I. Program Overview: Mission, Aims and Goals

**Overview**

The Human Research Protection Program (HRPP) at Boston Children’s Hospital (BCH) is committed to protecting the rights, safety and welfare of human subjects participating in research. The Education and Quality Improvement Program (EQuIP) was created in 2004 as a means of institutional oversight of the HRPP. EQuIP is responsible for providing services aimed to:

1. ensure on-going compliance with the applicable regulations and institutional policies regarding human subject protections
2. proactively educate and inform the HRPP of applicable regulations and policies, and of good clinical practices regarding research conduct and documentation
3. provide resources that facilitates overall compliance to ensure human subject protections and that promotes the integrity and reliability of resultant research data

**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 research team, the Institutional Review Board (IRB) and the human subject. Other departments (e.g. Pharmacy, ICCTR) will be included dependent upon the role in 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 audits, 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**
2. Random and For-cause Study Reviews
3. Requested Study Reviews
4. **Institutional Review Board (IRB) Reviews/Audits**
5. General review of IRB protocol file per selected or requested study review
6. Focused audit of specific area(s) based on areas of concern or questions; or by request
7. Random review of selected metrics to ensure consistent and adequate review and documentation
8. **New/Transfer Investigator Training**
9. **Talks/Presentations/Trainings**
10. **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

Senior Quality Improvement Specialist Tonya Ferraro, M.Ed.