

PHS Research Grant, Compliance, and Administration Consulting Services for Academic Research Institutions, Medical Schools, Research Programs

Recipients of PHS biomedical and behavioral research awards need to identify and track all clinical trial revenue in order to ensure that program costs are accurately allocated and billed to the correct funding source.

The conduct of sponsored clinical research is overseen by the DHHS Office of the Inspector General, ("OIG"). Compliance guidelines are designed to eliminate erroneous and improper expenditures of Federal funds.

An institution's implementation of a serious, meaningful and effective research compliance program requires a significant commitment of time and resources which should be supplemented by a periodic independent, external consulting support to insure the highest level of due diligence.

For more information, contact:
James M. Cesare

Bay Area Healthcare Advisors, LLC's ("Bay Area") professional staff has provided research consulting oversight and management services to academic medical centers and community hospitals throughout the United States. More recently, James Cesare President, and CEO of Bay Area served as the lead consultant for a 500 bed Southern California Hospital and associated regional cooperative hospitals, providing clinical research management/expertise in the areas of Cardiology, Diabetes, Cancer, Lung and Respiratory studies. The engagement primarily focused on restructuring and reorganization of the entire research department due to inadequacies and substandard cooperative audit results. The research cooperatives involved in this project include ACOSOG, NSABP, RTOG, and SWOG. The hospitals main research component was cancer related trials in association with Duke University Hospital. There were in excess of 100 different clinical studies being performed within the listed coops involving over 400 subjects. The studies included both preventive and treatment regimens by design.

The Bay Area team has provided similar projects to hospitals throughout the country. Hospital financial management and compliance departments rely on our engagement and leadership expertise to provide appropriate Corrective Action Plans ("CAP") resulting from our analysis. We also provide process improvement which insures that our recommendations are carried forward and implemented in the existing corporate compliance plan. Our professionals have worked with national children's hospitals, academic medical center, free standing research centers, and acute care hospitals. Bay Area professionals have served as interim management in research positions that has required the entire restructuring of the research department at a hospital. The project involved but was not limited to: IRB reporting requirements, adverse events reporting, COOP (NSABP and ACOSOG) audit reporting requirements, reimbursement audits, clinical trial medical records review, and formulation of CAP for approval by the National Cancer Research Institute and the Office of Inspector General.



Bay Area Healthcare Advisors, LLC

Specializing in healthcare reimbursement and regulatory solutions

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