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**Boston
Children's
Hospital**

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

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

Institutional Official: Selection and Responsibilities 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

This policy establishes the method by which the Institutional Official is selected and outlines the major responsibilities of the position.

Boston Children's Hospital assigns responsibility for the Human Research Protection Program (HRPP) to an official with the appropriate authority to ensure the implementation and maintenance of a program of excellence.

Procedures

Selection

The Chief Executive Officer of Boston Children's Hospital is responsible for selecting the Institutional Official.

Responsibilities

The responsibilities of the Institutional Official are as follows:

1. Assuming on behalf of the institution the obligations of the federal assurance of compliance for the protection of human subjects.
2. Implementing the obligations of an institutional official, within the scope of applicable regulations and accreditation standards.
3. Setting the "tone" for an institutional culture of respect for human subjects by effectively communicating the importance of human subject protections.
4. And demonstrating an ongoing strong commitment to human subject protections at Boston Children's Hospital.
5. Possessing a thorough knowledge of human subject regulations.
6. Serving as a point of contact for the Office of Human Research Protections (OHRP).
7. Meeting periodically with the Chair of the Institutional Review Board (IRB) and the Senior Director of Clinical Research Compliance.
8. Providing the IRB and the Education and Quality Improvement Program (EQulP) with the necessary resources and staff.
9. Supporting the implementation of IRB decisions.
10. Ensuring effective, institution-wide communication of and access to human subject information.
11. Encouraging participation in human subject educational activities.
12. Communicating with and advising other senior management representatives, the Chief Operating Officer, and the Chief Executive Officer on human subject protection issues as they pertain to Boston Children's Hospital.

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/26/2025
Steering Committee	Dwight Mayfield	2/26/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025

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Applicability

Boston Children's Hospital- Policies & Procedures

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