An Integrated Quality Assurance Program for Human Subjects Protections
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Problem Statement: Institutions provide assurance that human subject research will be conducted in compliance with Federal regulations and the ethical principles of the Belmont Report. In addition to IRB review, a functional research protections program must include other mechanisms of oversight. In our institution, a traditional compliance program audited protocols based on annual risk assessments and for cause. Findings were consistent across the institution and over time. To address a critical gap between identification and prevention of problems, the institution restructured the compliance program and implemented an Integrated Quality Assurance (QA) Program. The change from compliance (retrospective) to quality assurance (prospective) was a paradigm shift that required acceptance by the Administration, Internal Audit and Legal Affairs, the IRB, and Research Teams.

Methods: The program had to balance institutional concerns about adequate reporting of events, and the concern of research teams related to disclosure and confidentiality. The Integrated QA Program was implemented in 2012. QA Analysts were assigned to research departments identified based on clinical research portfolios, volume, and risk. Analysts work directly with the research team, have space within the units, attend research team meetings, and have access to staff, investigators, and management to address immediate concerns. A firewall between the IRB and the QA team was established to facilitate the communication necessary for continuous quality improvement. Direct communication is limited to serious noncompliance and events that have the potential for immediate subject harm. The program utilizes key principles of compliance, Lean Six Sigma, and Risk Based Monitoring. Outcome data is provided quarterly to administration and includes metrics based on study start up assessments, first subject reviews, monitor surveys, and monitor reports.

Additional Information: It is too early for data on clinical trial completion, but initial metrics are positive. Buy-in has increased across all organizational levels. A new clinical trial manager group and shared governance structure is leading to higher levels of QA adoption. QA tools have been developed with collaboration of the research team and continuing education is based on identified needs. Other institutions, sponsors, and a commercial education company have expressed interest in this novel program. Keys to successful transition from traditional compliance to an integrated QA model include: accommodating institutional culture and structure; assurance of timely reporting of problems and noncompliance; and, establishment of trust between the QA and research teams.