Title: SARMC Institutional Review Board(s): Research Involving Medical, Investigational, and Humanitarian Devices

Policy Statement: A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease;
- Intended to affect the structure or any function of the body

Procedure:

I. Device Classification

The FDA has established three regulatory classes for medical devices based on the level of control necessary to ensure safety and effectiveness of the device. Classification is risked based—the risk the device poses to the patient and/or user is considered.

A. Class I devices are subject to general controls and typically are the lowest potential for harm and are simple in design. Examples include: elastic bandages, examination gloves and hand-held surgical instruments.

B. Class II devices are those that require special controls identified by the FDA, which may include labeling requirements, performance standards, and post market surveillance. Examples include: powered wheelchairs, infusion pumps and surgical drapes.

C. Class III devices are those for which insufficient information exists to determine what type of general or special controls are needed to provide reasonable assurances of safety and effectiveness. Examples include: replacement heart valves, silicone gel-filled breast implants and implanted stimulators.

II. Investigational Device Exemption

Investigational devices are medical devices that are the object of clinical research studies designed to determine their safety and effectiveness. Studies undertaken to develop safety and effectiveness data for medical devices involving human subjects must be conducted according to the requirements of the investigational device exemption (IDE) regulations (21 CFR 812). An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor’s/investigator’s research study and all the requirements under 21 CFR 812 are met.
An IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA. Clinical studies are most often conducted to support a PMA. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of significant risk investigational devices, unless exempt, must have an approved IDE before the study is initiated. Non-significant device studies do not have an IDE application approved by the FDA and may begin as soon as approval is granted by the IRB. The FDA, in most cases, is not aware of non-significant risk device studies.

### III. Significant and Non-significant risk determination

The Institutional Review Board will determine whether the device presents significant (SR) or non-significant risk (NSR). The sponsor initially makes the determination of non-significant or significant risk. The IRB may ask the sponsor whether other IRBs have reviewed the proposed study and what determination was made.

In deciding if a device presents significant or non-significant risks, the IRB will consider the device’s total risks, not as compared with the risks of alternative devices or procedures. If the device is used in conjunction with a procedure involving risk, the IRB will consider the risks of the procedure in conjunction with the risks of the device. The IRB must review the sponsor’s SR or NSR determination for each investigational medical device/study.

If a sponsor determines a device study as NSR, the sponsor and/or investigator must provide the IRB with an explanation of its determination and provide information that may help the IRB evaluate the risk of the study/device. If the IRB disagrees with the NSR determination made by the sponsor, then the IRB must notify the sponsor/investigator in writing that the study involves a significant risk device. If the IRB needs help in making the SR/NSR determination, it may ask for a written determination from the FDA.

- **Note:** IRBs do not have to make the SR or NSR determination if the FDA has already made the risk determination, as the agency’s determination is final. Most often, investigators/sponsors will submit to IRBs once the study has already received IDE approval from the FDA. The IRB will require from the investigator/sponsor a copy of the FDA’s IDE approval letter to be submitted at time of a new study application.

### IV. Definitions

A. Significant risk device (SR device) is defined as an investigational device that:

1. is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject;
3. is for a use of substantial importance in diagnosing, curing,
mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
4. otherwise presents a potential for serious risk to a subject.

B. Non-significant Risk Device is one that does not meet the definition for an SR device.

V. IRB Review for IDE
Once a decision on the degree of risk is reached, the IRB will consider whether the study should be approved or not. Some studies involving non-significant risk devices may also be considered minimal risk studies and, thus, may be reviewed through the expedited review procedure established by the IRB. FDA considers studies of all significant risk devices to present more than minimal risk; thus, review for all studies involving significant risk devices will occur at a full-convened IRB meeting. In considering whether a study should be approved, the IRB will use the same criteria it would use in considering approval of any research involving an FDA regulated product, including:
A. Description of the device;
B. The FDA's assessment of the device’s risk if such an assessment has been made;
C. Reports of prior investigations with the device;
D. The proposed investigational plan;
E. A description of patient selection criteria and monitoring procedures;
F. Any other information that the IRB deems necessary to make its Decision;
G. If other IRBs have reviewed the proposed study and what determination was made.

Risk determination and study approval decisions will be documented in IRB meeting minutes.

VI. Humanitarian Device Exemption
A Humanitarian Device Exemption (HDE) application is similar to a PMA, but is not required to contain results of scientifically valid clinical investigations demonstrating that the device is effective for the intended purpose. The HDE must contain sufficient information for the FDA to determine that the probability of benefit to health outweighs the risk of injury or illnesses, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD). HUDs may only be administered at institutions that have an IRB operating as outlined in 21 CFR 56 and where the IRB has prospectively approved the use of the device.

VII. IRB Review for HDE/HUD
The IRB must ensure that the FDA has granted HDE approval before approving the device for use at SARMC. Documentation of the HDE approval will be provided to the SARMC IRB by the person requesting approval for use. This documentation should include:
A. The HDE approval letter from the FDA;
B. An explanation of how the HUD will be obtained and monitored;
C. An explanation of how the IRB will be notified of HUD use within 24 hours of its use (this must include the patient name and date of procedure/use of the HUD)
D. A copy of the informed consent form that will be used for patients receiving the HUD.

The IRB will render a decision of approval at a full-convened meeting detailing the requirements of prospective consent.

Typically, the use of a humanitarian device is for a certain prescribed population and limited in use/scope, and does not meet the regulatory definition of human subject research. However, sometimes an investigator or HDE holder may develop a research protocol designed to collect safety and effectiveness data to support a PMA for the device. As a result, if the research is for a new use, the IDE regulation must be followed.

Continuing reviews for an HDE may be conducted utilizing the expedited review process, as the use of the HUD within its approved labeling does not constitute research. The type of review will be documented as well as the approval status.

Related Policies: Research Studies; Institutional Review Board

Related Forms: None

References:


http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Code of Federal Regulations. (Last revised April 1, 2012). Title 21 – Department of Health and Human Services; Parts 812 (IDEs) and 814 (Medical Devices).
