Advancements in clinical research in the United States and abroad have significantly changed the way that health care services are delivered. It is possible that in the next 20-30 years, many of the diseases that we face today will be eradicated as a result of the efforts of scientists and research institutions such as academic medical centers.

As these advancements proliferate, however, federal dollars for discoveries in science and medicine are dwindling and the federal government’s enforcement agenda has grown dramatically. Some of the areas in which the government has been most active include: research billing, conflicts of interest, research misconduct, federal grants compliance, effort reporting, and compliance with human research protections regulations. FTI Consulting’s Clinical Research and Compliance Practice -- which includes some of the nation’s foremost authorities on research compliance and human research protections -- is well positioned to assist research organizations in navigating and/or avoiding issues with research, enforcement and regulatory agencies.

**How We Do It?**

**Research Billing**
- Medicare Coverage Analyses (Training and MCA Prep)
- Release of Bill Holds (in concert with Rev Cycle Team)
- Research Billing Assessments and Performance Improvement
- Policy and Procedure Development and Training

**Human Subject Protections**
- Establishment of Human Research Protection Programs
- AAHRPP Accreditation Preparation
- Best Practices Assessments of HRPPs and IRBs
- Interim IRB management and staffing, (IRB Chair, IRB staff)
- Policy and Procedure Development and Training
- Management of Tissue Repositories
- HIPAA/HITECH Act Research Compliance

**Conflicts of Interest**
- Preparation of Policies and Procedures
- Development of Institutional COI Policies and Procedures
- COI Training and Interim COI management
- Investigations
- Physician Payment Sunshine Act Compliance

**Research Compliance Services**
- Development and Implementation of Compliance Programs per PhRMA and Advamed Code Guidelines
- Investigations (Off-Label Uses, Fraud and Abuse, etc.)
- Compliance Training
- Clinical Trial Agreements
- Clinical trial agreements and Ad Board Agreements
- Interim Staffing
- Expert Witness Services

**Research Administration**
- Best Practices Assessments
- Operations and Performance Improvement Assessments
- Research Program Redesign
- Automation of Processes (CTMS purchase and implementation)
- Interim Staffing
- Assessments of Clinical Operations Efficiencies
- Assessments of Research Compliance Programs
- Development and Implementation of Research Compliance Programs

**Grants Management and Compliance**
- Advice Related to Grant Accounting
- Effort Reporting Advice and Assessments
- Performance Improvement and Enhancement
- Interim Staffing

**Research Misconduct**
- Training on PHS standards for Inquiry and Investigation
- Conduct of Inquiries and Investigations into Research Misconduct Allegations
• Ad hoc advice
• Expert Witness Services

**Good Clinical Practice Standards**
• Best Practices Assessments
• Operations and Performance Improvement Assessments
• Policy and Procedure Development and Training
• Management of Data Bases

**Representative Engagements Led by Members of Our Core Team**

• Led a multiyear performance improvement engagement for a community hospital system aimed at strengthening general hospital and research compliance, redeveloping the hospital’s restricted fund accounting processes, developing new strategic initiatives to improve the hospital operation.

• Led assessment and operational improvement engagement of pre-award research activities of a notable health system in New York. Identified process inefficiencies and contributed to preparation of a financial model aimed at enhancing performance.

• Assessed the clinical research billing and compliance activities for two top-ranked academic HPHs within a large healthcare system. Identified gaps in the existing infrastructure and presented opportunities for improving clinical research billing operations, management, and compliance.

• Performed Medicare coverage analyses for a large academic medical center. Determined the billable nature of clinical trial services based upon the CMS Final National Coverage Determination (NCD).

• Led assessment and operational improvement engagement at a large academic medical center that needed assistance in transforming its clinical research operations to be more compliant and financially viable. Project required a detailed workflow redesign associated with its clinical research billing program.

• Identified internal control deficiencies at a major academic medical center conducting research and clinical trials. Helped to lead improvement of the financial position of research grants, enhance the infrastructure, and streamline accounting operations.

• Redesigned the clinical trial billing process for a large academic medical center in order to enhance operational efficiency and reduce billing errors for clinical trials. Helped to better integrate the clinical trial office, hospital registration department, hospital patient financial services, hospital billing and coding department, and other research departments to streamline the operation.

• Evaluated research business processes for a specialty hospital including the clinical trial contracting and negotiation process. Fiscal feasibility assessment, budget development, sponsor invoicing, and project closeout processes.

• Reviewed the organizational structure, business processes, technology, resources, and performance metrics of a centralized clinical research office for a leading research university. Delivered recommendations for enhancing operational performance, improving administrative and financial management, and mitigating compliance risk.

• Served as interim clinical trials billing manager for a large healthcare system.

FTI Consulting’s Clinical Research and Compliance Practice is poised to assist healthcare organizations with all of their research consulting needs. Please allow us to help your organization improve compliance and enhance operations. We look forward to hearing from you soon.