened IRB for initial approval of the HDE are as follows:



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- Copy of the FDA HDE Approval Order
- A description of the device
- The product labeling
- The patient information packet
- A sample consent form (if required)
- A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, test, or procedures
- A statement from the investigator 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.

The HDE Approval Order, product labeling, and HUD patient information packets can be found at:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm#2>

The IRB shall ensure that the physicians distribute the patient information packet to patients prior to receiving their HUD.

#### 5.3: Continuing Review

The IRB will approve the device for a period of time not to exceed one year. In the case of a HUD with higher risk, the IRB may approve the device for a specific number of patients with a summary report required before approving the device for additional patients.

Continuing review must follow the requirement found at 21 CFR Part 56. The FDA has determined that it is appropriate to conduct the review using expedited review procedures if the IRB so determines since the initial review was performed by a convened IRB and the use of the HUD within its approved labeling

#### 5.4: Medical Device Reporting

The IRB shall receive and review all Medical Device Reporting (MDR) reports that are submitted to the FDA in accordance with 21 CFR Part 803.

#### 5.5: Device Use Tracking

All HUD device use should be recorded in real-time (or within 5 days in emergency situations) in a standardized log book. Required information should be logged on the form provided by the IRB, and must include the following:

- Date and time of device placement
- Name, age, and medical record of patient receiving the device
- Unique device identification number
- Documentation of procedure consent process, with evidence of discussion regarding the device being used classified as "Humanitarian Use Device"; If separate consent not required, the nature of HUD must be disclosed under routine consenting process and documented as such
- Name(s) of individual(s) involved in the consent process, as well as evidence of information materials (i.e., product brochures) being given to the patient

The original copy of the log should be kept in the Department / Clinical Unit performing the procedure. A copy of the log should be sent to the IRB / Clinical Trials Office for regulatory record-keeping.

#### 5.6: Emergency Use

If a physician in an emergency situation determines that IRB approval for the use of the HUD cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used without prior IRB approval. The physician must report the emergency use within five (5) days by providing written

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notification of the use to the IRB Chair, including identification of the patient involved, the date of the use, and the reason for the use.

### **6. REFERENCES**

FDA Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors: Frequently Asked Questions about Medical Devices (January 2006)

FDA Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff (July 2010)

Code of Federal Regulations: 21 CFR 50, 21 CFR 56, 21 CFR 812, 21 CFR 814

**Approved by: Fully Convened Institutional Review Board – Nov Session 2014**

**Date: 2014-11-17**

**Approved by:**

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**Senior Vice President for  
Medical and Academic Affairs**

**Date:** \_\_\_\_\_

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**Medical Director, IRB**

**Date:** \_\_\_\_\_