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Approved By: ORI Director	Signature	Date	Date First Effective: 10-15-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 04-30-12

Objective

To describe the procedures for Institutional Review Board (IRB) determinations of Significant Risk (SR) and Non-Significant Risk (NSR) investigational devices and evaluation of investigator plans to control investigational devices as required by the Food and Drug Administration (FDA) Investigational Device Exemption (IDE) Regulations.

GENERAL DESCRIPTION

The sponsor and the IRB categorize the device investigation as either SR or NSR. The sponsor makes the initial determination of risk. The principal investigator (PI) submits the proposed study to a convened IRB for formal determination of the appropriate SR/NSR category.

Unless the study is exempt from Investigational Device Exemption (IDE) requirements, a SR device study must be conducted under an FDA approved IDE and a NSR device study may be conducted under an abbreviated IDE with the IRB acting as surrogate for the FDA. An exemption from the IDE requirement is not an exemption from the requirement for prospective IRB review or informed consent. In the event of any question regarding need for an IDE, the IRB may request that the PI consult FDA and provide documentation of FDA's response.

Each PI using an investigational medical device is responsible for control of the devices received in accordance with regulatory requirements. PIs develop and submit to the IRB a plan for control, storage, and accountability of the device. During review of the research protocol, the IRB evaluates these plans and PI responsibilities to control investigational devices. The investigator is responsible for implementing the plan as approved by the IRB. Post IRB-approval monitoring to evaluate whether the investigator is meeting these responsibilities falls under the Quality Improvement Program (QIP). (See the Quality Improvement Program Directed On-Site Review SOP for details.)

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If a protocol involving a medical device is subject to review under more than one department or agency's regulations, the protocol must meet the requirements of each set of regulations.

Definitions

A *medical device* is defined as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized.

An *investigational device* is a medical device which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.

A *significant risk device study* is a study of a device that presents a potential for serious risk to the health, safety, or welfare of a participant and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

A *nonsignificant risk device study* is one that does not meet the definition for an SR study. A study is considered NSR if it (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; and (4) is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure.

An *Investigational Device Exemption (IDE)* permits a device, which otherwise would be required to comply with a performance standard or to have premarket approval, to be shipped lawfully for the purpose of conducting investigations of that device. An approved IDE exempts a device from specific Food and Drug Administration (FDA) requirements as laid out under 21 CFR 812. An approved IDE means that the IRB (and FDA for SR devices) has approved the sponsor's study application and that the study meets all the requirements under 21 CFR 812.

RESPONSIBILITY

Execution of SOP: IRB Members, Office of Research Integrity (ORI) Staff, FDA, Principal Investigator (PI)/Study Personnel, Study Sponsor

PROCEDURES

Significant vs. Nonsignificant Risk Determination

1. An investigator conducting research that involves collection of safety or efficacy data on a medical device completes the applicable device section of the IRB application.

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2. If the study is being conducted under a valid IDE, the PI includes in the IRB application the IDE number, name of IDE holder/sponsor, and sponsor protocol imprinted with number or written communication from FDA or the sponsor documenting the IDE number.
3. If the study is not being conducted under a valid IDE at time of IRB submission, the PI includes in the IRB application the sponsor's initial assessment of the risk (SR or NSR), and the rationale used in making the risk determination. The PI includes FDA correspondence or documentation if available.
4. The IRB makes its own determination of the risk category (SR or NSR). 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.
5. The IRB may request that the PI consult with the FDA as appropriate. If FDA provides a determination, it is considered final and the IRB does not duplicate the effort.
6. If the IRB determines that a protocol submitted for approval involves a SR device, which has been deemed NSR by the sponsor, the IRB notifies the investigator who notifies the sponsor. The sponsor notifies the FDA that the IRB has made an SR determination.
7. If the IRB determines that a study involves the use of a SR device, the PI must obtain an IDE and IRB approval before the study begins and must conduct the study in accordance with full IDE requirements.
8. If the PI considers a SR device to be exempt from IDE requirements, he/she references the exemption category being claimed and provides documentation from FDA or sufficient justification to support the exemption category.
9. The PI is responsible for consulting FDA to determine if the device meets specific criteria to be exempt from IDE requirements.
10. If the 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.
11. After making the risk determination, the IRB conducts the review of the study using the same criteria it would use in considering approval of any full review application. (See Initial Full Review SOP.) The IRB considers the risks and benefits of the medical device compared to the risks and benefits of alternate devices or procedures as listed in the IRB application.
12. The IRB may approve or disapprove the proposed research based on local context and its responsibilities to protect human subjects in research.

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13. ORI staff document the decision of the IRB (both risk assessment and approval) in correspondence sent to the PI and in the meeting minutes or protocol file depending on the type of review. (See Minutes of IRB Meetings SOP.)
14. In a study of an investigational device in which an unanticipated problem/adverse event to subjects or others occurs, the investigator submits to the sponsor and to the IRB a report of the problem or adverse event occurring during the investigation. (See Unanticipated/Anticipated Problem/Adverse Event Reporting SOP.)

IRB Evaluation of PI's Plan to Control Device

1. During review of the research proposal, the IRB evaluates the information provided by the PI that describes plans for control of the investigational device(s) including policies and procedures for storage, control, dispensing, and accountability.
2. If the IRB determines the PI's plans are inadequate, the IRB may request changes and/or additional information.
3. The QIP Coordinator is responsible for conducting periodic reviews of protocols involving use of an investigational device.
4. The QIP Coordinator provides the IRB with a follow-up evaluation regarding whether the PI is meeting investigator responsibilities for control, storage, and accountability of the device. (See the QIP Directed On-Site Review SOP for details.)

REFERENCES

21 CFR 812.2
21 CFR 56
21 CFR 50
21 CFR 812.66
21 CFR 56.108(a)(1)
21 CFR 812.2(b)
Quality Improvement Program Directed On-Site Review SOP