I. Program Overview: Mission, Aims and Goals

Introduction

Boston Children’s Hospital (BCH) is committed to a consistent, proactive effort to continually educate and update the research community of regulations regarding human subject protections, and of good clinical practices regarding research conduct and documentation.

BCH is equally committed to providing an ideal environment conducive to maintaining compliant research practices and protecting human subjects participating in clinical research.

Mission and Aims

The mission is to improve policies and practices in clinical research at Boston Children’s Hospital (BCH) with the aim to continually maximize the protection of human subjects, and to ensure the quality of research conduct and documentation.

This aim will be achieved through observing, evaluating and educating all branches of research at BCH: the principle investigator and the research team, the Institutional Review Board (IRB) and the human subject. Other departments (e.g. Research Pharmacy, Clinical Research Program) will be included dependent upon the role in an observed study.

The aim is three-fold:

1. **OBSERVE** to identify strengths and weaknesses in clinical research policies and practices pertaining to human subject protections through evaluations, monitoring and one-on-one meetings;

2. **LEARN** to gain insight into each research teams’ interpretation and application of hospital policies and practices as well as federal regulation and guidelines;

3. **EDUCATE** to improve identified deficiencies and to promote identified strengths through a collaborative and educational effort.

Goals

Goals will be set to examine current policies and practices to determine what works, what needs improvement and what needs to yet be developed to facilitate a safe, compliant and constructive research process for both the research team and human subjects.

EQuIP sets a goal to review 2-4 on-going studies per month, (randomly selected or for-cause audit), but this may vary based on the number of other EQuIP services requested at the time. In addition to study reviews, the EQuIP office will provide services aimed at new/transfer investigators, new research staff and sponsor-investigators as needed; periodic review of IRB selected metrics; and on-going general educational support and materials for the research community.

Through this review and evaluation process, all findings, observations and feedback will be assessed to identify 'areas needing improvement' pertaining to human subject protections. When identified, EQuIP will conduct further review if necessary and will develop a plan of action aimed at the IRB and research team levels with the goal to facilitate human subject protections.
EQuIP Services

To meet program aims and goals, EQuIP will provide the following services. Each service will be described in greater detail in following sections.

1. **Study Reviews/Audits**
   a. Random and For-cause Study Reviews
   b. Requested Study Reviews

2. **Institutional Review Board (IRB) Reviews/Audits**
   a. General review of IRB protocol file per selected or requested study review
   b. Focused audit of specific area(s) based on areas of concern or questions; or by request
   c. Random review of selected metrics to ensure consistent and adequate review and documentation

3. **New/Transfer Investigator Training**

4. **Sponsor-Investigator Responsibilities Training**

5. **Talks/Presentations/Trainings**

6. **Educational Initiatives and Materials**

Staff and Reporting Structure

EQuIP is staffed with 2 FTE. The Quality Improvement Specialist reports to the EQuIP Manager, who in turn reports the Director of Research Compliance. EQuIP serves as its’ own entity, separate from the IRB, under the Office of Clinical Research Compliance.

**Staff**

- **Director of Research Compliance** Susan Kornetsky, MPH
- **Manager of EQuIP** Eunice Yim Newbert, MPH
- **Quality Improvement Specialist** Susie Corl, MSW, MPH