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**Boston
Children's
Hospital**

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Effective 3/1/2025
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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 Administration

EVP, Chief Scientific Officer

Scope

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

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.

This policy 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.

The reason that a verification has been requested and the nature of the study will determine the method and source of any verification is required. A request for verification that no material changes have occurred since prior IRB review may be prompted by a potential incident of noncompliance, a concern is raised to the IRB, information provided during a continuing review, not for cause audits, or other quality

improvement initiatives.

Procedure

Individuals who may request verification include: the Institutional Official, IRB Chair, IRB member, IRB administrative staff, and Investigative subcommittee, or an independent audit team.

The following are examples of the most common sources from which verification may be requested:

- Pharmacy distribution records
- Data Safety Monitoring Boards
- Materials submitted to Sponsors
- Grant applications and clinical trial agreements
- Research subject records
- Hospital medical records
- Regulatory Binders
- Quality Improvement records

The Senior Director of the IRB and IRB Chair will determine the best process to verify from sources other than the investigator, that no material changes have occurred since prior IRB review.

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 | 1/17/2025 |
| Committee Chair(s) | Susan Kornetsky: Manager | 1/17/2025 |
| Contributor(s) | Susan Kornetsky: Manager | 1/17/2025 |
| Document Owner | Susan Kornetsky: Manager | 1/17/2025 |

Applicability

Boston Children's Hospital- Policies & Procedures