Joining Forces: Using Education and Quality Assurance to Reduce For-Cause Audits
Julie T. Martin, RN, MEd, CCRP; Christine Epps, BS; Brandy Hutchinson, BS, CIP
University of South Florida

Submission Type: Programmatic
Topic Area: Quality Assurance/Quality Improvement
Poster Number: 90

Problem Statement: Noncompliance among researchers is a concern for HRPPs. While processing applications for continuing review, the IRB reviews the two most recently signed informed consent documents, protocol deviations, serious adverse events, the number of subjects enrolled in the study, and a summary of research activities since the last review. It is during the review of this information that instances of noncompliance are often identified. Most common are the use of unstamped or expired informed consent documents, informed consent obtained by individual(s) not included as study staff in the IRB application, incomplete reporting of serious adverse events, and deviations from the IRB-approved protocol. When these issues are identified, the Chairperson or fully convened IRB may request the Quality Assurance/Quality Improvement (QA/QI) Program conduct an audit to determine if the rights, safety, or welfare of subjects were adversely affected. In 2012, the IRB at this institution requested 13 for-cause audits.

Description of the Program: Education and QA/QI programs are part of the HRPP. In most cases, study teams unknowingly commit noncompliance. Once educated regarding regulations and institutional policies, researchers can implement corrective action plans to prevent recurrence. In 2012, the Education and QA/QI programs joined forces to expanded education initiatives and conducted routine audits focused on partnering with researchers, not penalizing them. The Education Program offered two, four-hour study team retreats covering topics such as ethics in human subjects research, serious adverse event reporting, utilizing policies and procedures, and ways to avoid noncompliance. The presentations included humorous skits to dramatize irregularities in the informed consent process, violations of privacy in an open waiting room, and coercion. In 2013, the Education Program continued to expand, increasing the number of individuals who received education on research ethics, noncompliance, and good clinical practice. In addition, the QA/QI Program more than doubled the number of routine audits that were conducted in the previous year, significantly increasing the educational reach of the program.

Evaluation: The increased education initiatives and routine audits were successful in educating study teams. In 2013, the IRB requested only six audits, a 54% reduction from the previous year. When implementing this type of program, it is important to partner with researchers and convey a desire to want to help them. It may take time to break down barriers between the HRPP and the research community, but providing free educational opportunities is a great way to start.