Education and Training: Administrative Staff, IRB Members and Others

Policy

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 type and amount of training required is contingent upon the individual's role in the performance and oversight of the research.

Purpose

Boston Children's Hospital recognizes the importance of having a strong, comprehensive educational program that ensures that any individual involved in the performance of human subject experimentation at the Hospital understands the ethical principles and regulatory requirements related to the protection of human subjects. The Boston Children's Hospital educational program tailors training to the specific needs of those involved in clinical research at multiple levels. The following information describes the current and future activities developed to provide the necessary education.

Procedure

Medical Staff Executive Committee

The Institutional Review Board (IRB) is a standing committee of the Medical Staff Executive Committee (MSEC). The MSEC is comprised of all of the Chiefs of service, as well as the President and other senior management representatives. The Chair, the Director of Clinical Research Compliance, and the Institutional Official report to the MSEC as necessary to inform them of issues specific to the human research protection program. One purpose of presenting to the Medical Staff Executive Committee members is to educate them about new federal regulations, IRB initiatives, and policy changes that affect the human subject protections program at Boston Children's Hospital. This occurs, as necessary and as requested by the IRB chair or at the request of the Medical Staff Executive Committee.

Institutional Official

The Director of Clinical Research Compliance reports directly to the 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. The Director of Clinical Research Compliance meets with the Institutional Official as part of the Directors meeting and on an as needed basis. The Institutional Official is kept apprised of new regulations, mandates and changes in federal policy.

IRB Members and Chair

Orientation

Newly appointed IRB members are required to attend an individualized, comprehensive orientation with the Director of Clinical Research Compliance or designated senior IRB / Education and Quality Improvement (EQuIP) staff. At this orientation the history of human subject protections, ethical principles, pertinent federal regulations, and specific institutional policies and practices are discussed. 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. Members are made aware of a human subject library, which is a collection of books and journal articles that pertain to human subject experimentation. The Director of Clinical Research Compliance maintains this library. In addition they are trained on the electronic protocol system.

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. Newly selected members are also encouraged to seek the assistance of other or outgoing members as they begin to review protocols. Members are encouraged to contact the Assistant Director or Director of Clinical Research Compliance whenever specific issues or questions arise.

Additional Training

- Each IRB member is provided with a copy of several resource books which include the Amdur IRB member book and the Institute of Medicine report on research Involving Children.
- All IRB members must complete the CITI web-based training.

Ongoing and Continuing Education

All IRB members regularly receive relevant articles and materials as part of their ongoing education. Articles and publications are provided with the protocols that are distributed every other week. Bibliographies of articles pertinent to human subject protections are also distributed on a regular basis. A portion of each meeting may be dedicated to the discussion of new and relevant training information. When necessary, the IRB seeks outside assistance and expert advice on new procedures that raise unexpected ethical concerns. IRB members are offered the opportunity to attend the PRIMR national meeting as well.

IRB Administrative Staff

All staff involved with the IRB report either to the Assistant Director or the Director of Clinical Research Compliance, who is responsible for their education, training, and performance. Each newly hired IRB staff member receives intensive, individualized training from the Assistant Director of Clinical Research Compliance. Each new staff member also receives the materials mentioned above and are trained on the electronic protocol system. All new staff members are required to complete the CITI web-based training. All newly hired staff members are required to take the PRIMR IRB 101 course and the Administrator 101 course, and to attend PRIMR/ARENA meetings and other appropriate regional workshops as resources permit. In addition, the administrative staff of the IRB are urged to take the CIP (Council for the Certification of IRB Professionals) certification exam once they have had sufficient experience. They are also informed and invited to attention local educational offerings.

Other Research Administration Staff and Ancillary Reviewers

On an as needed basis, individual seminars and "in services" are held by the Director and Assistant Director of Clinical Research Compliance for members of the Office of Sponsored Programs, the Clinical Trials Business Office, the Technology Development Office, 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.

Document Attributes

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Reviewed/ Revised by	Susan Kornetsky		
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Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		