Human Research Compliance: A Journey not just a Destination for One Department of Veterans Affairs (VA) Medical Center
Sheron L. Salyer, DNSc, RNC, CHRC; Virginia Wiley, MSN, MBA, RN; Jeannie Helton, BS
VA Tennessee Valley Healthcare System

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**Problem Statement:** 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) conduct periodic reviews and include the results in the FDC. The FDC results are used nationally to assess research program compliance with applicable laws, regulations, and policies system wide. Our Compliance-Quality Assurance Program uses extensive resources to generate the annual FDC data reported to ORO. The challenge is how to best use national FDC data to improve our local HRPP.

**Program Description:** The Compliance-Quality Assurance Program uses the following processes: collaboration between the Research Program staff and RCO(s) to conduct a programmatic review as part of the FDC; informed consent documentation (ICD) review for assurance of regulatory compliance and prompt identification and correction of deficiencies; triennial protocol reviews unless deemed exempt; collection of RCO audit data using ORO administrative templates that is then entered into an electronic database for reporting purposes; intermittent meetings between the RCO(s), Research Program staff, investigators, and other stakeholders to review compliance results and provide education; ORO returns nationally aggregated FDC data to the medical center for benchmarking and quality improvement.

**Lessons Learned on Our Journey:** Real time ICD review identified a decrease in the number and level of noncompliance issues. FDC and audit data identified deficiencies were used to assess compliance trends and evaluate success of educational and remedial actions over time. Outliers on the FDC resulted in customized educational opportunities and enhanced awareness and self-reporting by research personnel. Protocol lapses reported on the FDC highlighted problems with the submission and approval processes resulting in a switch to an electronic submission and tracking system. The electronic submission and tracking system facilitated transparency and unlimited access to research documents and compliance reviews.

**Suggestions for the Future:** Standardize key aspects of audit summaries to ensure accurate and consistent information is provided. Provide protocol specific summaries of audit results to investigators and relevant committees as well as quarterly reporting of aggregated compliance issues and status of reportable issues. Continue incorporating oversight data into the ongoing compliance-assurance program operations.