

Status **Active** PolicyStat ID **17505861**



**Boston  
Children's  
Hospital**

Where the world comes for answers

Effective 3/1/2025  
Next Review 2/29/2028

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

## Requirements for Sponsor-Investigators of Investigational New Drugs (INDs) 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 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. The requirements applicable to a sponsor-investigator includes both those applicable to an Investigator and a Sponsor.

### 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 INDs.

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 the U.S. Food & Drug Administration (FDA) 21 CFR Part 312 Subpart D: Responsibilities of Sponsors and Investigators

and be familiar with and review the applicable FDA guidance documents.

Before approving a protocol, the Institutional Review Board (IRB) requires that any Boston Children's Hospital (BCH) staff member holding an Investigational New Drug (IND) application—either as the Sponsor or Sponsor-Investigator (excluding Individual Patient Expanded Access)—must meet with the BCH Regulatory and Education Program to:

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

## Procedures

Sponsor-investigators are responsible for establishing recordkeeping and retention systems that comply with the requirements in 21 CFR 312 Subpart D: Responsibilities of Sponsors and Investigators.

1. The FDA may inspect sponsor-investigators' records at any time.
  - a. During these inspections, FDA representatives hold Sponsor-Investigators to the same recordkeeping requirements as corporate or government sponsors.
  - b. 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
2. 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. Submit amendments (New Protocol, Change in Protocol, New Investigator) to the FDA	21 CFR 312.30
4. Comply with FDA regulations regarding emergency use.	21 CFR 312.54
5. 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
6. 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

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

9. Send safety reports to the FDA and investigator(s)	21 CFR 312.32
---	---------------

**Select Qualified Investigators**

10. Select qualified investigators based on training and experience.	21 CFR 312.53
11. Obtain FDA Form 1572 from the investigator(s).	21 CFR 312.53
12. Obtain a written statement that the investigator(s) will conduct the study as outlined in the protocol.	21 CFR 312.53
13. 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
14. Require investigator(s) to meet local IRB requirements.	21 CFR 312.66
15. Terminate investigator(s) participation when investigator(s) fails to follow protocol.	21 CFR 312.56

**Monitoring of Investigations**

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

**Ensure Control and Representation of Investigational Drug**

18. Label the investigational drug in accordance with FDA regulations.	21 CFR 312.6
19. Promote and distribute the drug in accordance with FDA regulations.	21 CFR 312.7
20. Ship investigational drugs only to investigator(s) participating in the investigation.	21 CFR 312.53
21. Maintain adequate records that show the receipt, shipment, or other disposition of the investigational drug.	21 CFR 312.57
22. Require investigator(s) to store the investigational drug in a secure area.	21 CFR 312.69
23. Require that investigator(s) maintain adequate drug records.	21 CFR 312.62
24. Ensure that investigator(s) return all unused investigational drugs.	21 CFR 312.59
25. 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**

26. Maintain complete and accurate records of payments made to clinical	21 CFR
---	--------

investigator(s).	312.57
27. 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
28. Collect reports (financial, progress, safety, and final) from investigator(s).	21 CFR 312.64
29. 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

## Related Content

- U.S. Food & Drug Administration CFR – Code of Federal Regulations
  - 21 CFR.312: Investigational New Drug Application
  - 21 CFR.312 Subpart D: Responsibilities of Sponsors and Investigators
- U.S. Food & Drug Administration Guidance
  - [Investigator-Initiated Investigational New Drug \(IND\) Applications](#)
- IRB Policy
  - Drugs, Biologics, and Dietary Supplements
- Boston Children's Hospital Resources
  - [CRO Regulatory & Education Program: Regulatory Support](#)

COPY

## 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
Contributor(s)	Susan Kornetsky: Manager	2/1/2025
Document Owner	Susan Kornetsky: Manager	2/1/2025

---

## Applicability

Boston Children's Hospital- Policies & Procedures

COPY