

Guidance - Sponsor-Investigator Research Requirements

(When a Geisinger investigator is the sponsor on a non-significant risk device study)

The information below provides an overview of abbreviated IDE regulations and responsibilities when Geisinger has a Sponsor-Investigator studying nonsignificant devices, regulated by the FDA when there is no industry sponsor.

Definitions

Sponsor-Investigator: Investigator who sponsors and conducts research with a non-significant risk device.

Non-significant Risk (NSR) Device: An investigational device that does not meet the definition of a significant risk device. The FDA considers an NSR device study to have an approved IDE (Investigational Device Exemption) after IRB approval and when the abbreviated FDA requirements at [21 CFR 812.2\(b\)](#) are met.

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; (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.

FDA Requirements

A Sponsor-Investigator assumes all sponsor responsibilities required by the FDA of the sponsor and the investigator, including those related to record keeping and prompt reporting of safety reports to the FDA. The responsibilities on a non-significant risk study include:

- Properly labeling the device
- Obtaining IRB approval, with an IRB determination that study is NSR
- Obtaining informed consent from each participant under the project
- Monitoring the investigation
- Maintenance of accurate, complete and current records relating to the investigation
- Timely submission of reports to the FDA:
 - Unanticipated adverse device effects (10 working days of learning of event)
 - Withdrawal of IRB approval (5 working days of receipt of notice of withdrawal)
 - Recall and device disposition (30 working days after request is made)
- Reporting to the IRB:
 - Progress report (at least annually)

- Final report (within 6 months of completion or termination of investigation)

For further information on the FDA requirements, see [Title 21 Code of Federal Regulations part 812](#), particularly sections:

- [21 CFR 812.2](#) Applicability
- [21 CFR 812.5](#) Labeling of investigational devices
- [21 CFR 812.46](#) Monitoring Investigations
- [21 CFR 812.140](#) Records
- [21 CFR 812.150](#) Reports

IRB Requirements

A sponsor-investigator on a non-significant risk project has the following abbreviated FDA responsibilities in conducting the research and in communicating information to the FDA:

- Proper labeling of the device: The labeling must include the name and address of device manufacturer and **“CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.”**
- Report to the FDA any of the following:
 - (1) evaluations of any unanticipated adverse device effects (within 10 working days of notice of the effect);
 - (2) any withdrawal of IRB approval; or
 - (3) any request for the return, repair or disposal of any units of a device (within 30 days of the request with information for the request).
- IRB determination of nonsignificant risk
- Accurate and complete documentation of the investigation

A condition of initial IRB approval is agreement to comply with the above requirements. To ensure continued compliance with these requirements over the course of the research, the IRB through the Office of Research Compliance (ORC), will conduct an annual compliance review of the study prior to the IRB’s continuing review of the project.