III. IRB Audit

**Purpose**

The purpose of the IRB Audit policy is to outline the procedure for conducting study Audits specific to IRB activities and other QA/QI activities as deemed necessary

**Responsibility**

Quality Improvement Specialist

Manager, EQuIP

Director, Clinical Research Compliance

**Procedure**

**1. IRB Study Audits**: for each full study audit conducted (see *EQuIP Study Audits policy*), regardless of selection type, the IRB will automatically undergo review.

Once a full study Audit is scheduled with the PI, the QI Specialist will conduct a preliminary Audit of the IRB study-specific files and applicable meeting minutes in CHeRP. The **Study Audit Checklist** will be used as a general Audit outline, but the QI Specialist will conduct the Audit as to evaluate IRB compliance, organization, record-keeping and documentation, focusing on the following categories:

* + - Record Keeping and Documentation
    - IRB Administrators: Protocol Processing and Audit
    - IRB Committee Members: Protocol Audit
    - Meeting Minutes: Protocol Audit Documentation
    - Timeliness: Processing, Audit and Response

During the on-site study audit of the PI files, the QI Specialist will refer to the Study Audit 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 Audit Monitoring Form will be updated accordingly to capture this and IRB notified accordingly.

IRB Findings and Report: once the IRB Audit 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 directly 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 Audits**: in addition to study specific audits, the EQuIP office may conduct an audit focused on a specific areas and topics based on the role and responsibilities specific to the IRB office and committee. Focused audits are conducted as deemed necessary (e.g. concern based on other study audit findings), by requested (from IRB, Director of Research Compliance or IO) or randomly selected by EQuIP office to ensure consistent and adequate IRB Audit and documentation. Focused audits include (but not limited to):

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

**References**

* Study Audit Monitoring (Prep) Form
* Meeting Minutes Audit Checklist