

Definitions

Sponsor-Investigator: An individual who both initiates and actually conducts, alone or with others, an investigation under whose immediate direction the investigational device is administered, dispensed or used.

Investigational New Device: A device permitted by the FDA to be tested in humans, but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

Investigational Device Exemption (IDE): Exemption from certain regulations to allow shipment of an unapproved device for use in a clinical investigation.

Sponsor-Investigator 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 include:

- Selection of research staff qualified by training and experience
- Commitment to personally conduct or supervise the investigation according to the research plan
- Selection of study monitor(s) qualified to monitor the progress of the project
- Maintenance of accurate, complete and current records, including correspondence with the FDA, monitor and IRB, records on shipment and disposition of devices and records of participants' case histories and exposure to the device
- Completion of regulatory filings, including amendments (supplemental applications)
- Timely submission of reports:
 - Unanticipated adverse device effects (10 working days of learning of event)
 - Progress (regular intervals, but no less than annually)
 - Current investigator list (6-month intervals)
 - Recall and device disposition (30 working days after request is made)
 - Final Report (within 30 days 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 812.40 General responsibilities of sponsors
- 21 CFR 812.100 General responsibilities of investigators
- 21 CFR 812.110 Specific responsibilities of investigators
- 21 CFR 812.140 Records
- 21 CFR 812.145 Inspections
- 21 CFR 812.150 Reports

ClinicalTrials.gov Requirements (see [Title 21 CFR 50.25 \(c\)](#))

When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), 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

Prior to approving a protocol that involves a sponsor-investigator, the IRB must be satisfied that the sponsor-investigator is knowledgeable about his/her responsibilities and has adequate policies and procedures in place to comply with the FDA regulatory requirements. The IRB may rely on feedback from the STANFORD entity providing the education in its determination of proficiency, but may also contact or site visit the sponsor-investigator as deemed necessary. An on-site compliance audit, designed to evaluate compliance with the FDA regulatory requirements, will be conducted on at least an annual basis and is a condition of continuing review approval by the IRB.

For background on this requirement, see the [Memorandum from Dr. Ann Arvin](#), Dean of Research.

Procedures (New Protocols)

After submission of a new sponsor-investigator protocol, the Protocol Director and Administrative Contact on a sponsor-investigator project will receive an email from the Research Compliance Office with information on arranging the education session.

The education session will cover the following areas for compliance and understanding:

- Investigational Device Exemption Application (IDE) and FDA correspondence (21 CFR 812.20 and 812.30)
- Plan to amend the IDE as needed (21 CFR 812.35)
- Copy of the investigational plan (21 CFR 812.25 and 812.45)
- Summary of prior investigations (21 CFR 812.27)
- Monitoring procedures (21 CFR 812.46)
- Plan to select qualified investigators and monitors (21 CFR 812.43)
- Investigator's CV and relevant experience (21 CFR 812.43)
- Commitment to personally conduct or supervise the investigation (21 CFR 812.110)
- Involvement of other participating institutions (21 CFR 812.20)
- Review of consent materials and plan to obtain informed consent from each participant (21 CFR 812.2)

Procedures (Continuing Review)

Investigators will be contacted by the Research Compliance Office a few months before the expiration of the protocol to arrange the compliance audit. Follow-up education will be available if needed.

Compliance Audit includes a review the following:

- FDA correspondence (21 CFR 812.20 and 812.30)
- Amendments to the IDE (21 CFR 812.35)
- Current copy of the investigational plan (21 CFR 812.25 and 812.45)
- Records of monitoring and review of the study (21 CFR 812.46)
- Informed Consent Forms and materials associated with informed consent
- Changes to investigators and staff - qualifications of new staff
- Records of staff training (21 CFR 812.45)
- Complete records for each device received (21 CFR 812.140)
- Records of participants' case histories (21 CFR 812.140)
- Documentation of unanticipated adverse events and reporting to the IRB and FDA (21 CFR 812.150)
- Copy of annual progress report to the FDA or plan to write a timely report (21 CFR 812.150)
- Plan for long term record retention (21 CFR 812.140)

Assistance in planning a sponsor-investigator project is available prior to submission of the protocol; Contact Stanford Center for Clinical and Translational Education and Research (Spectrum) at (650) 498-6498 or Cancer Clinical Trial Office (CCTO) at 736-0176, if a cancer study.