

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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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: 07-31-09

## **OBJECTIVE**

To describe the procedures for Institutional Review Board (IRB) review of significant risk (SR) and non-significant risk (NSR) investigational device use and the IRB's procedures for evaluating investigator plans to control investigational devices

## **GENERAL DESCRIPTION**

Both the sponsor and the IRB categorize an investigational device as either SR or NSR unless the device is exempt from the Investigational Device Exemption (IDE) regulations. The sponsor makes the initial determination of risk. The principal investigator (PI) submits the proposed study to a convened IRB for SR and NSR studies for formal determination of the appropriate SR/NSR category.

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.) 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.

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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.

A claim that the device is exempt from the IDE requirements of the FDA must reference the exemption category being claimed; it is the sponsor's responsibility to provide sufficient justification to support the exemption category. An exemption from the IDE requirement is not an exemption from the requirement for prospective IRB review or informed consent.

## **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. The PI includes in the IRB application the sponsor's initial assessment of the risk (SR or NSR), FDA correspondence or documentation if available, and the rationale used in making the risk determination.
2. 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.

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3. 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 Research Description in the application.
4. The IRB may request that the PI consult with the FDA for an opinion as appropriate.
5. 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. The PI may conduct the study as an SR investigation following FDA approval of an IDE application.
6. If the FDA 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 IDE requirements.
7. If both the FDA and the IRB determine 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.
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. 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.)
10. In a study of an investigational device in which an unanticipated problem or 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. An investigator conducting research that involves use of an investigational device completes "Form P" and includes it with the IRB application submission.
2. During review of the research proposal, the IRB evaluates the information provided by the PI in "Form P" that describes plans for control of the investigational device(s) including policies and procedures for storage, control, dispensing, and accountability.

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3. If the IRB determines the PI's plans are inadequate, the IRB may request changes and/or additional information.
4. The QIP Coordinator is responsible for conducting periodic reviews of protocols involving use of an investigational device.
5. 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