Title: **Determination of Significant Risk Device**	*Applicable to: **Beaumont Health**	Effective Date: **01/11/2018**
		Last Periodic Review Date: **01/11/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **IRB and Clinical Research, Research Institute**

***For This Document, Beaumont Health Includes**:
Beaumont Corporate Shared Services
Beaumont Hospital, Dearborn
Beaumont Hospital, Farmington Hills
Beaumont Hospital, Grosse Pointe
Beaumont Hospital, Royal Oak
Beaumont Hospital, Taylor
Beaumont Hospital, Trenton
Beaumont Hospital, Troy
Beaumont Hospital, Wayne
Beaumont Medical Group
Beaumont Pharmacy Solutions
Post Acute Care

I. PURPOSE:

The purpose of this policy is to establish a procedure for evaluating the relative risk of investigational medical devices used in research at Beaumont Health (Beaumont).

II. SCOPE:

This policy applies to Institutional Review Board (IRB) members and IRB staff, investigators and research staff.

III. POLICY:

The Beaumont IRB serves as the primary IRB, and IRB of record for human participant research conducted at Beaumont, and is responsible for the initial and continuing review and oversight of such research. (See IRB policy *Review by an External Institutional Review Board* for guidance on use of external IRBs).

The IRB is responsible for evaluating the risks imposed on research participants being diagnosed or treated with investigational devices. The IRB is charged by federal regulations to make such determinations of risk, to report decisions to regulators, sponsors and investigators as required, and assure the studies have the appropriate regulatory oversight.

IV. PROCEDURE:

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The Investigational Device Exemption (IDE) regulations of the Food and Drug Administration (FDA) describe two types of device studies, "significant risk" (SR) and "non-significant risk" (NSR). Significant risk devices always require an Investigational Device Exemption (IDE) from the FDA. When submitting a device study for IRB review, the iMedRIS application will ask a number of device related questions, which provides the IRB with the information necessary to conduct a risk assessment and make the determination whether the device is considered SR or NSR. **All SR devices must have an FDA assigned IDE number and letter prior to approval by the IRB.**

A. **Significant Risk Device (SR) -** A Significant Risk or SR device is defined as a device which presents a potential for serious risk to the health, safety or welfare of a participant and may be:
   1. Intended as an implant;
   2. Purported or represented to be for use in supporting or sustaining human life;
   3. For use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health
   4. Examples include sutures, cardiac pacemakers hydrocephalus shunts and orthopedic implants.

B. **Non-Significant Risk Device (NSR) -** An NSR device study is one in which the device(s) being used does not meet the criteria for significant risk device, as described above**.** Examples include daily wear contact lenses, lens solutions, ultrasonic dental scalers and Foley catheters. NSR devices do not require an IDE approval from the FDA. Instead, the IRB is responsible for approval and oversight of investigational NSR device studies.

C. **IRB Determination -** For device studies submitted without an IDE, the risk determination will be reviewed by Clinical Engineering and a written response will be submitted through iMedRIS to the IRB. The sponsor or sponsor investigator is required to justify the NSR determination. The investigational device is considered SR until the IRB accepts the sponsors/sponsor investigators NSR justification. The IRB, in the course of its' initial review will make a determination of SR or NSR for each device being used in a protocol. The information from Clinical Engineering will be documented in the IRB minutes and communicated in writing to the principal investigator (PI).

   If a PI or sponsor determines the device meets the criteria for NSR and Clinical Engineering and the IRB concurs the study may begin without submission of an IDE application to the FDA.

   If a PI identifies a device as NSR, but Clinical Engineering and the IRB determines the device is SR, the IRB will notify the investigator and the sponsor (when appropriate) of the decision. The study will not be approved by the IRB until the PI has provided an IDE approval letter or

documentation of an FDA determination of NSR. No research may begin at Beaumont until IRB approval is granted.

If there is any question about whether the device may be a SR device, the IRB may request information such as determinations made by other Institutional Review Boards, correspondence from the FDA or require a determination directly from the FDA. The FDA has the ultimate authority in determination of SR or NSR.

V. CLINICAL ENGINEERING REVIEW:

All devices to be used in research studies where Beaumont IRB serves as the IRB of record must undergo review by Beaumont Clinical Engineering (CE). CE will provide the results of their review within iMedRIS.

A. **Clinical Engineering Review for Devices Holding an IDE**
CE review for devices being used under an IDE will include:
1. Verification the IDE letter submitted with the IRB application is current.
2. Any constraints in the IDE letter are present in the protocol and IRB application.
3. Protocol description of the device's use is consistent with IDE approval.
4. Device manufacturer is in good standing with the FDA. If regulatory actions, such as an FDA Warning Letter or product recalls for this or a similar device exist, CE will share this information with the IRB, Research Administration, the PI and the Clinical Research Manager (CRM) to determine if the study will move forward at Beaumont.
5. Ensuring the existing environment is not impaired by the utilization of the device e.g., communicate with existing IT networking systems, electromagnetic interference, MR compatibility.

CE does not have to physically examine devices with an IDE approval from the FDA. However, many of these devices will still require an Incoming Equipment Inspection, in accordance with Beaumont Health Policy *Equipment Management Program: Incoming Equipment*.

B. **Devices with Appropriate FDA PMA or 510K Clearance or Approval**
Clinical Engineering review will include:
1. Determination of whether the investigation's planned device utilization is consistent with FDA's cleared/approved indications.
2. Device sample may or may not be needed by CE, but must be directed by CE if the study is reviewed by the Beaumont IRB.

C. **All Other Devices** - Devices without an IDE, PMA, or 510(k) (typically investigator-initiated research), CE review will include:

1. Full review of the device, including a physical device inspection.
2. Planned research use based on the engineering of the device.

VI. REGULATORY REFERENCES:

21 CFR 56.108 - IRB Functions and Operations
21 CFR 812.3(m) – Definitions
21 CFR 812.46(c) - Monitoring Investigations
21 CFR 812 - Significant Risk Device Determinations
42 CFR 405 Subpart B
FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicate and Medicaid Services (CMS) with Coverage Decisions/ Draft Guidance for Sponsors, Clinical Investigators, Industry, Intuitional Review Boards and Food and Drug Administration Staff dated June 1, 2016 CDRH-Guidance@fda.hhs.gov document number 1500074

VII. ASSOCIATED POLICIES:

IRB Policy *Investigational Device Studies*
IRB Policy *Review by an External Institutional Review Board*
Beaumont Health Policy *Equipment Management Program: Incoming Equipment*

CORPORATE AUTHORITY:

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.