Policy Name: **Review of Research Involving Medical Devices Policy and Procedures**			
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I. POLICY

A. Introduction

This document describes the policies and procedures for conducting studies involving investigational new *devices* at MUSC Hospitals & Clinics (MUSC) as well as the secure storage of those devices and new biologics, in keeping with the policy of MUSC's Human Research Protection Program (HRPP). This policy does not cover use of investigational radiopharmaceuticals.

B. Federal Regulations

Clinical investigations of investigational medical devices at MUSC are subject to Federal regulations and are required to comply with Investigational Device Exemption (IDE) regulations as outlined in FDA document 21 Code of Federal Regulations (CFR) § 812 and 21 CFR § 814, unless exempted under certain specified conditions. All principal investigators (PI) are expected to fulfill all of the responsibilities delineated in the FDA regulations, other federal and State laws and regulations relating to clinical research and MUSC policies and procedures.

C. Storage and Control

Investigational devices and biologics under the control of principal investigators and used at MUSC must be procured, stored, secured, dispensed, and monitored in accordance with the MUSC Human Research Protection Program (HRPP) and specific device requirements.

D. Approval for Use

Investigational devices may only be used after research studies and associated documentation have been approved by the MUSC Institutional Review Board (IRB) and any other governing committees, excluding the exemption which permits emergency use of an investigational device on a one-time basis per institution without IRB review and approval [21 CFR 56.104(c)].

E. Classification of Devices

Devices are classified as a Significant Risk Device [21 CFR § 812.3m] or Non-significant Risk (NSR) Device, unless EXEMPT from the regulations for Investigational Device Exemptions (IDE).

1. Device studies require review and approval by the MUSC IRB.

2. NSR device studies require MUSC IRB review and approval with regard to informed consent, record keeping, and study monitoring.

3. If a principal investigator (PI) proposes the initiation of a NSR device investigation to the IRB, and if the IRB agrees the device study is NSR and approves the study, the investigation may begin immediately, without submission of an IDE application to the FDA.

   Note: If the IRB disagrees with a claim the device is non-significant risk or agrees with the claim and disagrees with the investigator's rationale, the primary reviewer will document the rationale for the IRB's determination in the IRB meeting minutes.

4. Any safety and efficacy data collection on a significant risk device for other than approved indication requires an IDE in advance of IRB approval.

F. Administration of Policy

Contact the MUSC Chief of Staff and/or the Chairman of the Safety Committee (Safety Officer) and/or consult the IRB in situations where guidance is required in administering this policy

II. DEFINITIONS

Definitions for the following terms may be found in the HRPP Program Guide Section 1.3 – Definitions of terms:

A. Custom Device
B. Emergency Use
C. Investigational Device
D. Investigation Device Exemption (IDE)
E. Life-Threatening
F. Medical Device
G. Non-Significant Risk (NSR) Device Study
H. Radiology Device
I. Severely Debilitating
J. Significant Risk (SR) Device Study
K. Unapproved Device

III. PROCEDURES

A. Informed Consent

The PI is required to obtain informed consent from the research participant or their legally authorized representative, unless the FDA requirements for exception from informed consent are met [21CFR § 50.23(a)]. Note: The signed informed consent document for research, which is contained in the medical record, will serve to notify hospital personnel that the patient is a research participant in a clinical study involving an investigational device.

B. Responsibilities of the Principal Investigator

1. **Prior to Use** – Prior to use of the investigational device for any reason, the PI must:

    a) Submit a scientific protocol, and all required initial and continuing documentation to the IRB committee. Follow all applicable policies of the MUSC HRPP, including, but not limited to, record keeping by the PI under 21CFR § 812.140(a).

    b) Adhere to the IDE regulations [21 CFR § 812.]. Research investigations involving NSR devices must adhere to the abbreviated requirements at 21 CFR § 812.2(b).

    c) Obtain IRB approval for research as well as the MUSC informed consent from the research participant or their legal representative [45 CFR § 46.116].

    d) Forward IRB acknowledgement of approval to the manufacturer and/or sponsor.

2. **During Use** – During the use of the investigational device, the PI must:

    a) Provide secure and controlled access storage for each investigational device through the MUSC clinical department where they will be utilized (e.g., OR, Cardiac Catheterization Laboratory) that satisfies storage requirements (e.g., controlled temperature, sterile conditions) and maintains proper control of the device for security, storage, inventory, dispensing and disposal purposes;

    b) Ensure proper dispensing and utilization of investigational devices as defined in the research protocol to those authorized to receive and use it. Note: The PI is responsible for the education of co-investigators, study personnel, and hospital personnel who prescribe, distribute, or administer the investigational device.

c) Protect the rights, safety, and welfare of the research participants enrolled in the study.

d) Maintain complete records as required by the policy of the MUSC HRPP.

e) Use investigational devices only in approved research protocols.

f) Maintain records of receipt, use or disposition (including retrieval of unused product) of the investigational device. Records should include the type and quantity of the device, the dates of receipt, the batch number or code mark, the names of all persons who received, used, or disposed of each device, and why and how many units of the device have been returned to the sponsor, repaired, or otherwise discarded.

3. **After Use** – After use of the investigational device the PI must:

a) Follow the policy of the MUSC HRPP when the investigational device is discontinued;

b) Return or dispose of the device in accordance with the manufacturer's specifications;

c) Report any adverse effects of the investigational device appropriately (see Section 8 "Adverse Event Reporting" below).

4. **Throughout** - Through the MUSC sponsoring department, in conjunction with the manufacturer or vendor sponsor of the device, the PI must:

a) Provide for the ongoing security, inventory, and dispensing of the investigational device to appropriate personnel for use by following the MUSC HRPP and MUSC policies, regulations and procedures.

b) Perform quality audits to insure security, integrity, and inventory of the investigational device.

C. Responsibilities of the MUSC Clinical Department

The MUSC clinical department where the device will be utilized will cooperate with and assist the PI in obtaining secure and controlled access storage in the clinical department for each investigational device satisfying its storage requirements (e.g., controlled temperature, sterile conditions)

and maintain proper control of the device for security, storage, inventory, dispensing and disposal purposes.

D. Use of Investigational Radiology Devices

1. Clinical investigations of radiology devices at MUSC will be initiated only after approval is gained from the MUSC IRB and the MUSC Committee on Radiation Safety (see MUSC Research Policy Handbook).

2. For workplace safety, instructions contained in the research protocol will be followed in the preparation, handling, storage, use, administration, discontinuation, and return, waste or disposal of the investigational device.

3. Policies and Procedures of the Department of Radiation Oncology ["Investigational New Devices"] will be followed when investigational radiation devices (e.g., brachytherapy) are implanted at the Radiation Oncology Department into consented research participants.

4. Hospital rooms at MUSC will be identified, properly labeled and marked for safety before research participants with investigational implanted radiology devices (e.g., brachytherapy) are admitted.

5. Hospital personnel at MUSC will follow the guidelines as established by MUSC's Patient Care Manual [Document R.05, "Radiation Therapy: Health and Safety Guidelines for all Patient Care Personnel"] in providing care for research participants with implanted investigational radiology devices.

6. For studies involving investigational radiation devices for diagnostic or therapeutic procedures, MUSC staff will be trained by the PI as to, but not limited to, the proper operation of the investigational radiation device, setup and technique sufficient to permit safe use, discontinuance, storage, removal, and disposal, according to the policy of the MUSC HRPP and all related MUSC policies and procedures.

7. The Health Physics Safety Officer of the MUSC Department of Environmental Health & Safety will survey the equipment to see that it is operating in a safe manner, keep an inventory of the device, and verify that it has been registered with the state Radiological Health Branch of the Department of Health Services. For a device that is also radioactive, SU's Department of Environmental Health & Safety will also verify that it is shielded in a safe manner, perform a safety survey, and verify that the PI is authorized to use the device.

8. This policy does not cover use of investigational radiopharmaceuticals.

E. Adverse Event Reporting

1. The PI who holds an IDE or a device with NSR has responsibilities for reporting adverse events associated with use of an investigational device.

    a) The PI must report any adverse effect to the sponsor, the IRB and the Medical Chief of Staff *within 10 days of discovery*.

    b) The sponsor is required to evaluate the specific adverse event & investigate under a sponsor's monitoring requirements [21 CFR § 812.46(b)].

    c) The sponsor must then report its findings to the FDA, to all participating investigators, and to (all) reviewing IRB committee(s) within 10 working days after the *sponsor* receives notice of the adverse effect.

2. The PI must also follow *all* MUSC reporting policies pertaining to Adverse Event Reporting, and must participate in any investigation and/or quality review, to include (but not limited to) instructions found in the following policies:

    a) "Protection of Evidence Related to an Adverse Event" Policy: Discontinue use, leave settings and disposables in place with the device, sequester and secure the device for further investigation and notify Risk Management.

    b) Follow "Medical Devices Incident Investigation and Reporting (SMDA)" Policy and "Regulatory Agencies Reportable Events" Policy instructions immediately.

3. The PI of a study using an investigational radiology device must also report any adverse event to the MUSC Clinical Radiation Safety Committee, which reports to the MUSC Administrative Panel on Radiological Safety.

F. Custom Devices for Clinical Research – Investigational Device Exemption (IDE)

1. Clinical application of custom and/or investigational devices must satisfy all of the requirements of *FDA 21 CFR part 812, Investigational Device Exemptions.* Custom devices are *exempt* unless the device is being used to determine safety or effectiveness

for commercial distribution [21 CFR §812.2(c)(7)]. A custom device is as follows [21 CFR §812.3(b)]:

a) The device necessarily deviates from devices generally available or from an applicable performance standard or pre-market approval requirement in order to comply with the order of an individual physician.

b) The device is not generally available to, or generally used by, other physicians or dentists.

c) The device is not generally available in finished form for purchase or for dispensing upon prescription.

d) The device is not offered for commercial distribution through labeling or advertising.

e) The device is intended for use by an individual patient named in the order of a physician, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician in the course of professional practice.

2. Custom devices attached to catheters, electrode lead-wires, or any artificial conductive pathway to the heart will be the type of design which uses optical or transformer isolation (or some other equally effective technique) to separate the patient input circuit from the balance of the circuitry of the device. The maximum allowable ground leakage current for the patient connections of such devices shall not exceed 10 microamperes at the patient end of the lead when 120 Volts AC current is applied to the patient leads.

3. If it is an electrical device, an inspection for safety and functionality must be conducted by the Clinical Technology & Biomedical Engineering Department prior to the use of the device as specified in this policy in section VIII (A) and (B).

IV. LEGAL AUTHORITY/REFERENCES

A. CDRH, 21 CFR § 812 and § 814, Investigational Device Exemptions, Center for Devices and Radiological Health, Food and Drug Administration

B. FDA, Department of Health and Human Services (DHHS), as reported in the Federal Register, Volume 62, No. 181, September 18, 1997

C. FD&C Act