Definitions

As a consequence of increased volume of investigator-initiated clinical research involving drugs and/or devices, there are numerous institutional considerations to ensure that investigators and their research staffs are appropriately equipped to manage all aspects of the regulatory responsibilities and obligations associated with initiating and conducting such research.

Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Sub-investigator" includes any other individual member of that team (21 CFR 321.3).

Sponsor means a person who takes responsibility for and initiates a clinical investigation (21 CFR 312.3). The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation.

Sponsor-Investigator means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed (21 CFR 312.3). The term does not include any person other than an individual. If an academic investigator submits an IND or IDE and is the principal investigator, the investigator is the Sponsor-Investigator and he/she is responsible for regulatory compliance.

Academic investigators sometimes equate the term "Sponsor" with the source of the study funding. In fact, there are two types of sponsors: regulatory sponsor and financial sponsor. A pharmaceutical company is often both, a regulatory and a financial sponsor in one.

- A regulatory sponsor is the person/entity who initiates (writes the protocol) and takes responsibility for a clinical investigation. The regulatory sponsor submits the IND or IDE and is responsible for communications with the FDA.
- A financial sponsor may be a company, a department, a non-profit or a government agency. If a private company pays for the study, and/or is supplying a drug/device for an academic study, but will not be submitting the IND or IDE, the company is not the regulatory sponsor.

Ownership of the study process

<table>
<thead>
<tr>
<th>Who authored the protocol?</th>
<th>Industry Sponsor initiated study</th>
<th>Investigator-initiated study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who authored IND or IDE?</td>
<td>Sponsor</td>
<td>Investigator</td>
</tr>
<tr>
<td>Who is responsible for payment in case of injuries?</td>
<td>Sponsor pays (except when caused by the institution or PI non-compliance, negligence or misconduct)</td>
<td>Institution pays (except for when caused by product defects)</td>
</tr>
<tr>
<td>Who owns data?</td>
<td>Sponsor owns case report forms (CRFs) and other reports; UC owns medical records and patient information</td>
<td>UC owns protocol, documents, research results, data</td>
</tr>
</tbody>
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Who owns intellectual property?
Ownership of inventions invented in the direct performance of a clinical trial is allowed under an exception to policy. The policy exception, in addition to other limitations, requires that the project be an FDA regulated study written by an industry sponsor, fully funded by industry, under a sponsor written protocol that includes the provision of the study material by sponsor. UC owns all inventions and IP.

Who pays for the study costs?
Sponsor

Multiple potential sources of funding (grants, contracts, clinical revenues).

Sponsor-Investigator Responsibilities

Sponsor-Investigator responsibilities under an IND or IDE are covered in:
- 21 CFR Part 312 (for drugs)
- 21 CFR Part 812 (for devices).
- Excellent FDA Guidance "Investigator Responsibilities — Protecting the Rights, Safety and Welfare of Study Subjects"
- ICH E6 (GCP)–Section 4 ([http://ichgcp.net/4-investigator](http://ichgcp.net/4-investigator))

Below is a brief summary of the responsibilities and available resources for Sponsor-Investigators under an IND. Sponsor-investigators carry both Sponsor AND Investigator responsibilities.

**Sponsors** are responsible for:
- Selecting qualified investigators,
- Providing them with the information they need to conduct an investigation properly,
- Ensuring proper monitoring of the investigation(s),
- Ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND,
- Maintaining an effective IND with respect to the investigations,
- And ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects of risks with respect to the drug.

**Investigators** are responsible for:
- Ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations,
- Protecting the rights, safety, and welfare of subjects under the investigator’s care;
- Keeping control of drugs under investigation.
- Obtaining the informed consent of each human subject to whom the drug is administered.

Practical Implementation

Use this helpful checklist (adopted from Partners Healthcare) to ensure that these documents that underscore fulfillment of investigator responsibilities are present on site the Regulatory Binder or other document binders. The checklist is created based on the Sponsor and Investigator responsibilities outlined in the FDA Code of Federal Regulations 21 CFR 312 (drugs/biologics) and 812 (devices).

The purpose of this checklist is to clarify which documents can provide evidence that the Sponsor – Investigator has fulfilled his/her responsibility.

The checklist is divided into the following sections:
- Sponsor responsibilities
- Investigator responsibilities
- Drug/Device responsibilities
- Record Retention
- FDA Inspection
Onsite documents (listed in the right column) correspond to the regulations written in 21 CFR 312 and 812. Depending on the specific study, additional documents may be needed.

Related articles

- Internal Budget in Unified Budget Template (UBT)
- Coverage Analysis
- Investigational Drug Services
- Negotiate Sponsor budget
- Data Safety Monitoring

Understanding FDA Regulatory Requirements for Investigational New Drug Applications for Sponsor-Investigators (M. E. Blair Holbein, PhD, J Inv Medicine (2009), v. 57, n. 6, p. 689-695).