VII. Reporting PI/Research Staff Audit Findings and Feedback

Purpose

The purpose of the Reporting PI/Staff Audit Findings and Feedback policy is to outline the process of reporting observations and outcomes from EQuIP audits and activities to the appropriate persons or groups, as to continually provide information and education deemed beneficial to improving the protection human subjects.

Responsibility

Senior Quality Improvement (QI) Specialist

Manager, EQuIP

Director, Clinical Research Compliance

Procedure

* 1. Documentation of and Response to Study Audit Observations and Feedback: during all EQuIP audits and activities, observations made by EQuIP staff and feedback provided by the research community are documented. Due to the diverse research community and types of research studies at BCH, combined with varying EQuIP outreach activities, observations and feedback are documented and addressed as the EQuIP staff and Director of Clinical Research Compliance deems appropriate based on significance and urgency. Significance of an issue or concern and urgency of the response will be based mainly on regulatory compliance and/or the effect on human subject participants.

▪ General Issues and Concerns: the EQuIP office maintains a specific file for each study audit, and a general file for minutes and notes from all EQuIP-related meetings (general and one-on-one) and informational sessions. Observations, comments or general feedback are documented in the appropriate file.

If common observations or discrepancies are noted over time, the EQuIP office will investigate the matter to determine if further action is required or could be beneficial. In such case, the appropriate individuals or groups will be contacted by the EQuIP office, informed of the issue and follow-up action will be requested as deemed necessary. Once the issue is resolved, the resolution should be documented with the EQuIP office.

On a periodic basis, audits will be accumulatively assessed noting common errors requiring corrective actions, and all meeting notes will be audited. At this time, the EQuIP office will ensure no patterns or discrepancies requiring attention were missed, and will make sure all issues were properly addressed and resolved. This information will be presented in a formal that will be submitted to the Director of Research Compliance and Vice President of Research. The report will also be given to the appropriate persons, groups and/or offices dependent upon any pertinent issues raised in the report.

▪ Significant Issues and Concerns: during any EQuIP audit or activity, if a noted observation from the QI Specialist and/or comment(s) from the BCH research community brings to light more significant issues or concerns, the EQuIP office will immediately notify the Director of Clinical Research Compliance to discuss the best means to address the issue or concern. At this time, the EQuIP office will document the issue in the appropriate file, and investigate as possible.

If the matter is deemed urgent by the EQuIP staff and requires an immediate response, the appropriate individuals or groups will be contacted by the EQuIP office, informed of the issue and follow-up action will be requested as deemed necessary.

Findings and observations from EQuIP audits are confidential to the entity audited, and shall not be reported to the IRB or other entities, unless the EQuIP office discovers a significant deviation or continuing non-compliance (as defined by IRB policies) and does not feel the PI will or has adequately addressed the issue per institutional policy and applicable regulations. In such case, the PI will be notified that the Director of Clinical Research Compliance will be contacted to address any significant unresolved issues. Any issue which EQuIP office feels increases places any subjects in immediate danger will be reported to the Director of Clinical Research Compliance immediately.

If it is not immediately known if the matter is a general issue or concern requiring immediate attention, or one that is specific to one person or group, the issue will be documented, and patterns for similar issues will be tracked over time. If a pattern is detected, the EQuIP office will then respond as described above.

2. Reporting Observations and Feedback: in addition to documenting observations and feedback from EQuIP-related activities, the research community will be encouraged to offer direct comments and feedback to the EQuIP office via phone or email. All comments will be investigated to determine further action.

3. Updating Research Community: on an annual basis, the research community will be updated of common errors observed and areas of improvement that are specific to their research sector, including a description of any follow-up actions already taken. If possible, applicable education materials may be referenced or provided at this time. The update will be made available on the EQuIP website and through the *Human Subject Protections Update* newsletter.