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**Boston
Children's
Hospital**

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Effective 9/1/2022
Next Review 1/1/2026

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

Verification of No Material Changes Since Prior IRB Review Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This guidance outlines the procedure for determining those research protocols that require verification from other sources other than the investigator, that no material changes have occurred since prior IRB review.

Policy Statements

Boston Children's Hospital complies with all applicable local, state, and federal regulations in the conduct of clinical research studies.

The Boston Children's Hospital Institutional Review Board (IRB), or other agents designated by the IRB, may determine at any time point during the period of approval for a particular protocol, that the protocol requires verification from sources other than the investigator, that no material changes have occurred since prior IRB review.

Procedures

What are some common sources for verification?

The nature of the study will determine the source from which verification is to be requested. The following are examples of the most common sources from which verification might be requested:

- Pharmacy distribution records
- Data Safety Monitoring Boards
- Sponsors
- Grant applications
- Research subject records
- Hospital medical records
- Investigative subcommittees
- Quality Improvement records

Requests: Who and Why?

A request for verification that no material changes have occurred since prior IRB review may be made by any of the following committees or individuals, at any time for any of the following reasons.

1. Who?
 - a. Institutional Official
 - b. IRB Chair
 - c. IRB member
 - d. IRB administrative staff
 - e. Investigative subcommittee
 - f. Independent audit team
2. Why?
 - a. If a potential incident of noncompliance or concern is raised.
 - b. Based upon information provided in the continuing review.



Approval Signatures

Step Description	Approver	Date
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