IV. New/Transfer Investigator Training

Purpose

The purpose of the New and Transfer Investigator Training policy is to outline the process of educating and orienting new investigators to Boston Children’s Hospital (BCH) who plan to conduct clinical research involving human subjects.

New Investigators (those conducting clinical research involving human subjects for first time) and Transfer Investigators (those who have clinical research experience involving human subjects from other institutions, but never conducted research at BCH before) must meet with the EQuIP office for a Pre-Review/Orientation prior to the release of IRB final approval.

Responsibility

Quality Improvement Specialist
Manager, EQuIP
Director, Clinical Research Compliance

Procedure

1. Identification and Notification of New/Transfer Investigators: IRB administrators will identify New and Transfer Investigators during the protocol pre-review process. Both the PI and the EQuIP office will be notified via CHeRP as a required Ancillary Review. The notice will inform the PI that this training must be completed prior to the release of IRB approval. Once notified, the PI will be responsible for contacting the EQuIP office to schedule this training.

2. EQuIP Pre-meeting Actions: once a New/Transfer Investigator contacts the EQuIP office, the meeting (approximately 1 hour) will be scheduled. Prior to the scheduled meeting, the EQuIP staff will:
   a. Obtain the IRB study file in CHeRP
   b. Review the protocol with the goal to tailor the pre-review material using the New/Transfer Investigator Meeting Checklist to best fit the needs of the proposed protocol/investigator (e.g. drug or device study vs. survey study), including any educational materials, handouts, templates or guidance which may be helpful.
   c. When possible, investigators will be encouraged to provide any available study documents such as draft protocols, case report forms, SOPs and methods for study documentation, filing and organization prior to meeting or to bring with them at the scheduled meeting.
New/Transfer Investigator Pre-Review Meeting: the goal of this pre-review meeting is to ensure the New/Transfer Investigator has an understanding of all applicable regulations and policies and are aware of the following:

- BCH Clinical Research Support Services & Resources
- BCH Principal Investigator Responsibilities
- BCH Policies and Procedures (highlighting policies and procedures that maybe unique to BCH, as well as common reporting procedures)
- BCH Reporting and Review structure, requirements and related policies.
- BCH Informed Consent Library
- Applicable issues pertaining to Study Documentation, Organization and Storage
- Applicable issues pertaining to Informed Consent and Assent
- Applicable resources available through BCH intranet (CCI, EQuIP, CRC).

The EQuIP staff will use the New/Transfer Investigator Meeting Checklist to guide the meeting. Handouts, references and templates will be given to PI as applicable to study.

Once the Pre-Review is complete, and the QI Specialist feels the New/Transfer Investigator is adequately prepared to conduct the proposed research safely and understands applicable regulations and policies, the QI Specialist enter the training in in CHERP for New PI Ancillary Review.

References

- New/Transfer Investigator Meeting Checklist