Institutional Review Board (IRB): Medical Devices

I. Policy Statement:

All clinical investigations using a medical device must have an approved IDE or be exempt from the IDE regulations (refer to 21 CFR 812.2(c)). Depending upon the nature of the investigation, those studies which are exempt from the requirements of the IDE regulations may not be exempt from the requirements of IRB review/approval or from obtaining participant informed consent.

An IDE is not required for non-significant risk (NSR) devices when the sponsor/investigator provides an explanation of why the device is NSR, and the IRB agrees with the justification for the NSR determination. An FDA Investigational Device Exemption (IDE) is required for Significant Risk (SR) devices used in studies involving:

- Unapproved devices considered to be a significant risk, i.e., may be collecting safety and efficacy data to support PMA FDA submissions, or
- Approved devices, which are being studied for a new indication, are considered to be a significant risk.

The purpose of this policy is to describe the requirements for the use of investigational devices , regulated by the Food and Drug Administration (FDA), in research. This policy applies to all research involving devices when the Human Subjects Research (HSR) is conducted within a Trinity Health West Region Site.

II. Definitions:

Medical Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement.
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans.
3. Intended to affect the structure or any function of the body of humans or other animals.

Significant Risk Device (SR device): An investigational medical device presenting a potential for serious risk to the health, safety, or welfare of a participant. These SR devices require an IDE if it is:

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

Non-significant Risk Device (NSR device): A medical device that does not meet the definition for an SR device.

Investigational Device Exemption (IDE): An IDE is issued by the FDA to allow the use of an investigational device in Human Subjects Research clinical studies to evaluate and gather data on the safety and efficacy of the device. The approval of an IDE application will be in the form of a letter from the FDA, which will also indicate the stipulations of the approval. This letter must be submitted to the IRB for review as part of the New Project Application.

Premarket Approval (PMA): Devices requiring premarketing applications are Class III high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process (21CFR814). The PMA process is more involved and includes the submission of clinical data to support claims made for the device.

Sponsor-Investigator: An investigator who assumes both investigator and sponsor responsibilities as outlined in the FDA Regulation 21CFR812.

III. Equipment: None

IV. Procedure:

A. Risk Determination

1. The initial assessment and determination of risk (significant or non-significant) related to the use of the device is the responsibility of the sponsor.
2. If the FDA has previously made a significant or non-significant risk determination for the investigational device being studied, the FDA determination is final and supersedes all other determinations.
3. If the FDA has not made a risk determination, the IRB must review the SR or NSR determination for the investigational device being studied.
4. If the IRB disagrees with the sponsor's NSR determination, the sponsor will be notified in writing and may be asked to contact the FDA regarding a SR determination. In the scenario, the IRB may approve the study as a SR device trial, **but** the study may not begin until the FDA approves the IDE application.

For studies that are exempt from the IDE regulations, the IRB does not need to decide whether the study poses a significant risk or nonsignificant risk. Examples of IDE exempt studies include but are not limited to:

- those using legally marketed devices in accordance with their approved labeling, or
- some non-invasive diagnostic tests,
- consumer preference studies,
- veterinary and laboratory studies,
- diagnostic confirmation studies, or
- devices in commercial distribution before May 28, 1976, when used in accordance with approved labeling or when considered substantially equivalent to a pre-May 26, 1976, marketed device.

B. Investigator Responsibilities

1. When participating in an investigational device study, the investigator must conduct the investigation in accordance with the agreements they signed with the sponsor, the investigational plan, the IDE regulations and other applicable FDA regulations, and any conditions of approval imposed by an IRB and/or FDA (21CFR812.100).

2. An investigator who is serving as a sponsor-investigator must adhere to additional responsibilities as defined in 21CFR812.

C. IRB Review

1. The IRB will review all studies involving significant and non-significant risk devices complying with the requirements of part 56.
2. When making both significant and non-significant risk determinations, the full board IRB will consider the device's total risks as used in the study. 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.
3. If the IRB needs help in making the SR/NSR determination, it may ask for a written determination from the FDA, and the study may be tabled until a risk determination is provided.
4. 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.
5. The IRB will use the same criteria it would use in considering approval of any research in accordance with HHS and FDA regulations at 45 CFR 46.111 and 21 CFR 56.111.

D. Breakthrough Devices Program

1. The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provides for more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases or conditions that are subject to premarket approval applications (PMA), premarket notification (510[k]) or requests for De Novo designation (See references section for further information).
2. IRB review/approval for devices used under this program will be conducted as indicated for IDEs.

E. Documentation & Correspondence

The Principal Investigator will be notified in writing of the IRB review and determinations. The IRB will document that the Criteria for Approval was met, the risk determination was assessed, and all study approval decisions in IRB meeting minutes as appropriate.

V. Ministry Specific Related Addendums, Procedures, and/or Policies:

A. Saint Agnes Medical Center: None

B. Saint Alphonsus Health System: None

VI. Additional Approval: Not applicable.

VII. References:

Significant Risk and Nonsignificant Risk Medical Device Studies - Information Sheet

Institutional Review Boards