

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Review of Medical Device Studies: Significant Risk / Nonsignificant Risk Determinations	
Category: IRB Review	

I. Policy Statement

PH IRB will review clinical investigations undertaken to develop safety and effectiveness data for Medical Devices according to the requirements of the Investigational Device Exemptions (IDE) regulations found in [21 CFR 812](#).

Certain research studies of devices may be exempt from IDE regulations (i.e. marketed devices). If the device is not exempt from IDE regulations, the device must be categorized as either “significant risk” (SR) or “nonsignificant risk” (NSR).

FDA considers all SR device studies to present more than minimal risk, and thus, full PH IRB review is necessary. It is the policy of PH IRB that prior to the initiation of any study related activities, all device studies will receive full PH IRB review. Device studies will not be eligible for expedited review.

II. Definition of Terms

Investigational Device Exemption (IDE): An approved IDE permits a device that 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.

Medical Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Investigational Device: A Medical Device which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.

Significant Risk Device: An Investigational Device that:

- (1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

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- (2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- (3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- (4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Nonsignificant Risk Device: An Investigational Device that does not meet the definition for an SR device.

III. Procedure

The Sponsor initially determines the risk category of the device. A proposed SR study is first submitted to FDA for an IDE approval prior to submission to PH IRB for its review and approval. A proposed NSR study may be submitted directly to PH IRB for review.

- A. Investigators desiring PH IRB review of a device study shall submit their proposal using PH IRB Protocol Submission Form.
- B. If FDA has already made the SR or NSR determination for the study, the agency's determination is final. Device studies submitted to PH IRB for review with an approved IDE will be considered SR studies. A copy of the Sponsor's FDA IDE approval letter must be submitted with the Investigator's request for PH IRB review of the study, if available.
- C. If a Sponsor determines the risk category to be NSR, PH IRB must also make a risk category determination. PH IRB may use the following to determine whether a Medical Device is SR or NSR per [21 CFR 812](#):
 - 1. A "Risk Assessment Report" from the Sponsor explaining the device classification; [21 CFR 812.150\(b\)\(10\)](#)
 - 2. FDA 510K clearance;
 - 3. A Pre Market Approval letter, supplement letter or amendment letter from FDA;
 - 4. Use of information from the Protocol, Investigator's Brochure (or package insert) and other risk evaluations presented by the applicant (Sponsor, Investigator, etc.);
 - 5. Reports of prior investigations conducted with the device;
 - 6. Description of subject selection criteria;
 - 7. Description of monitoring procedures;
 - 8. Risk determinations made by other IRBs which may have reviewed the proposed study;
 - 9. Other evaluations presented by the Sponsor;

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10. PH IRB shall also consider the proposed use of the device and the nature of harm that may result from its use in the study. A Medical Device will be considered a SR device if:
- a. The potential harm to subjects could be life threatening;
 - b. Result in permanent disability or impairment of a body function;
 - c. Result in permanent damage to a body part; or
 - d. Could necessitate medical or surgical intervention to preclude permanent impairment to a body function or permanent damage to a body structure.
- D. If PH IRB agrees with the Sponsor's risk determination of NSR, then PH IRB will continue with its review of the study.
- E. If PH IRB does not agree with the Sponsor's determination of NSR, PH IRB shall notify the Investigator in writing, who will then notify the Sponsor, that they must obtain an either IDE or a NSR determination from the FDA prior to PH IRB's review of the study.
- F. Any amendments or correction of deficiencies required by FDA during the IDE process must be submitted for review and approval of PH IRB.
- G. If an IDE application is or has been submitted to FDA, but final approval has not been granted, PH IRB may proceed with the review of the study, but final approval may be granted pending FDA approval and submission of all supporting documentation, at the discretion of PH IRB.
- H. Once the final SR/NSR decision has been rendered by PH IRB (or FDA), PH IRB will make its determination on approval of the study, considering the risks and benefits of the medical device compared to the risks and benefits of alternative devices or procedures.
- I. **Reports:** An Investigator shall prepare and submit the following complete, accurate, and timely reports:
1. **Unanticipated device effects.** Investigators are required to report these events to PH IRB within 10 working days of their receipt of the information. Should PH IRB determine that the information gained in these reports changes the risk assessment, PH IRB can reconsider any NSR decision and / or require the modification of the informed consent to contain the new information.
 2. **Withdrawal of PH IRB approval.** An Investigator shall report to the Sponsor, within 5 working days, a withdrawal of approval by PH IRB of the Investigator's part of an investigation.

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3. **Withdrawal of FDA approval.** A Sponsor/Investigator shall notify PH IRB of any withdrawal of FDA approval of the investigation, and shall do so within 5 working days after receipt of notice of the withdrawal of approval.
 4. **Progress.** An Investigator shall submit progress reports on the investigation to PH IRB at regular intervals, but in no event less often than yearly using the PH IRB Continuing Review Form.
 5. **Deviations from the investigational plan.** An Investigator shall notify PH IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the Sponsor is required for changes in or deviations from a plan. FDA and PH IRB approval is also required if these changes or deviations may affect the scientific soundness of the plan, or the rights, safety, or welfare of human subjects. ([21 CFR 812.35\(a\)](#))
 6. **Informed consent.** If an Investigator uses a device without obtaining informed consent, the Investigator shall report such use to the Sponsor and PH IRB within 5 working days after the use occurs.
 7. **Recall and device disposition.** A Sponsor/Investigator shall notify PH IRB of any request that an Investigator return, repair, or otherwise dispose of any units of a device. Such notice shall occur within 30 working days after the request is made and shall state why the request was made.
 8. **Final report.** An Investigator shall, within 3 months after termination or completion of the investigation or the Investigator's part of the investigation using a SR device, submit a final report to PH IRB using the PH IRB Study Closure Form. In the case of a NSR device, the Sponsor/Investigator shall submit a final report and Study Closure Form to PH IRB within 6 months after termination or completion.
- J. The SR/NSR determination and rationale for the determination by PH IRB shall be documented in the PH IRB meeting minutes along with its study approval or disapproval decision.

IV. References

- A. FDA Investigational Device Exemptions ([21 CFR 812](#))
- B. FDA Information Sheet: "Significant Risk and Nonsignificant Risk Medical Device Studies" located at <http://www.fda.gov/oc/ohrt/irbs/devrisk.pdf>;
- C. FDA Information Sheet: "Frequently Asked Questions About Medical Devices" located at <http://www.fda.gov/oc/ohrt/irbs/irbreview.pdf>

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