



Policy Name: Medical Devices Risk Determination Policy and Procedures			
Approved		Date: 11/01/08	
Effective Date: 12/01/09	Page 1 of 5	Section: HRPP 4.4	Policy Number: N/A
Replaces Policy: Effective 02/20/09			Dated: N/A

I. POLICY

A. Introduction

This guide section details the policies and procedures established at MUSC for evaluating the risk in use of medical devices in human subjects research.

B. Regulations

1. The IRB will determine if an investigational device is a “significant risk” (SR) or a “nonsignificant risk” (NSR).
2. A SR device will have a documented IDE number issued by the FDA before used in human research.
3. Off-label use of a marketed device in human research requires documented FDA review of the proposed use within the context of the research.
4. A protocol using a NSR device may be expedited if it fits the definition of “minimal risk” and fits one of the federally defined categories of research that may be approved by expedited review (21 CFR 56.110).

II. DEFINITIONS

Definitions of the following terms used in this section may be found in HRPP Guide Section 1.3 – Definition of terms

- A. Medical Device
- B. Investigational device
- C. 510K device
- D. Significant Risk Investigational Device
- E. Nonsignificant Risk Device
- F. Medical Device Class

III. PROCEDURES

- A. PI Submission

1. The principal investigator will submit a completed Device Information Sheet D if the research involves a SR investigational device provided by a sponsor; the principal investigator will submit documentation of the IDE number issued by the FDA to the sponsor and a current curriculum vitae.
2. The principal investigator will submit a completed Device Information Sheet D if the research involves a MUSC investigator-sponsored IDE submission. The attachments will include a copy of the IDE application and current curriculum vitae.
3. The principal investigator will submit a completed Device Information Sheet D if the research involves the use of a device approved by the FDA as a 510k device; the FDA letter of approval must be attached and the FDA “class” of the device must be indicated.
4. If the principal investigator is requesting the IRB to determine an investigational device is a NSR, the principal investigator will complete the Device Information Sheet D and attach the following:
 - a) an explanation as to why the device is a NSR including supporting literature evaluating the risks,
 - b) reports of prior investigations of the device if available,
 - c) names of other IRBs which have reviewed the proposed study and what device determination was made, and
 - d) the FDA’s assessment of the device if an assessment was made.

B. IRB Determination

1. During a convened meeting, the IRB will determine if a device fulfills the requirements for an abbreviated IDE in that the device meets the following criteria:
 - a) The device is not a banned device.
 - b) The sponsor labels the device in accordance with 21 CFR 812.5.
 - c) The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval.
 - d) The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject

under the investigator's care, consent under 21 CFR 50 and documents it, unless documentation is waived.

- e) The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations.
 - f) The sponsor maintains the records required under 21 CFR 812.140(b)(4) and (5) and makes the reports required under 21 CFR 812.150(b)(1) through (3) and (5) through (10).
 - g) The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a)(1), (2), (5) and (7).
 - h) The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.
2. During a convened meeting, the IRB will determine if device fulfills the requirements of one of the following 21 CFR 812.2(c) IDE exemption categories:
- a) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
 - b) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under Subpart E of part 807 in determining substantial equivalence.
 - c) A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
 - (1) Is noninvasive.
 - (2) Does not require an invasive sampling procedure that presents significant risk.
 - (3) Does not, by design or intention, introduce energy into a participant.
 - (4) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

- d) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.
 - e) A device intended solely for veterinary use.
 - f) A device shipped solely for research on or with laboratory animals and labeled in accordance with 21 CFR 812.5(c).
 - g) A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.
3. The IRB administrator will process protocols involving an investigational device with a documented IDE number, a documented FDA IDE application or a documented FDA approved 510k designation in the usual manner.
 4. If the principal investigator is requesting the IRB to determine the device is a NSR, the IRB administrator will review the FDA examples of nonsignificant risk and significant risk devices (FDA Information Sheets, Medical devices, 1998 Update). If the device is categorized as a SR device by the FDA, after consulting with the chair, the IRB administrator will inform the principal investigator that an IDE application is required before the IRB review will continue.
 5. If the device is listed by the FDA as a NSR device, this information will be given to the IRB reviewing members for their use as they make the decision if the device is a NSR or an SR within the context of the proposed research protocol.
 6. The IRB administrator will consult with the chair to determine if the expertise to make the determination regarding the risks and benefits of the device compared to the risks and benefits of alternative devices/procedures is available among the Board members or if consultation outside of the IRB members must be sought. IRB members may also request this consultation. The chair will secure outside consultation if needed.
 7. The IRB will discuss the risks to the subjects involving the use of the investigational device within the context of the research including interventions required to implant and/or monitor the device and procedures to mitigate and monitor these risks. The principal investigator may be requested to attend the meeting to discuss risks and plans to decrease and monitor these risks.

8. The Board may determine the investigational device is a NSR device as used in the protocol and approve the study with a continuation application cycle appropriate given the identified risks.
9. The Board may determine that the investigational device is a SR device within the context of the research. The chair will write a letter to the principal investigator copied to the sponsor as applicable giving the Board's rationale for determining the device is a SR device and requesting that the protocol be resubmitted with an approved FDA IDE.
10. The Board's discussion and decision will be documented in the meeting's minutes.

III. REFERENCES

- A. [FDA Guidance: Significant Risk and Nonsignificant Risk Medical Device Studies](#)
- B. [21 CFR 50](#)
- C. [21 CFR 56.110](#)
- D. [21 CFR 809](#)
- E. [21 CFR 812](#)