

Definitions

Sponsor-Investigators: Investigators who hold their own IND or IDE. The requirements of Sponsor-Investigators include both those of investigators and those of sponsors.

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. (OHRP IRB Guidebook)

Sponsor-Investigator Requirements

The Sponsor-Investigator assumes all sponsor responsibilities required by the FDA in 21 CFR 312, particularly Subpart D on record keeping and prompt reporting of safety reports to the FDA.

Some key FDA requirements in conducting Sponsor-Investigator research 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 other):
 - Written (Notify the FDA and PIs no later than 15 days from observation)
 - Serious, unexpected adverse experience associated with the use of the drug
 - Any findings from tests in laboratory animals that suggest significant risk for human subjects
 - Telephone or facsimile reports (Notify the FDA no later than 7 days from observation if fatal or life-threatening event)
 - Other reports
 - Safety information should be summarized in annual reports
 - Annual report (within 60 days of the anniversary date the IND went into effect)

Sponsor-Investigator requirements are in [Title 21, Code of Federal Regulations, Part 312](#)

- 21 CFR 312.57 Recordkeeping
- 21 CFR 312.60 General responsibilities of investigators;
- 21 CFR 312.62 Investigator record keeping and record retention;
- 21 CFR 312.64 Investigator Reporting Requirements;
- 21 CFR 312.68 Inspection of investigator's records and reports

IRB Requirements

Enhanced IRB requirements for Sponsor-Investigator research assist researchers to comply with the FDA reporting requirements. These include the successful completion of (1) a brief on-site education session and initial Compliance Review before IRB approval and (2) follow-up review prior to Continuing Review. See the [Memorandum from Dr. Ann Arvin](#), Dean of Research.

IRB approval (initial and at Continuing Review) is contingent on successful completion of both the brief on-site education session and the Compliance Review.

Initial Compliance Review includes review of the following:

- Completed 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 and review 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 & 312.33)
- Plan for accurate tracking and record keeping. (21 CFR 312.32 & 312.57)

Education is available prior to submission of the protocol.

For assistance, contact Stanford/Packard Center for Translational Research in Medicine (SPCTRM) at (650) 498-6498.

After submission of the protocol to the IRB, the Protocol Director will be contacted to arrange the brief on-site education and Compliance Review. The Protocol Director will be notified in writing of the results of the Compliance Review, which will include the anticipated schedule for follow-up.

Follow-up Compliance Review includes review of the following:

- Amendments to the IND (21 CFR 312.30, 312.31)
- Safety records reported to the FDA (21 CFR 312.32, 312.64)
- FDA Annual Report or plan to write a timely 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 312.55, 312.53)
- Informed Consent Forms (ICF) and materials associated with informed consent (21 CFR 312.66)
- Records of monitoring and review of the study (21 CFR 312.53)
- Records of shipping (or compounding), labeling, dispensing, and disposal of the drug (21 CFR 312.59, 312.62)
- Records of participants case histories (21 CFR 312.62)
- Plan for long term record retention (21 CFR 312.62)