Requirements for Sponsor-Investigators of Investigational New Drugs (INDs)

Purpose

This policy describes the responsibilities and provides guidance for Sponsor-Investigators.

Policy

Individual investigators who hold an Investigational New Drug (IND) assume all the regulatory responsibilities of the sponsor. They are referred to as Sponsor-Investigators.

Sponsor-Investigators must be knowledgeable of the regulatory requirements found in ***21 CFR Part 312*** – Investigational New Drug Application and be familiar with applicable FDA guidance documents.

The IRB requires first-time IND holders (with the exception of Individual Patient Expanded Access INDs) to both participate in an IND/IDE Resource Group (IIRG) meeting and to review their regulatory responsibilities as Sponsor-Investigators with BCH Regulatory Affairs before final approval can be given for the clinical investigation to begin.

Procedure

A Sponsor-Investigator is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. A physician might submit a research IND to propose studying an unapproved drug or biologic, or an approved product for a new indication or in a new patient population.

For additional information on requirements for clinical investigations of drugs, biologics and dietary supplements at BCH please refer to the policy, "Drugs, Biologics, and Dietary Supplements Regulations."

Investigators considering submitting an IND are advised to review information and tools available at the FDA's site ***Investigator-Initiated Investigational New Drug (IND) Applications*** and at the ***BCH Regulatory Resources*** page.

Regulatory Responsibilities

A Sponsor-Investigator is responsible for all requirements as both a sponsor and an investigator. Regulatory responsibilities for investigators and sponsors are detailed in ***Subpart D*** of 21 CFR 312.

Prior to approval of a protocol in which the IND is held by a Sponsor-Investigator, BCH Regulatory Affairs will conduct Sponsor responsibility training with Sponsor-Investigator, and IIRG Meeting will be held.

The following checklist is designed to help Sponsor-Investigators meet their ***Sponsor*** regulatory responsibilities and be ready for an audit.

IND Sponsor Responsibilities Checklist

■ Maintain effective IND

1. Submit IND Application Form 1571 and other required documents to FDA.	21 CFR 312.23
2. Submit annual reports of the progress of the investigation to the FDA	21 CFR 312.56
3. Comply with FDA regulations regarding emergency use.	21 CFR 312.54
4. Review and evaluate the evidence that relates to the safety and effectiveness of the drug as it is obtained from each investigator(s).	21 CFR 312.56
5. Discontinue the study if the investigational drug presents an unreasonable and significant risk to subjects.	21 CFR 312.56

■ Prompt Reporting to FDA and Investigators

6. Keep investigator(s) informed of the safety and effectiveness of the drug.	21 CFR 312.55
7. Notify the FDA, IRB, and the investigator(s) if the study is discontinued.	21 CFR 312.56
8. Send safety reports to the FDA and investigator(s)	21 CFR 312.32

■ Select Qualified Investigators

9. Select qualified investigators based on training and experience.	21 CFR 312.53
10. Obtain FDA Form 1572 from the investigator(s).	21 CFR 312.53
11. Obtain a written statement that the investigator(s) will conduct the study as outlined in the protocol.	21 CFR 312.53
12. Maintain documentation of the financial interests from investigators, for the duration of any covered studies under the IND, plus 1 year following study completion.	21 CFR 312.53
13. Require investigator(s) to meet local IRB requirements.	21 CFR 312.66
14. Terminate investigator'(s) participation when investigator(s) fails to follow protocol.	21 CFR 312.56

■ Monitoring of Investigations

15. Select a monitor to oversee the progress of the investigation.	21 CFR 312.53
16. Monitor the progress of all IND investigations.	21 CFR 312.56

■ Ensure Control and Representation of Investigational Drug

17. Label the investigational drug in accordance with FDA regulations.	21 CFR 312.6
18. Promote and distribute the drug in accordance with FDA regulations.	21 CFR 312.7
19. Ship investigational drugs only to investigator(s) participating in the investigation.	21 CFR 312.53
20. Maintain adequate records that show the receipt, shipment, or other disposition of the investigational drug.	21CFR 312.57
21. Require investigator(s) to store the investigational drug in a secure area.	21 CFR 312.69
22. Require that investigator(s) maintain adequate drug records.	21 CFR 312.62
23. Ensure that investigator(s) return all unused investigational drugs.	21 CFR 312.59
24. Ensure the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals in compliance with the requirements of § 501(a)(2)(B) of the FD&C Act.	21 CFR 201

■ Record Keeping and Documentation

25. Maintain complete and accurate records of payments made to clinical investigator(s).	21 CFR 312.57
26. Require investigator(s) to keep case histories on each individual administered the investigational drug or employed as a control in the investigation.	21 CFR 312.62
27. Collect reports (financial, progress, safety, and final) from investigator(s).	21 CFR 312.64
28. Ensure any electronic data and source documentation for the studies covered under the IND meets the same fundamental elements of data quality expected of paper records.	21 CFR 11

NOTE: Sponsor-investigators are responsible for establishing recordkeeping and retention systems that comply with the requirements in Subpart D – Responsibilities of Sponsors and Investigators. The FDA may inspect sponsor-investigators' records at any time. During these inspections, FDA representatives hold Sponsor-Investigators to the same recordkeeping requirements as corporate or government sponsors. Establishing good recordkeeping systems before the clinical investigation begins will make FDA inspections easier and minimize the likelihood that the inspection will result in issuance of Form FDA 483 citing observations of objectionable practices.

Related Content

BCH Guidance

BCH Regulatory Resources page.

Regulatory Guidance

21 CFR Part 312

Investigator-Initiated Investigational New Drug (IND) Applications

Subpart D of 21 CFR 312.

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