

## I. Principal Investigator Open Communication

### Purpose

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The purpose of the PI Open Communication Standard Operating Procedure (SOP) is to outline the process of encouraging PIs and the CHB research community to communicate concerns, opinions, ideas and suggestions regarding research and human subject protections.

### Responsibility

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Quality Improvement Specialist  
Manager, EQuIP  
Director, Clinical Research Compliance

### Procedure

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1. General Program Awareness: All EQuIP activities and program procedures that involve the research community emphasizes the importance of feedback from investigators and their research staff. EQuIP staff strongly encourages investigator feedback through many efforts, including the following:
  - EQuIP, separate from IRB: the EQuIP office was created as a separate entity from the IRB as one means to ensure investigators and research staff feel comfortable to freely express their concerns and feedback regarding the research process.
  - Open Communication: the EQuIP office continually encourages open communication with investigators as a means to understand their concerns and needs regarding research.  
  
The EQuIP office will maintain a general list of concerns and suggestions, which will be continually assessed to determine what needs CHB as an institution can address and what improvements can be made. If any issues or concerns can be addressed immediately, the EQuIP office will attempt to do so.
  - CHB Policy: Children's Hospital has communicated to all investigators that any IRB-related concerns or problems may be communicated to the EQuIP office.
2. Feedback Forms/PI Response Forms: When a research study is reviewed and final reports sent, all departments and services reviewed are required to respond using a provided response format. At the end of each response form, there is a section for PI comments about the review and research as a whole.
3. Anonymous Feedback: Investigators and research staff that participated in a study review, will receive an anonymous feedback form encouraging responses regarding the EQuIP program and to openly express concerns and suggestions regarding research and human subject protections. PIs will have the option to mail back the form, or email it electronically to an anonymous email box, that de-identifies the sender.