SPONSOR-INVESTIGATOR GUIDELINES AND RESPONSIBILITIES

Description

A sponsor-investigator is an individual who both initiates and conducts a clinical investigation. The sponsor-investigator may conduct the research alone or with others. Investigators who conduct studies involving an FDA test article and for which they hold the IND or IDE must abide by the same regulatory requirements as any other sponsor. In other words, the FDA will hold the investigator to the same regulatory requirements as if they were an industry sponsor, regardless of whether the investigator has the same resources.

The sponsor-investigator is held responsible for all sponsor requirements such as annual reporting requirements, labeling requirements, and record keeping requirements. Some questions which may need to be considered are:

1. If a drug is manufactured at the University of Utah, do you (or others) follow Good Manufacturing Practice (GMP)?
2. Have the labs been inspected for compliance with GMP?
3. Do you have monitors for the conduct of the research?
4. Do you (and your co-investigators) maintain Conflict of Interest Disclosures and the FDA 1572 form on all investigators?
5. Should the sponsor functions be outsourced to a Contract Research Organization (CRO) so you are only responsible to abide by the federal requirements for investigators?

The FDA regulatory requirements for sponsors can be found in the Code of Federal Regulations. The following is a list that a sponsor-investigator will need to comply with depending upon the project (e.g., if a study does not involve an investigational device the regulations dealing with devices are not applicable).

Drugs or devices:

- 21 CFR §11 (Electronic records and electronic signature)
- 21 CFR §54 (Financial Disclosure by Clinical Investigators)

Drugs and Biologics:

- 21 CFR §210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, Or Holding of Drugs; General)
- 21 CFR §211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)
- 21 CFR §312 (Investigational New Drug Application)
- 21 CFR §314 (Drugs for Human Use)
- 21 CFR §320 (Bioavailability and Bioequivalence Requirements)
- 21 CFR §330 (Over-The-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded)
- 21 CFR §601 (Biologics Licensing)

Devices:

- 21 CFR §807 (Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices)
- 21 CFR §812 (Investigational Device Exemptions)
- 21 CFR §814 (Premarket Approval of Medical Devices)
- 21 CFR §820 (Quality System Regulation)
- 21 CFR §860 (Medical Device Classification Procedures)

The University of Utah IRB requires that sponsor-investigators submit a monitoring plan or standard operating procedures describing how they will fulfill all the additional requirements of sponsors within their IRB application. The sponsor-investigator is required to provide all supporting documentation from the FDA.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

The University of Utah Clinical Research Support Office Quality Assurance Group (CRSO QA) provides required monitoring support for all investigator-initiated trials (IITs) where a University of Utah Sponsor-Investigator holds an IND/IDE with the FDA. Please see https://ctsi.utah.edu/crso/monitoring-qa for additional information.

Sponsor-investigators must provide documentation of an audit performed by a CRO QA before the initiation of the study to verify the sponsor-investigator meets the sponsor function. The sponsor-investigator will also be held to the requirements declared in the University of Utah Hospitals and Clinics Policy Manual, Medication Management for Investigational Drugs, as applicable.

Pre-IND/IDE audits should be scheduled with the CRSO QA (crsoqa@hsc.utah.edu) as soon as possible.

If a sponsor-investigator out-sources the sponsor functions to a CRO, the sponsor-investigator must provide documentation that sponsor functions will be the responsibility of that CRO.

Sponsor-investigators should also be aware of the International Council for Harmonization (ICH) Guideline for Good Clinical Practice (GCP) E6(R2). THE ICH E6(R2) provides standardization for the conduct of clinical trials. The FDA has adopted ICH E6(R2) as guidance and ICH E6(R3) as draft guidance. Several of the additions require additional oversight for Sponsor-investigators.

The RED 550: Preparation for Investigator-Initiated Drug and Device Studies course provides important information on the workflow, regulations, responsibilities, and resources for these types of trials.

References & Links

Electronic Code of Federal Regulations Title 21 Food and Drugs	*https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl*
Preparation Packet Investigator-Initiated Drug and Device Studies	*https://irb.utah.edu/guidelines/fda-requirements-guidance/prep-initiated-studies/*
Investigator Guidance Series: Investigator Responsibility for Drug Studies	*https://irb.utah.edu/investigator-guidance-series/*
Investigator Guidance Series: Investigator Responsibilities for Device Studies	*https://irb.utah.edu/investigator-guidance-series/*
E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6 (R1)	*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1*