Education and Training: Investigators and Research Staff

Policy

- Boston Children's Hospital policy requires all individuals who are involved in the performance of clinical research to be trained in human research protection issues prior to their involvement in human subject research.
- The type and amount of training required is contingent upon the individual's role in the performance of the research.
- Boston Children's Hospital requires evidence of continuing education every three years.

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 activities developed to provide the necessary initial and continuing education.

Procedure

General Training

Boston Children's Hospital requires all individuals who conduct human subject research to be appropriately trained prior to conducting human subject research. In addition continuing education is required every three years. Because investigators and their staff assume different roles and responsibilities in the conduct of human subject research, Boston Children's Hospital has developed training requirements that take into consideration the different roles assumed in the research project. Investigators are asked, on a per protocol basis, to list the individuals who work on the research protocol. The Institutional Review Board (IRB) has determined that the type and amount of training required depends on whether or not there is actual intervention or interaction with the subject.

As part of their review to determine whether appropriate initial and continuing training has taken place, the IRB and the IRB administrative staff will review each subject listed on the protocol and his or her role in the project. If an investigator has not completed initial or the required continuing education training, the protocol/continuing review will not be approved. If a staff member listed on the protocol has not completed training, he or she will be informed of this as part of the IRB review and report of action. The staff member must complete the training in order to remain on the protocol, or his or her name will be removed

from the protocol at the time of protocol approval. If a name is removed it may be added in the form of an amendment at a later date, after training is completed.

All IRB-required training activities are tracked in the Children's Hospital e-Research Portal (CHeRP) electronic system using each individual's user profile. The Collaborative IRB Training Initiative (CITI) website provides reports of course completions which are periodically downloaded and merged into CHeRP, where employee and affiliate learner profiles are updated using the unique Children's ID numbers that learners provide to the CITI site upon registration. IRB staff update users' profiles when other qualifying educational activities are completed or when documentation of qualifying activities are provided to the office. Through CHeRP, investigators are able to access the training activities they or their colleagues have completed and print out a certificate, as necessary.

Staff/Personnel Who Intervene/Interact with Research Subjects

Any individual listed as a **principal investigator** (PI) on a research protocol that involves any intervention or interaction with research subjects, must complete the Boston Children's Hospital version of the CITI training regardless of whether or not they have completed training programs at other institutions. Exceptions are made on a case-by-case basis only. This is a requirement regardless of whether or not the PI actually performs the research procedures. A PI has ultimate responsibility for compliance with human subject protections and, therefore, must complete this more intensive training. There are two different module tracks, biomedical and behavioral/social science. Investigators may choose either track.

Any **other individual (e.g., co-investigator, research nurse) listed on a Boston Children's Hospital protocol** who intervenes or interacts (including obtaining informed consent) with a research subject who is at the Hospital (inpatient, outpatient, satellite facility, Martha Elliott) is required to complete the web-based CITI training program. If the individual has completed training at one of the Harvard- based institutions, the IRB will accept that training as long as he or she has evidence of completion.

Any individual listed on a Boston Children's Hospital protocol who intervenes or interacts with a research subject (including but not limited to obtaining informed consent) at an offsite location but under the primary auspices of the Hospital, is required to complete the CITI training or have evidence of completed training at another institutions (e.g., schools, community health settings). If a research project has recognized subcontracts or collaborator arrangements, and the subcontractors or collaborators are involved with human subjects at an offsite location or another institution, personnel may either complete the CITI tutorial or provide evidence of completion of human subject training from another institution.

Specialized training may be offered to research staff associated with the community when community based participatory research is being conducted. Human subject training may be individualized to meet the needs of the community members who are included as research personnel under the auspices of Boston Children's Hospital. The Director of Clinical Research Compliance will work with the principal investigator to determine the most appropriate training to be provided and the method of delivering any education. Examples may include other types of web-based training or actual in person training. Culture, language and the role of the community will be considered.

Staff/Personnel Who Do Not Intervene/Interact with Research Subjects

Individuals whose work on human subject research protocols is limited to the following:

- Chart/medical record review
- Discarded biological specimens
- Database inquires
- Data analysis or statistical support

must complete a reduced number of CITI modules. If at any time the research role changes to include intervention or interaction with subjects, an individual must complete the full CITI training course. If personnel listed on a protocol perform the activities listed above at other institutions or locations but are listed as personnel on the Boston Children's Hospital research protocol, they may either complete the CITI modules or provide evidence of completion of human subject training from another institution.

New Principal Investigator Orientation

Any new principle investigator for any protocol that intervenes or interacts with research subjects is required to attend a brief PI orientation with a member of the EQuIP staff. A new PI is defined as this is their first protocol application or they are new to the institution and are submitting their first application. The purpose of this orientation is to provide an overview of PI responsibilities and to provide additional resources such as a regulatory binder. Approval of a protocol that is submitted by a new PI, will not be released until this orientation is complete.

Continuing Education

All investigators and associated research staff that are listed on a human subject protocol application will be required to complete continuing education every three years. This includes principal investigators, research nurses, coordinators, co-investigators, research staff and individuals listed as authorized to administer investigational drugs. Continuing education may be accomplished in a variety of ways. The methods for completing continuing education are the same for those who both intervene and interact with human subjects and those who do not. The following are ways to obtain credit for continuing education

CITI Refresher

The web based training application used by Boston Children's Hospital (CITI, University of Miami) has developed refresher modules for continuing education.

Attendance at lectures and seminars

Many individuals attend local institutional presentations on topics related to human subject protection. This will also satisfy the continuing education requirement. The Institutional Review Board and EQuIP offices often provide lectures, seminars, and round table discussions. If an event requests "sign in attendance", your registration will be entered into our training database. The seminar /lecture/presentation must be recognized by the Institutional Review Board office in order to satisfy continuing education requirements. The following list represents the currently recognized activities. A further description of these activities is included below

a. Introduction to Clinical Research Course for Junior Faculty, Fellows, Nurse Investigators (sponsored by CRC/CRP)
b. Research Coordinators Rounds at which human subject protection issues are discussed
c. Human subject related presentations at department/division faculty meetings organized by IRB. Department Chairs and Division Chiefs may request a specialized educational activity for their faculty at any time.
d. Human subject case presentations organized by IRB to faculty/staff groups.

e. Completion of continuing education requirements at another Harvard affiliated institution.

f. Other activities designated by the Director of Clinical Research Compliance to meet continuing education requirements.

Education and Quality Improvement Program (EQuIP) Reviews:

Any investigator who undergoes an EQuIP review will receive automatic continuing education credit. In addition, any research staff listed on the protocol who attends the initial and exit interviews will also receive credit.

Ongoing Educational Initiatives at Boston Children's Hospital

Introduction to Clinical Research Course

The Clincal Research Center (CRC), independent of but working closely with the IRB, provides a week long intensive course for fellows entitled, "An Introduction to Clinical Research." This course exposes new investigators to the concepts and practices of clinical research, including study design, clinical trials, biostatistics, research ethics, data management, and grant writing. The target audience includes junior faculty, fellows, nurse investigators, and any others who may develop and write their own research protocols. This course is offered twice a year and is limited to 50 students per offering. The Director of Clinical Research Compliance serves as faculty for this course.

New Study Coordinator Orientation

The CRC offers a monthly one day Orientation for all new study coordinators and research assistants. The Orientation covers many topics that are relevant to conducting clinical research at Boston Children's Hospital Boston including human research protection issues:

Coordinator Rounds: The CRC organizes Coordinator rounds that are held once a month and open to the research community. Various topics that are pertinent to research coordinators are presented and discussed.

Career Development Block: Creating and Applying New Knowledge

The career development block is an innovative, three-month component of training for all senior residents in the Combined Residency Program in Pediatrics. Faculty and residents designed the rotation jointly to enhance resident skills, one of which is applying new knowledge. The CRC and Institutional Review Board Offices lead the session entitled, "Creating and Applying New Knowledge." This session includes information about major study designs, how to analyze scientific papers, the role of data and safety monitoring, and human subject protection issues. This course is offered four times a year as the residents rotate

Other Lectures

Other lectures are provided by the staff of the IRB on an ongoing basis. Whenever possible, the Chair and staff of the IRB provide lectures pertinent to the IRB. Outside speakers are invited to lecture and to participate at grand rounds.

Faculty Meeting Presentations

The IRB Chair and the Director of Clinical Research Compliance are available to attend established faculty meeting. The Department may request a presentation on any topic they would like covered. These presentations also provide staff with the ongoing opportunity to

interact with the leadership of the Institutional Review Board, to express issues, concerns, and problems, and to ask pertinent questions

Case Presentations

IRB staff offer departments the opportunity to have research protocol case-based discussions with their faculty at a group meeting. A member of the IRB staff will attend a departmental meeting and lead discussion on research protocol cases that are specifically selected and developed for the particular discipline. This gives investigators and their staffs the opportunity to consider human subject protection issues as they apply to an example protocol.

Individualized Training

IRB administrative staff members provide ongoing individualized training. Investigators are encouraged to seek the assistance of the administrative staff when planning a protocol or when responding to other IRB questions and concerns. Administrative staff members are trained to identify each requirement, describe what it is, and provide a rationale for why it is required. In this way, human subject protection training is continually reinforced.

Related Content

Document Attributes

Title	**Education and Training: Investigators and Research Staff**		
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