III. IRB Review

Purpose

The purpose of the CCI/IRB Review policy is to outline the procedure for conducting study reviews specific to IRB activities and other QA/QI activities as deemed necessary.

Responsibility

Quality Improvement Specialist
Manager, EQuIP
Director, Clinical Research Compliance

Procedure

1. CCI/IRB-Study Reviews: for each full study review conducted (see EQuIP Study Reviews policy), regardless of selection type, the CCI/IRB will automatically undergo review.

   Once a full study review is scheduled with the PI, the QI Specialist will conduct a preliminary review of the IRB study-specific files and applicable meeting minutes in CHeRP. The Study Review Monitoring Form will be used as a general review outline, but the QI Specialist will conduct the review as to evaluate IRB compliance, organization, record-keeping and documentation, focusing on the following categories:
   - Record Keeping and Documentation
   - IRB Administrators: Protocol Processing and Review
   - IRB Committee Members: Protocol Review
   - Meeting Minutes: Protocol Review Documentation
   - Database Documentation
   - Timeliness: Processing, Review and Response

   During the on-site study review of the PI files, the QI Specialist will refer to the Study Review Monitoring Form to compare the content of pertinent files. If any significant discrepancies are discovered or missing documents noted in the IRB files, the Study Review Monitoring Form will be updated accordingly to capture this and IRB notified accordingly.

IRB Findings and Report: once the IRB review is completed, the QI Specialist will document all noted observations and areas of concern. For minor observations or general questions, the QI specialist may resolve the query by working with the appropriate IRB staff.

If there is a notable or significant finding, the Director of Research Compliance will be notified as soon as possible. These findings will be described in a formal letter for the IRB to respond. Any questionable observations will be discussed with the Director of Clinical Investigations for clarification and resolution.
2. **IRB Focused Reviews**: in addition to study specific reviews, the EQuIP office may conduct a review focused on specific areas and topics based on the role and responsibilities specific to the IRB office and committee. Focused reviews are conducted as deemed necessary (e.g. concern based on other study review findings), by requested (from IRB, Director of Research Compliance or IO) or randomly selected by EQuIP office to ensure consistent and adequate IRB review and documentation. Focused reviews include (but not limited to):

- **Meeting Minutes**: review of meeting minutes from randomly selected IRB meetings to ensure all required information was adequately documented. Any notable observations requiring response/acknowledgment will be listed in a formal letter.

- **Data Safety Monitoring Plans**: review a number of randomly selected New Protocols that were approved during the prior 3 months to ensure that all requirements were met before approval. Any notable observations requiring response/acknowledgment will be listed in a formal letter.

- **Expedited Reviews**: review of randomly selected protocols that were approved through expedited review within the past 12 months to ensure protocols adequately met criteria for expedited review. At this time, the CCI/IRB will receive a formal letter listing any notable observations requiring response/acknowledgement.

**References**

- Study Review Monitoring (Prep) Form