

Public Health Division Research Involving Investigational Medical Devices

An investigational device is one which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Research of medical devices must comply with FDA informed consent and IRB regulations, and must be conducted according to FDA regulations: 21 CFR 812. For all research involving investigational medical devices, the Public Health Division and the Public Health IRB (PH IRB) will follow guidance established by the U.S. Food and Drug Administration (FDA) entitled, "Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors – Significant Risk and Nonsignificant Risk Medical Device Studies."

All medical devices are placed into one of three regulatory classes based on the level of control necessary to ensure safety and effectiveness of the device. Classification is based on the risk the device poses to the subject and/or the user:

- Class I > Examples: elastic bandages, exam gloves, and hand-held surgical instruments;
- Class II > Examples: powered wheelchairs, infusion pumps, and surgical drapes; and
- Class III > Examples: replacement heart valves, silicone gel-filled breast implants, and implanted cerebellar stimulators.

All clinical investigations of devices must have an FDA-approved Investigational Device Exemption (IDE) or have been determined to be exempt from the FDA IDE regulations. An IDE is required except when the clinical investigation of an investigational medical device falls into one of the following categories:

- An FDA approved device used or investigated in accordance with the labeled indications;
- A diagnostic device, if the testing is:
 - Non-invasive;
 - Does not require an invasive sampling procedure that presents significant risk;
 - Does not by design or intention introduce energy into a subject; and
 - 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; or
- A custom device, unless the device is being used to determine safety or effectiveness for commercial distribution.

Research that involves devices exempt from IDE regulations must still be reviewed by the PH IRB in accordance with 21 CFR 56.111.

In reviewing research involving a non-exempt investigational device, the PH IRB must make a determination of whether the investigational device is either "significant risk" (SR) or "non-significant risk" (NSR), unless the FDA has already made a risk determination. A SR Device is 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;

2. is professed or represented to be for use 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.

A NSR device is one that does not meet the definition for SR.

The following information will be used by the PH IRB at a convened meeting, in determining whether a device is considered SR or NSR:

- Description of the device;
- Reports of prior investigations conducted with the device;
- Proposed investigational plan;
- Subject selection criteria; and
- Initial risk assessment and rationale made by the sponsor (the PH IRB may agree or disagree with this assessment).

If the PH IRB finds the study to be NSR, a submission of an IDE application to the FDA is not required. The PH IRB may approve the study using the criteria set forth at 21 CFR 56.111. Sponsors must follow requirements set forth at 21 CFR 812.2(b).

If the PH IRB determines the study is SR, the PH IRB will inform the investigator, and where appropriate, the sponsor. The sponsor may not begin the investigation until FDA approves an IDE application and the study and consent form are approved by the PH IRB.

The PH IRB will make a determination of SR or NSR prior to conducting its review under 21 CFR 56.111. The IRB will document its findings of SR or NSR in the IRB meeting minutes.

Applicable Regulations:

21 CFR 812

21 CFR 56