MUSC
Medical University of South Carolina

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 “non-significant 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. Investigation Device Exemption (IDE)
D. 510K device
E. Significant Risk Investigational Device
F. Non-significant Risk Device
G. Medical Device Class

III. Major Differences between Significant Risk and Nonsignificant Risk Device Studies

A. *Significant Risk (SR) Device Studies*

1. SR device studies must follow all the IDE regulations at 21 CFR 812.

2. SR device studies must have an IDE application approved by FDA before they may proceed.

B. *Non-significant Risk (NSR) Device Studies*

1. NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b).

2. These abbreviated requirements address labeling, IRB approval, informed consent, monitoring, records, reports, and prohibition against promotion. However, there is no need to make progress reports of final reports to FDA.

3. NSR device studies do not have to have an IDE application approved by FDA.

4. Sponsors and IRBs do not have to report the IRB approval of an NSR device study to the FDA. Thus the IRB's NSR determination is important because the IRB serves as the FDA's surrogate for review, approval, and continuing review of the NSR device studies. An NSR device study may start at MUSC as soon as the MSUC IRB reviews and approves the study and without prior approval by the FDA.

IV. Procedures

A. Principal Investigator Submission

1. The Principal Investigator conducting research that involves use of a medical device selects "Investigation of medical device, instrument, machine, computer program or other device, FDA approved or non-FDA approved, including HUD" on the Application Checklist SmartForm page in the IRB application submission.

2. The Principal Investigator will complete the appropriate Device Smartform application pages if the research involves an investigational device provided by a sponsor/investigator sponsor; the Principal Investigator will submit documentation of the IDE number issued by the FDA to the sponsor and a current curriculum vitae. The IRB Administrator will confirm that there is an IDE and the IDE number is valid by review of the required FDA correspondence stating the IDE #.

3. The Principal Investigator will complete the appropriate Device Smartform application pages if the research involves the use of a device approved by the FDA as a 510k device.

4. If the Principal Investigator is requesting the IRB to determine if an investigational device is a NSR, the Principal Investigator will complete the appropriate Device Smartform application page and include 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. The IRB will make the SR or NSR determination for a study by convened meeting. The IRB reviews reports of prior investigations conducted with the device, the proposed investigational plan, a description of subject selection criteria, monitoring procedures, and any other information the IRB deems necessary to make its decision.

2. The IRB is not required to make a SR/NSR determination for studies involving devices that meet the criteria for exemption from the IDE regulations.

3. The IRB may request that the PI consult with the FDA for an opinion as appropriate.

4. If the IRB determines the study is SR, then the IRB notifies the investigator who notifies the sponsor. The sponsor notifies the FDA that the IRB has made an SR determination. The PI may not conduct the study until the FDA approves the sponsor's IDE application.

5. When research is conducted to determine the safety or effectiveness of a device, where the device is not a significant risk device, the IRB staff, the convened IRB, or the reviewer using the expedited procedure determines whether:

   a) The device has an IDE issued by the FDA. The IDE for each device must be supported by one of the following:
      - The sponsor protocol imprinted with the IDE number

- A written communication from the sponsor documenting the IDE number
- A written communication from the FDA documenting the IDE number (required if an investigator listed on this protocol holds the IDE)

OR

b) The device fulfills the requirements for an abbreviated IDE [Criteria in 21 CFR 812.2(b)(1)]

- The device is not a banned device.
- The sponsor labels the device in accordance with 21 CFR 812.5.
- 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.
- 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.
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- 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);
- 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); and
- The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

OR

c) The device fulfills one of the IDE exemption categories [Criteria in 21 CFR 812.2(c)]:

- 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.

- 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.

- 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 subject.

    4) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

- 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 subjects at risk.

- 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.

6. If IRB determines that the study is NSR, there is no requirement for submission of an IDE application to the FDA. The PI conducts the study in accordance with abbreviated IDE requirements.

7. If the FDA has made the SR or NSR determination prior to IRB review, the IRB is not required to make this determination; the FDA's determination is final.

8. The IRB may approve or disapprove the proposed research based on local context and its responsibilities to protect human subjects in research even when approval of the device has been granted by the FDA.

9. IRB staff document the decision of the IRB (both risk determination and approval), including a description of the reason (s) for the Board's decision, in the meeting minutes.

III. References

A. **FDA Guidance: Significant Risk and Non-significant Risk Medical Device Studies**

B. **21 CFR 50**

C. **21 CFR 56.110**

D. **21 CFR 809**

E. **21 CFR 812**