

Institutional Review Board (IRB) Policies & Procedures Manual



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Verification of No Material Changes Since Prior IRB Review

Purpose

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

Policy

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.

Procedure

Common Sources

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, for any of the following reasons:

1. By the Institutional Official, the IRB Chair, an IRB member, or IRB administrative staff at any time or if a potential incident of noncompliance or concern is raised.
2. By the IRB, based upon information provided in the Continuing Review form.
4. By an investigative subcommittee or independent audit team.

Related Content

None Identified

Document Attributes

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