Marshfield Clinic

IRB Review of Investigational Device Research

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Investigational Device

- A medical device that is the subject of a clinical study designed to evaluate the effectiveness and or safety of the device.

2.2. Significant Risk (SR) Device

- A device that presents a potential for serious risk to the health, safety or welfare of a subject and is
  - ◊ An implant or
  - ◊ Is used in supporting or sustaining human life or
  - ◊ Is of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise presents impairment of human health or
  - ◊ Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2.3. Non-significant Risk (NSR) Device

- A device study that does not meet the definition of a significant risk device study. Examples include: daily wear contact lenses, wound dressings, non-implantable electronic incontinence devices, etc. This term should not be confused with the term "minimal risk" to identify certain studies that may be approved through an "expedited review" procedure.

3. PROCEDURE BODY

This document discusses the requirements for IRB review and approval of research involving investigational medical devices.

3.1. Background

a. Clinical investigations of medical devices must comply with the Food and Drug Administration (FDA) Investigational Drug Exemption (IDE) regulations [21 CFR 812] and FDA informed consent and Institutional Review Board regulations [21 CFR parts 50 and 56, respectively].

b. Unless exempt from the IDE regulations, an investigational device must be categorized as either "significant risk" (SR) or "non-significant risk" (NSR). The determination is initially made by the sponsor and submitted either to the FDA (for SR studies) or to an IRB (for NSR studies).

c. SR device studies must be conducted in accordance with the full IDE requirements (21 CFR 812). The FDA may impose restrictions on the study to

ensure that risks to subjects are minimized and do not outweigh the anticipated benefits to the subjects and the importance of the knowledge to be gained.

d. NSR device studies do not require submission of an IDE application to FDA. Instead, the sponsor is required to conduct the study in accordance with the "abbreviated requirements" of the IDE regulations [21 CFR 812.2(b)]. The abbreviated requirements address, among other things, the requirement for IRB approval and informed consent, record keeping, labeling, promotion and study monitoring.

3.2. Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB) will consider approval of studies involving investigational devices only after receiving the sponsor's initial determination of Significant Risk (SR) or Non-Significant Risk (NSR), or documentation of exemption from the IDE regulations (i.e., citation of the exempting regulation). If the sponsor's initial determination is one of SR, an IDE number must be provided to MCRF IRB prior to review. MCRF IRB will then make its own independent determination of risk. The IRB's determination will be based upon the risk level of the proposed use of the device and not the device alone. This determination will be made through the IRB's consideration of information in FDA regulations and guidance and the risk evaluation provided in the IRB application or its attachments.

a. If the sponsor's initial assessment is one of NSR, and the IRB agrees with this assessment and approves the study, the study may begin without submission of an IDE application to FDA.

b. If the IRB disagrees with an initial NSR determination, the review process will be put on hold until the FDA has granted an IDE number and this number has been provided to the IRB.

3.3. Procedures for Review

a. The MCRF IRB Application will ask the Principal Investigator (PI) to disclose whether the proposed protocol includes the use of an investigational device. If so, the application will ask for the sponsor's initial risk determination (SR versus NSR) or documentation that the study is exempt from the IDE regulations (i.e., citation of the exempting regulation).

- If the study is exempt from the IDE regulations, standard IRB review may proceed and minutes from the review must indicate the applicable category of IDE Exemption
- If the sponsor's risk determination is one of SR, the application will ask for the FDA-issued IDE number, and the study will be scheduled for convened IRB review.
- If the sponsor's risk determination is one of NSR, IRB staff will determine whether the study qualifies for expedited review. If not, the study will be scheduled for convened IRB review.

b. Whether reviewed through the convened Board or through expedited review, a risk determination will be made (SR versus NSR).

c. The IRB's risk determination is documented in the IRB minutes, on the reviewer's guide, on the expedited reviewer's form, or in the letter from the IRB to the PI.

d. If the IRB convened or expedited reviewer is in agreement with the initial risk determination made by the sponsor, review using the standard IRB review and approval criteria is initiated.

e. If the sponsor's risk determination is one of NSR and the IRB determines that the study is of SR, further review is tabled.

f. The PI is notified in writing of the IRB's risk determination.

g. The PI must notify the sponsor of the IRB's determination, and the sponsor must file an IDE application with the FDA. If there is no external sponsor, the PI will assume sponsor responsibilities in this area.

h. Standard IRB review resumes after the PI submits the FDA-issued IDE number to the IRB.

4. ADDITIONAL RESOURCES

4.1. References:
- None.

4.2. Supporting documents available:
- None.

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy Library & Handbook - #1669.1 Add "IRB" to title otherwise no changes made.
2.0	
3.0	

6. DOCUMENT PROPERTIES

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