Guidance - Sponsor-Investigator Research Requirements
(When a Geisinger investigator holds the IDE)

This guidance provides an overview additional requirements necessary if the Geisinger investigator holds the IDE. Prior to the IRB approving a protocol that involves a sponsor-investigator, the IRB must be satisfied that the sponsor-investigator is knowledgeable about his/her responsibilities with both the IRB and FDA and has adequate policies and procedures in place to comply with the FDA regulatory requirements. This could include how the device is dispensed, stored, and tracked.

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 Clinical Trials.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. 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.

Procedures *(Continuing Review)*

Investigators will be contacted by the Office of Research Compliance (ORC) 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)

The **Office of Clinical Research Support Services (OCRSS)** is a core facility that supports the overarching Geisinger mission to ***enhance quality of life through an integrated health service organization based on a balanced program of patient care, education, research and community service***. OCRSS can provide assistance in planning a sponsor-investigator project is available prior to submission of the protocol. Provide research coordination and participant care services for all types of sponsored studies including Industry, Internally Funded and Grant Based and engages the community in research efforts by providing training for clinical research investigators and staff in the research management process.

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