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

Definitions

Sponsor-Investigator: An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed.

Investigational New Drug (IND): A drug 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.

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 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 adequate records showing the receipt, shipment, or other disposition of the investigational drugs and records of participants' case histories
- Completion of regulatory filings, including submission of amendments, annual and final reports
- Timely submission of reports (adverse events and others)
- Serious, unexpected adverse experience associated with the use of the drug
    - Written reports (no later than 15 days from observation)
    - Telephone or facsimile reports (no later than 7 days from observation if fatal or life-threatening event)
- Any findings from tests in laboratory animals that suggest significant risk for human subjects
- Other reports - Annual report (within 60 days of the anniversary date the IND went into effect)

For further information on the FDA requirements, see Title 21, Code of Federal Regulations, Part 312, particularly sections:
21 CFR 312.57 Recordkeeping and record retention
21 CFR 312.60 General responsibilities of investigators
21 CFR 312.62 Investigator record keeping and record retention
21 CFR 312.64 Investigator 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. 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:

- Amendments to the IND (21 CFR 312.30 and 312.31)
- Safety records reported to the FDA (21 CFR 312.32 and 312.64)
- FDA Annual Report or plan for timely submission of report (21 CFR 312.33)
- Documentation of any unanticipated adverse events and reporting to the IRB and FDA (21 CFR 312.64)
- Changes to investigators and staff; qualifications of new staff (21 CFR 312.53)
- Records of supervision and staff training (21 CFR 312.53 and 312.55)
- Informed Consent Forms (ICF) and materials associated with informed consent (21 CFR 312.66)
- Records of study monitoring (21 CFR 312.56)
- Records of shipping, labeling, dispensing, and disposal of the drug (21 CFR 312.59 and 312.62)
- Records of participant case histories (21 CFR 312.62)
- Plan for long term record retention (21 CFR 312.62)

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.

Contact

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