EQuIP Routine Quality Improvement Audit Summary

The following information outlines what to expect during the EQuIP Routine Quality Improvement Audit process, what should be available for review, and the actual time required of the PI and research staff. If you have any questions, please contact the EQuIP office (5-3022 or 5-5308).

Pre-Meeting Responsibilities

1. **Please send a list of Subject IDs for all enrolled subjects to the QI Specialist at your earliest convenience, and no later than 1 week prior to scheduled review date.** Do not include subject names or other PHI at this time.

   Once received, the QI Specialist will randomly select a percentage of subjects for review and notify the PI prior to the review date, which complete subject files should be available for review.

   In addition to the selected subjects’ research files, the **signed consent forms for all subjects** should be available for review.

2. **Please ensure there will be available space (e.g. available desk, room) at time of review**

   The QI Specialist will need space to review the study documents on the date scheduled. Depending on the study and number of subjects, the review can last a few hours or the entire day.

3. **Please have all study and subject documents, binders, and files available at time of review.**

   **Note:** if any study/subject documents are filed electronically, please let the QI specialist know prior to review. **If any files are stored electronically (e.g. CHERP IRB, Sharepoint, or REDCAP materials), please do not make paper copies for purposes of this review.** Whether a study document is electronic or paper, a reviewer must ensure they exist, are reliable and stored safely and securely, so we want to ensure we obtain adequate rights to review electronic files if needed and/or will have access to required electronic files during the review date. **Reviewer access to electronic source documents will only be necessary upon specific request.**

   In general, the following should be ready for review (list is not inclusive).

   - **IRB Documentation,** including but not limited to:
     - All IRB Reviews: Submissions, IRB Action Letters, PI Responses, Approval Letters & Acknowledgement Notices
       1. Initial Review
       2. Continuing Reviews
       3. Amendments
       4. Unanticipated Event Reports
       5. Significant Deviation Reports and Exception Requests
     - Scientific Review documentation as required by department/division process
     - IRB correspondence – pertinent to study protocol

   - **General Study Documentation,** including but not limited to:
     - Approved Protocol, current and expired versions
     - Manual of Operations (MOO) or Standard Operating Procedures (SOP)
     - Approved consent and assent forms, current and expired versions
     - Subject Enrollment and/or Screening Records/Logs (if applicable)
     - Other study tracking logs (e.g. recruitment activity, monitoring, etc)
     - Recruitment materials
     - Other study materials (e.g. surveys, case report forms, questionnaires)

   - **Complete Subject Study Records,** for requested subject IDs (see #1 above)

   - **Signed consent/assent forms for all subjects**

   **If applicable,** Regulatory Documentation for Drug/Device trials
     - e.g. FDA Forms 1571/1572, FDA Financial Disclosure Form, study drug or device accountability logs.

   **If applicable,** investigator agreements and/or correspondence with sponsor
Initial Meeting with Principal Investigator  
 approximately 30-45 minutes

1. The QI Specialist will present a summary of the EQuIP program and review process.
   The PI and staff will be encouraged to ask questions throughout.

2. The QI Specialist will ask study specific questions.
   The questions will pertain to study information not easily observed from study documents and
   regarding actual study practices.

3. The PI and staff will be encouraged to ask questions and provide feedback.
   The PI and research staff will be given the opportunity to ask any questions and offer opinions
   about the EQuIP program, as well as about conducting research in general at CHB.

4. Final Meeting Scheduled
   Ideally scheduled at the end of the day of the Study/Subject Review or within 1 week of meeting,
   at which time any study findings will be reviewed with PI and staff.

Study and Subject Review  
 time dependent on study

1. The QI Specialist will review provided study and subject materials in the reserved space.
   PI and staff do not need to be present, but please have one study staff available via phone/page.
   Once the review is complete, study files/records will be returned as instructed by research team.
   
   Note: the length of the Routine Audit is dependent on many factors such as the type of study, how
   long study has been open, number of subjects enrolled. We do aim to complete the review of
   study and subject files within 1 day. To facilitate this, we try to schedule the start time during the
   am. If we think the review may take longer, we will let you know as soon as possible.

Final Meeting (scheduled either at end of day of Study / Subject Review or within one week after review)  
 approximately 1 hour

1. The QI Specialist will review the findings and observations noted from the review.
   At this time, the research staff can make any clarifications as needed. If there are
   findings and/or observations, they will be broken into three categories:
   - Notable Best Practices: study strengths will be highlighted
   - Require Corrective Actions: corrective actions required to meet regulations and policies
   - Recommended Actions: actions to be considered if PI feels them beneficial to study.

2. The PI and Research Staff will be encouraged to ask questions and offer feedback
   At this time, the PI and research staff will be encouraged to share feedback about the review
   experience and to offer any opinions and ideas regarding research at CHB in general.
**Final Report and PI Response Form (as needed)**

1. **In approximately 2 weeks, a FINAL REPORT and PI RESPONSE FORM will be sent to the PI if there are observations requiring follow up.**
   
   After the final meeting, the QI specialist will incorporate any changes to the report based on clarifications and discussion provided by the PI and research staff, and will be sent out within 2 weeks.

2. **PI Response to Final Report**
   
   Once the PI has reviewed the report, all Required Corrective Actions must be addressed and Recommended Actions considered. The PI must complete, sign and return the PI Response Form within 1 month of receipt, unless more time is requested and approved. The Response Form allows the PI to explain what actions were taken, and to explain why certain recommended actions were not implemented.

3. **PI Responses Reviewed**
   
   Once the EQuIP office receives the signed PI Response Form, the QI Specialist will review the responses to ensure all actions were adequately addressed. If any issues are still unresolved, the QI Specialist will contact the PI to ask for clarifications or to request further resolution.

4. **EQuIP Review Approved and Closed**
   
   Once all actions were adequately addressed, the review will be formally closed. The report will be kept confidential and will not be shared with any other departments without PI permission and/or notification.

**Confidentiality of the Final Report and PI Responses**

Any observations made by the EQuIP specialist, the Final Report and PI Responses will be kept confidential, and will not be shared with the IRB unless serious or continuing noncompliance is noted; or, if a PI repeatedly fails to adequately address corrective actions required by regulations and CHB policies. In both cases, the PI will be informed prior to IRB notification. The report will not be shared with any other individuals unless the PI wishes to do so.

**Questions and EQuIP Contact**

If you have any questions regarding the EQuIP program and review, please contact the EQuIP office:

- Eunice Newbert     ext. 5-3022     email: eunice.newbert@childrens.harvard.edu
- Susie Corl         ext. 5-5308     email: susan.corl@childrens.harvard.edu

You may also visit the EQuIP website: [www.childrenshospital.org/research/equip](http://www.childrenshospital.org/research/equip)