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

Education and Training: IRB Administrative Staff, IRB Members, and Others 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 describes the current and future activities developed to provide the necessary education to the Boston Children's Hospital research community.

Boston Children's Hospital recognizes the importance of having a strong comprehensive educational program that ensures any individual involved in the performance of human subject research at the Hospital understands the ethical principles and regulatory requirements related to the protection of human subjects.

Boston Children's Hospital policy requires all individuals who are involved either in the performance of clinical research or the oversight of clinical research to be trained in human research protection issues. The educational program tailors training to the specific needs of those involved in clinical research at multiple levels. The type and amount of training required is contingent upon the individual's role in the performance and oversight of the research.

Procedures

Institutional Official

The Senior Director of Clinical Research Compliance reports directly to the Senior Vice President of Research Administration who serves as the Institutional Official. The Institutional Official maintains copies of all pertinent federal regulations and institutional policies and procedures and receives IRB minutes. The Senior Director of Clinical Research Compliance meets with the Institutional Official on an ongoing basis. The Institutional Official is kept apprised of new regulations, mandates, and changes in federal policy.

IRB Members and IRB Chair

1. **Orientation:** Newly appointed IRB members are required to attend an individualized comprehensive orientation with the Director of Clinical Research Compliance or designated Senior IRB administrative staff or Education and Quality Improvement (EQuIP) staff.
    a. At this orientation the history of human subject protections, ethical principles, pertinent federal regulations, and specific institutional policies and practices are discussed.
    b. Each member is provided with a copy of the Belmont report, 45 CFR 46, Food and Drug Administration regulations, institutional policies and procedures, a list of resources that includes pertinent web sites, and any other material that is deemed necessary at that time.
    c. In addition, they are trained on the electronic protocol system, CHeRP.
2. **Observing IRB Meetings:** Each newly selected IRB member is required to attend at least one IRB meeting as an observer before undertaking the review of research protocols.
    a. Newly selected members are also encouraged to seek the assistance of other or outgoing members as they begin to review protocols.
    b. Members are encouraged to contact the Senior Director or Director of Clinical Research Compliance whenever specific issues or questions arise.
3. **Additional Training:** Each IRB member is provided with a copy of several resource books which include the IRB Member book and the Institute of Medicine report on research Involving Children.
4. **Collaborative Institutional Training Initiative (CITI):** All IRB members must complete the CITI web-based training.
5. **Ongoing and Continuing Education:** All IRB members regularly receive relevant articles and materials as part of their ongoing education.
    a. Articles and publications are provided with the protocols that are distributed.
    b. The IRB strives to offer 30 minutes of in person trainings on relevant topics prior to an IRB meeting several times a year. In addition, a portion of each meeting may be dedicated to the discussion of new and relevant training information. Training

sessions are recorded so that members who cannot attend have the opportunity to view the training at a later date.

c. When necessary, the IRB seeks outside assistance and expert advice on new procedures that raise unexpected ethical concerns.

d. IRB members are offered the opportunity to attend the PRIM&R national meeting as well.

IRB Administrative Staff

All staff involved with the IRB report either to the Senior Director of Clinical Research Compliance, the Director of Clinical Research Compliance, or to the IRB Operations Manager, who are responsible for their education, training, and performance.

1. Each newly hired IRB staff member receives intensive individualized training from the Senior Director of Clinical Research Compliance, the Director of Clinical Research Compliance, or the IRB Operations Manager.
2. Each new staff member receives the materials mentioned below and are trained on the electronic protocol system. Some of the materials all new staff members are required to review include:
    a. CITI web-based training
    b. Belmont Report
    c. 2018 Common Rule
    d. HHS FAQ on Children
    e. Boston Children's Hospital IRB Policies
    f. Multiple sections of the OHRP website
    g. PRIM&R educational opportunities as resources permit (e.g., IRB 101 course, PRIM&R/ARENA meetings, webinars and other appropriate regional workshops)
3. In addition, IRB administrative staff are urged to take the CIP (Council for the Certification of IRB Professionals) certification exam once they have had enough experience.
4. Staff are also informed and invited to attention local educational offerings.

Other Research Administrative Staff and Ancillary Reviewers

On an as needed basis, individual seminars and "in services" are held by the Senior Director and Director of Clinical Research Compliance for members of the Office of Sponsored Programs (OSP), the Clinical Trials Business Office (CTBO), the Technology Development Office (TIDO), and any other group or individual participating as an ancillary reviewer.

The "in services" review the responsibilities of these departments in the institution's human subject protection program, and in assuring compliance with federal regulations.

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
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Document Owner	Susan Kornetsky: Manager	1/17/2025

Applicability

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