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Owner	Susan Kornetsky: Manager
Department	Research
Applicability	Boston Children's Hospital- Policies & Procedures

Requirements for Sponsor-Investigators of Investigational Devices (IDEs) Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Definitions

Sponsor-Investigator: 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.

Policy Statements

This policy outlines the responsibilities and provides guidance for investigators who are sponsor-investigators conducting a clinical trial who assume all the responsibilities of the sponsor for IDEs.

The obligations of a **sponsor-investigator** under U.S. Food & Drug Administration (FDA) 21 CFR 812 include those of an investigator and those of a sponsor.

Non-Significant Risk Devices: Prior to initiating a clinical trial involving a medical device, the Sponsor-Investigator must obtain approval from the Institutional Review Board (IRB).

Significant Risk Devices: Prior to initiating a clinical trial involving a medical device, the Sponsor-Investigator must submit and receive approval from both, the FDA and the IRB before initiating the study.

Prior to IRB approval of a protocol, any BCH staff member serving as Sponsor-Investigator for Non-Significant Risk Devices and Significant Risk Devices (with the exception of devices used under expanded access) must meet with Boston Children's Hospital's Regulatory and Education Program to:

1. Review the responsibilities of a Sponsor-Investigator of SR device or abbreviated responsibilities of NSR device.
2. Discuss study feasibility in context of available BCH resources and services.

Procedures

Investigators considering submitting an IDE are advised to review information and tools available at:

1. FDA's website: ***Device Advice Comprehensive Regulatory Assistance***
2. CRO Regulatory & Education Program: Regulatory Support

IDE Sponsor Responsibilities Checklists

The following checklists are designed to help Sponsor-Investigators meet their sponsor regulatory responsibilities and be ready for an audit. They cite the appropriate FDA regulation for each item.

The following overview is divided into two sections:

1. Responsibilities of Sponsors for Significant Risk Device Studies
2. Responsibilities of Sponsors for Nonsignificant Risk Device Studies

Before referencing the overview, please review the federal regulations (21 CFR 812.3(m)) to determine if the study is a Significant Risk Device study or a Non-significant Risk Device study.

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

5. Submit annual progress reports to the FDA.	21 CFR 812.150
6. Submit supplements (i.e. protocol amendments) to the FDA.	21 CFR 812.35

☐ **Prompt Reporting to FDA and Investigators**

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

☐ **Select Qualified Investigators**

9. Select investigator(s) with appropriate training and experience.	21 CFR 812.43
10. 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**

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

☐ **Ensure Control and Representation of Investigational Device**

13. Ship investigational devices only to qualified investigators.	21 CFR 812.43
14. Label the device in accordance with FDA requirements.	21 CFR 812.5
15. Promote the device in accordance with IRB and FDA requirements.	21 CFR 812.7
16. 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**

17. Maintain accurate and complete records in accordance with FDA regulations.	21 CFR 812.140
18. 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
19. 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. 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

- U.S. Food & Drug Administration CFR – Code of Federal Regulations
    - 21 CFR.812: Investigational New Device Exemptions
- U.S. Food & Drug Administration Guidance

    - ***Device Advice Comprehensive Regulatory Assistance***
    - ***Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Medical Device Studies***
    - ***Sponsor's Responsibilities for Significant Risk Device Investigations (November 1995)***
- Boston Children's Hospital Guidance
    - CRO Regulatory & Education Program: Regulatory Support

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	2/2/2025
Committee Chair(s)	Susan Kornetsky: Manager	2/1/2025
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Applicability

Boston Children's Hospital- Policies & Procedures