**Continuous Quality Improvement: Encouraging the Feedback Loop**

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**Evaluation of Program**

- Repeated QA/QI audits of IRB files focused on prior problem areas to identify inadequate corrective action**
- Qualitative data collection from Research Team at subsequent study reviews
- EQuIP Services Survey for Investigators—planned, mid-2014
- IRB Services Survey for IRB Members – in progress, administered September, 2013

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**Strengths of Program Model**

- Confidential, education-focused nature of the not-for-cause study review promotes collegiality and openness between EQuIP, PI, and the IRB.
- Shared oversight by Director provides for close working relationship and mutual understanding of policies and practices between EQuIP and IRB.
- Dotted line relationship to Vice President ensures EQuIP autonomy in decision making*.

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**Background**

The Education and Quality Improvement Program (EQuIP) was established in 2003 with the goal of promoting institutional and investigator compliance with human subject regulations and the use of best practices. EQuIP conducts random, not-for-cause, confidential study reviews. Each study review evaluates both PI conduct of the research, and IRB review of the research.

**Issue**

To address the issue of how to maintain PI confidentiality when a finding that involves the IRB arises from a PI-specific study review, EQuIP implemented a process to initiate a ‘for-cause’ IRB-focused audit without compromising PI confidentiality.

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**Study Review: Reporting Process**

- **Pl-specific Study Review**
  - PI study files and overall conduct are evaluated

- **IRB Process Review**
  - IRB-specific findings are tracked by EQuIP for further QI evaluation and education purposes

- **Report to PI**
  - Summary of review findings and corresponding corrective action

- **PI Response to EQuIP**
  - PI must submit a summary of corrective actions taken.
  - EQuIP will instruct the PI to contact the IRB independently about a proposed corrective action.

- **Clarification or further action needed**

- **Response Accepted**

- **Continue to monitor trend/issue**

- **Response Accepted**

- **Study review closed**

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**Study Review: Case Study**

Clinical trial involving children. IRB-approval required permission of both parents if reasonably available

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**Conclusion**

This process allows EQuIP to effectively investigate an issue to determine if further corrective action is required at both the study-specific and program-level, and ensure adequate corrective and preventative plans are implemented.