Requirements for Investigators Who are Also Considered Sponsors of Investigational Devices

Policy

- A Sponsor-Investigator is an individual investigator who both initiates and conducts a clinical trial and assumes all the responsibilities of the sponsor.
- A Sponsor-investigator means an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under 21 CFR 812 include those of an investigator and those of a sponsor. Prior to initiating a clinical trial involving a medical device, the Sponsor-Investigator must obtain approval from the IRB (for Non-significant Risk Devices (NSR)) or from both the IRB and the FDA (for Significant Risk Devices (SR)). Specifically, for SR device studies, an IDE application must be submitted to and approved by FDA prior to initiating the study.
- The IRB requires first-time Sponsor-Investigators for Non-Significant Risk Devices or Significant Risk Devices (with the exception of Emergency Use IDEs) to review their responsibilities as sponsor-investigators with a representative from BCH Regulatory Affairs before final IRB approval can be given for the clinical investigation to begin.
- Investigators requiring assistance with the submission of an IDE application to FDA may contact a regulatory affairs specialist at 617-919-2777.
- Investigators considering submitting an IDE are advised to review information and tools available at FDA's site ***Device Advice: Investigational Device Exemptions*** Applications and at the ***BCH Regulatory Resources*** page.

Procedures

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 21 CRR 812.

Prior to approval of a protocol in which the IDE (SR or NSR) is held by a Sponsor-Investigator, BCH Regulatory Affairs will conduct Sponsor responsibility training with the Sponsor-Investigator.

The following checklists are designed to help Sponsor-Investigators meet their ***sponsor*** regulatory responsibilities and be ready for an audit. EQuIP staff is available to assist

investigators with setting up recordkeeping systems and organizing regulatory documents. They can also advise investigators on proper study management and best practices.

The following overview is divided into two sections, Responsibilities of Sponsors for Significant Risk Device Studies and Responsibilities of Sponsors for Nonsignificant Risk Device Studies; and it cites the appropriate FDA regulation for each item. Before referencing the overview, please review the federal regulations (21 CFR 812.3(m)) to determine if the device is a Significant Risk Device or a Non-significant Risk Device.

Responsibilities of Sponsors for Significant Risk Device Studies

If an investigator is also the sponsor for a Significant Risk Device, the following requirements must be met.

☐ Maintain effective IDE

1. Obtain FDA and IRB approval for IDE.	21 CFR 812.42
2. Conduct an evaluation of unanticipated adverse events and terminate the study if necessary.	21 CFR 812.46
3. Resume terminated studies only after receiving approval from the FDA and IRB.	21 CFR 812.46
4. Comply with federal regulations regarding emergency use.	21 CFR 812.47

☐ Prompt Reporting to FDA and Investigators

5. Supply the investigator(s) with copies of the investigational plan and copies of prior device investigations.	21 CFR 812.45
6. Provide required reports to IRB, investigator(s), and FDA in a timely manner.	21 CFR 812.150

☐ Select Qualified Investigators

7. Select investigator(s) with appropriate training and experience.	21 CFR 812.43
8. Create an investigator agreement and obtain a signed copy from each participating investigator that including items specified in FDA regulations	21 812.43

☐ Monitoring of Investigations

9. Select monitors qualified by training and experience to monitor the investigation in accordance with FDA regulations	21 CFR 812.43
10. Ensure that investigator(s) are complying with FDA, IRB, and sponsor requirements.	21 CFR 812.46

☐ Ensure Control and Representation of Investigational Device

11. Ship investigational devices only to qualified investigators.	21 CFR 812.43
12. Label the device in accordance with FDA requirements.	21 CFR 812.5

13. Promote the device in accordance with IRB and FDA requirements.	21 CFR 812.7
14. Ensure the minimum current good manufacturing practice of devices in compliance with 21 CFR 820, Quality System Regulation	21 CFR 820

☐ Record Keeping and Documentation

15. Maintain accurate and complete records in accordance with FDA regulations.	21 CFR 812.140
16. Maintain, complete and accurate records documenting the financial interests (FDA form 3454 or 3455) of all participating clinical investigators, including sponsor payments.	21 CFR 812.43 21 CFR 54
17. Ensure any electronic data and source documentation meets the same fundamental elements of data quality that are expected of paper records	21 CFR 11

Responsibilities of Sponsors with Non-significant Risk Device Studies

If an investigator is also the sponsor for a Non-Significant Risk (NSR) Device, the following requirements must be met.

☐ Maintain effective IDE

1. Obtain IRB approval of the investigation as a Non-significant risk device study and maintain IRB approval during the investigation.	21 CFR 812.2

☐ Monitoring of Investigations

2. Comply with FDA requirements for monitoring the study. (see 8-9 above)	21 CFR 812.46
3. Ensure that each investigator obtains consent for each subject unless the IRB grants a waiver.	21 CFR 812.2
4. Ensure that each investigator maintains accurate and complete records in accordance with FDA regulations and reports the results to the appropriate parties.	21 CFR 812.140 and 21 CFR 812.150

☐ Ensure Control and Representation of Investigational Device

5. Label the device in accordance with FDA requirements.	21 CFR 812.5
6. Ensure the minimum current good manufacturing practice of devices in compliance with 21 CFR 820, Quality System Regulation	21 CFR 820
7. Promote the device in accordance with IRB and FDA requirements.	21 CFR 812.7

☐ Record Keeping and Documentation

8. Ensure that each investigator maintains accurate and complete records in accordance with FDA regulations and reports the results to the appropriate parties.	21 CFR 812.140 and 21 CFR 812.150
9. Create an investigators agreement and obtain a signed copy from all participating clinical investigator(s), including complete and accurate records documenting the financial interests (FDA form 3454 or 3455).	21 CFR 812.43 21 CFR 54
10. Ensure any electronic data and source documentation meets the same fundamental elements of data quality that are expected of paper records	21 CFR 11

Related Content

Document Attributes

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