

## A. EQuIP Introduction: Mission, Aims and Goals

### Introduction

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Children's Hospital, Boston (CHB) 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.

CHB 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

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The mission is to improve policies and practices in clinical research at Children's Hospital, Boston (CHB) 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 CHB: the principle investigator and the research team (anyone involved in the clinical research process), the Institutional Review Board (IRB) and the human subject. Other departments (e.g. Research Pharmacy, Clinical and Translational Study Unit) 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

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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.

One goal of EQuIP is to review 2-3 on-going studies per month (randomly selected, PI-requested or IRB-requested/For-cause). In addition to the study reviews, the EQuIP office will provide pre-reviews for new/transfer investigators, new research staff and sponsor-investigators as needed; periodic review of CCI/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.