Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 500: Investigational Medical Devices

POLICY

The DMH IRB shall review and evaluate clinical research that involves medical devices in accordance with applicable FDA Regulations. In reviewing research that involves a medical device, the DMH IRB shall make a determination as to whether the medical device is a significant risk or non-significant risk device.

PROCEDURES

1. Device Classes

1.1 Class I - Devices present minimal potential for harm to user and are usually simpler in design. Examples: Crutches, band aids, examination gloves, handheld surgical equipment.

1.2 Class II - Devices for which Class I controls are not enough to ensure safety and effectiveness. Examples: Wheelchairs, infusion pumps, surgical drapes.

1.3 Class III - Usually devices that support or sustain human life, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. Examples: Heart valves, implantable pacemaker, pulse generators, and other devices known to present hazards requiring clinical demonstration of safety and effectiveness OR devices for which there is not enough known about safety or effectiveness to assign to Class I or Class II.

2. Marketing of New Medical Devices

2.1 Except for certain low risk devices, a person or company who wants to introduce a new medical device on the market must submit a Premarket Notification to the FDA. The FDA reviews the notification to determine if the medical device is similar to medical devices that were marketed prior to the passage of the Medical Device Agreement of 1976 to the Food and Drug Act. If the FDA determines that the new medical device is "substantially equivalent" to a medical device approved before the amendments, it can be marketed immediately and is regulated under the same medical device class that applied to the previous medical device. If the medical device is not substantially equivalent, then it has to be clinically tested and receive Premarket Approval from the FDA for safety and effectiveness before it can go on the market. IRB review is required for any clinical investigation of such medical devices before their initiation.

3. Off-Label Use of Medical Devices

3.1 Medical devices may be marketed only for the uses approved by the FDA. A physician may use an FDA-approved medical device "off label" for a use other than the FDA-approved use only in the physician's practice of medicine. The physician may not conduct research regarding the off-label use of the device to develop information regarding the safety or effectiveness, or to support marketing of the medical device UNLESS the physician is using the device under an FDA-approved Investigational Device Exemption (IDE).

4. Investigational Device Exemption

4.1 In order for an Investigator to conduct clinical trials for the purpose of collecting safety and effectiveness data necessary to support the marketing of a new non-FDA approved medical device or a new use for a current marketed FDA-approved device, the DMH IRB requires that the Investigator provide documentation to the IRB establishing that the sponsor of the device has obtained from the FDA, and is conducting research under the auspices of an Investigational Device Exemption (IDE). In cases in which the Investigator is also the sponsor for a medical device clinical trial, the Investigator should hold the IDE.

4.2 The approved IDE permits the manufacturer of the device to lawfully ship the device for use in the clinical trial. When submitting to the IRB a protocol involving a medical device that requires an IDE, the Investigator must provide the IRB with

evidence of the IDE, i.e. a copy of the industry-sponsored protocol with the IDE number; or a letter from the FDA or industry sponsor outlining the IDE number. If the study involves a medical device and no IDE number is provided to the IRB, the Investigator will be required to provide an explanation as to why an IDE is not required and how the study qualifies for one of the FDA exempt categories.

5. Significant Risk vs. Non-Significant

5.1 The DMH IRB will consider a medical device to be a significant risk device if its use in the study could result in potential harm to research subjects that:

5.1.1 Could be life-threatening;

5.1.2 Could result in permanent physical impairment of a body function or part; or

5.1.3 Could necessitate medical or surgical intervention to preclude permanent impairment of a body function or part.

5.2 The DMH IRB will consider a medical device to be a non-significant risk device if the device poses only minimal risks to research subjects.

6. IRB Role

6.1 The IRB will determine whether, in the context of the study or by the nature of the investigational device, the study presents a significant risk (SR) or a non-significant risk (NSR) of harm to research subjects. The assessment will be based on the information provided by the Investigator and/or sponsor. The IRB discussion and risk determination will be documented in the IRB meeting minutes.

6.2 If an investigator submits an NSR device research protocol that is determined by the IRB to be a significant risk device study, the Investigator and the FDA will be notified in writing. No further action will be taken by the IRB on the research until the Investigator or sponsor has met the requirements for an SR study as described in 21 CFR 812.

SCOPE

This SOP applies to all Investigators and sponsors conducting medical device clinical trials within the confines of Decatur Memorial Hospital.