



Education and Training: Investigators and Research Staff

Policy

- 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.
- Children's Hospital requires evidence of continuing education every three years.

Purpose

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 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

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, 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 Committee on Clinical Investigation (CCI) 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 CCI and the CCI 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 CCI 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 training activities are tracked in a Children's Hospital database. The Collaborative IRB Training Initiative (CITI) provides a weekly spreadsheet of those individuals who have completed initial and continuing web-based training. This is uploaded into the Children's Hospital database on a weekly basis. Other training activities are entered by the staff of the Clinical Investigation Office.
- Investigators are able to access the training activities they 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 CITI training regardless of whether or not they have completed training programs at other institutions. 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 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 CCI will accept that training as long as he or she has evidence of completion.

Any individual listed on a 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.

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 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 an 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 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 Clinical Investigation 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 Clinical Investigation 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 Clinical Research Program/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 CCI. Department Chairs and Division Chiefs may request a specialized educational activity for their faculty at any time.
- d. Human subject case presentations organized by CCI to faculty/staff groups.
- e. Completion of continuing education requirements at another Harvard affiliated institution.

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 Children's Hospital

Introduction to Clinical Research Course

The Clinical Research Program Office, an office that is independent of but works closely with the CCI, 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 Clinical Research Program 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 Children's Hospital Boston including human research protection issues:

Coordinator Rounds: The Clinical Research Program office 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 Clinical Research Program and Clinical Investigation 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 CCI on an ongoing basis. Whenever possible, the Chair and staff of the CCI provide lectures pertinent to the IRB. Outside speakers are invited to lecture and to participate at grand rounds.

Faculty Meeting Presentations

The CCI 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 Committee on Clinical Investigation, to express issues, concerns, and problems, and to ask pertinent questions

Case Presentations

CCI staff offer departments the opportunity to have research protocol case-based discussions with their faculty at a group meeting. A member of the CCI 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

CCI 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 CCI 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		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05 6/20/05 06/13/07
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