Sponsor-Investigator Research Requirements (when a STANFORD investigator is the sponsor on a non-significant risk device study)

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

ClinicalTrials.gov Requirements

When seeking informed consent for applicable clinical trials, as defined in 42CFR 11.22(b)), and NIH-funded clinical trials, as defined by NIH Policy, the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial

subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

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 Research Compliance Office, will conduct an annual compliance review of the study prior to the IRB's continuing review of the project.