Introduction:

The VA Office of Research Oversight (ORO) requires an annual Facility Director’s Certification (FDC) of research oversight in part to ensure the protection of human subjects. Research programs are required to have at least one Research Compliance Officer (RCO) to conduct periodic reviews and include the results in the FDC. Our medical center uses extensive resources to generate the annual FDC data reported to ORO. The FDC data are used nationally to assess research compliance with applicable laws, regulations, and policies system wide. The challenge is how to best utilize national FDC data to improve our local Human Research Protections Program (HRPP).

Program Description:

Our Compliance Quality Assurance Program (CQAP) is a collaborative effort. There is a shared responsibility to compile the data for the FDC and enhance the overall quality of the program.

- RCOs report directly to the Medical Center Director (MCD); independent of the Research Program
- Informed consents (ICs) are reviewed for regulatory compliance and prompt identification of deficiencies; involves real-time assessment with annual reporting of findings to investigators and oversight committees
- Eligible research studies receive a triennial review with formal reporting to investigators and oversight committees using an electronic management system (EMS)
- ORO administrative templates are used to collect required data on human subject protocols
- An assigned IRB reviewer utilizes a checklist to document IRB review and determination for RCO audit results

Intrusions Implemented to Improve Local Practices:

- IRB customized notifications regarding approval expiration in addition to automatic renewal notice sent by the EMS
- Removal of expiration dates on IC templates
- Shift to real-time IC audits with annual summary
- Implementation of tracking component of the EMS
- Formalized IRB review and determination of RCOs audit findings
- RCO reviews/IRB determinations are available outside the VA infrastructure through the EMS

Summary of Findings:

Our compliance-quality assurance processes enable us to promptly address stakeholders’ inquiries and enhance quality assurance of IRB and RCO activities.

- EMS facilitates transparency and provides unlimited access to research documents outside the VA infrastructure by R&DC/subcommittee members, RCOs, and researchers.
- Facilitates real-time tracking of study status and reduction in lapses
- Decrease in the number and/or seriousness of IC related noncompliance issues
- FDC/local audit data helped to identify deficiencies and evaluate success of educational and remedial actions over time
  - One-on-one training enhanced awareness and self-reporting by research personnel
  - Revision of the ICD templates and changes in processes reduced the number of incorrect ICD used
  - Identified areas of noncompliance above national average for intervention
  - Protocol lapses highlighted persistent problems with continuing review processes
  - Enhanced communication resulted in more timely submission of continuing review requests

Future Considerations:

- Continue use of FDC quality metrics data into ongoing compliance-quality assurance operations.
- Explore ways to reduce lapses in approvals of protocols followed exclusively by the R&DC
- Formalize RCO reporting of quarterly aggregated summaries to relevant committees
- Collaboration between RCOs at the VISN level sharing local experiences to establish best practices