Routine Quality Improvement Audit Summary

The following information outlines what to expect during an EQuIP Routine Study Audit. This is a general description and is subject to change based on factors such as type of research and availability. While this audit is required, we will work with you throughout the process to ensure the process goes smoothly and when needed, can be flexible to accommodate schedules.

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** (do not include subject names or other PHI).

   Once received, a QI Specialist will randomly select a percentage of subjects for review and notify you (PI/research staff) prior to the review date. For the selected subjects, please have their complete study file/binder available for review.

   In addition to selected subjects' research files, we will review the signed consent forms for 100% of subjects enrolled

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

   In general, the following should be ready for review. If any of the following are stored electronically (e.g. CHeRP IRB, Sharepoint, REDCap, department shared drive), please do not make paper copies for the purposes of this review. We will send a document checklist before audit asking where documents are stored, and if electronic, how we can access at time of audit.

   - IRB Documentation, including but not limited to:
     All IRB Reviews below: Submissions, IRB Action Letters, PI Responses, Approval Letters & Acknowledgement Notices and IRB correspondence pertinent to study protocol
     - Initial Review
     - Continuing Reviews
     - Amendments
     - Unanticipated Event Reports
     - Significant Deviation Reports and Exception Requests
   - 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 selected subjects (see #1 above)
   - Signed consent forms for all enrolled subjects
   - Regulatory Documentation for Investigational Drug/Device trials*, if applicable*
     - E.g. FDA Forms 1571/1572, FDA Financial Disclosure Form, device accountability logs (drug accountability logs will be audited through Research Pharmacy which we will arrange separately)
   - Investigator Agreements, and/or Correspondence with sponsor or coordinating center
     - E.g. FDA Forms 1571/1572, FDA Financial Disclosure Form, device accountability logs (drug accountability logs will be audited through Research Pharmacy which we will arrange separately)

3. **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

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.

Study and Subject Records Review

~4-6 hours (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 morning. If we think the review may take longer, we will let you know as soon as possible.

Final Report and PI Response

1. **Within 1 week, a FINAL REPORT and PI RESPONSE FORM**
   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 BCH 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.