

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

Stanford University HRPP Guidance	Sponsor-Investigator Research Requirements (When a STANFORD investigator holds the IND)	GUI-3m 2/2
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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:

- Documentation of the IND application and FDA correspondence (21 CFR 312.20)
- Plan to provide critical information/updates to researchers when applicable. (21 CFR 312.55)
- Plan to select, supervise and train personnel on an ongoing basis. (21 CFR 312.53)
- Plan for monitoring of ongoing investigation. (21 CFR 312.56)
- Plan for preparation, disposition and destruction of investigational drug. (21 CFR 312.57, 312.59 and 312.62)
- Plan to comply with reporting obligations. (21 CFR 312.32 and 312.33)
- Plan for accurate drug tracking and record keeping. (21 CFR 312.57)

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:

- 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)

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.