Education and Training: Investigators and Research Staff

Purpose

This policy describes the current activities developed to provide the necessary initial and continuing education for investigators and research staff.

Policy

Boston Children's Hospital (BCH) recognizes the importance of having a strong, comprehensive educational program that ensures that any individual involved in the performance of human subject experimentation at BCH understands the ethical principles and regulatory requirements related to the protection of human subjects. The BCH educational program tailors training to the specific needs of those involved in clinical research at multiple levels.

Boston Children's Hospital (BCH) 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.

BCH requires evidence of continuing education every three years.

Procedure

General Training

Because investigators and their research staff assume different roles and responsibilities in the conduct of human subject research, BCH has developed training requirements that take into consideration the different roles assumed in a research project. The Institutional Review Board (IRB) has determined that the type and amount of training required depends on whether there is actual intervention or interaction with the subject.

Investigators are asked, on a per protocol basis, to list the individuals who work on the research protocol.

As part of their review to determine whether appropriate initial and continuing training has taken place, the IRB administrative staff will review each subject listed on the protocol and their role in the project.

- If a Principal Investigator (PI) has not completed initial or the required continuing education training, then the protocol/continuing review will not be approved.
- If a research staff member listed on the protocol has not completed training, they 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 their name will be removed

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

All IRB-required training activities are tracked in the BCH's e-Research Portal (CHeRP) using each individual user profile.

The Collaborative IRB Training Initiative (CITI) website provides reports of course completions which are periodically downloaded and merged into CHeRP. Employee and affiliate learner profiles are updated using the unique BCH ID numbers that learners provide upon CITI registration. IRB staff update users' profiles when other qualifying educational activities are completed and/or when documentation of qualifying activities are provided to the IRB office. Through CHeRP, investigators are able to access the training activities they or their colleagues have completed and print out a certificate, as necessary.

Principal Investigators who Intervene/Interact with Research Subjects

CITI Training

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. There are two different module tracks, biomedical and behavioral/social science. Investigators may choose either track.

If a PI has completed CITI training at other institutions the modules, they completed will be compared to the BCH requirements, to determine if it can be accepted

PI training is required regardless of whether the PI performs the research procedures. A PI has ultimate responsibility for compliance with human subject protections and, therefore, must complete this more intensive training.

New PI/Transfer Orientation

Any new PI 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 someone who has submitted their first protocol application at BCH or someone 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. Approval of a protocol that is submitted by a new PI will not be released until this orientation is complete.

For more information about the responsibilities of a PI, see IRB policy: ***Principal Investigator Responsibilities.***

Staff/Personnel Who Intervene/Interact with Research Subjects

Any other individual (i.e. co-investigator, research nurse) listed on a BCH protocol who intervenes or interacts (including obtaining informed consent) with a research subject who is at a BCH location (i.e. inpatient, outpatient, satellite facility, Martha Elliott) is required to complete the web-based CITI training program.

If the individual has completed training at another institutions, the IRB will accept that training if they have evidence of completion and the modules completed are similar

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Any individual listed on a BCH 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 BCH is required to complete the CITI training or have evidence of completed training at another institution (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 BCH.

The Director of Clinical Research Compliance will work with the PI 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

A reduced number of CITI modules are required for individuals whose work on human subject research protocols is limited to the following:

- Secondary use of data and biological specimens
- Data analysis or statistical support

If at any time the research role of the individual changes to include intervention or interaction with subjects, the 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 BCH research protocol, they may either complete the CITI modules or provide evidence of completion of human subject training from another institution.

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

PIs, 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/or 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 BCH (CITI, refresher modules for continuing education).

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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 IRB and EQuIP offices often provide lectures, seminars, and round table discussions. Individuals will be asked to "sign in", so there is evidence of their attendance. The seminar/lecture/presentation must be recognized by the IRB office in order to satisfy continuing education requirements. The Director of Clinical Research Compliance determines what lectures/seminars may serve a continuing education purpose. The following list represents some of the currently recognized activities. A further description of these activities is included below:

1. Research Coordinators Rounds at which human subject protection issues are discussed
2. Human subject related presentations at department/division faculty meetings organized by the IRB. Department Chairs and Division Chiefs may request a specialized educational activity for their faculty at any time.
3. Human subject case presentations organized by IRB to faculty/staff groups.
4. Completion of continuing education requirements at other Harvard affiliated institution.
5. Other activities designated by the Director of Clinical Research Compliance to meet continuing education requirements
6. The CITI GCP course

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.

Related Content

IRB Policies

Principal Investigator Responsibilities

Document Attributes

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