Research Quality Improvement Team: Monitoring Research Compliance in a Decentralized Research Model
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Problem Statement: Within our health system, the Research Center functions as a decentralized model that serves as the “Hub” to all the “Spokes” that conduct research within the entire system. One of our roles within the Research Center is to ensure research conducted within the health system is in compliance with the Research Center policies and federal and state regulations, and to improve the education of study staff. Research Investigators are responsible for ensuring that their clinical investigation is conducted according to an approved protocol, applicable regulations, and institutional policies. With a decentralized model of research, how can we monitor investigator compliance with Good Clinical Practice?

Description of the Research: In 2007, the Research Center created the Research Quality Improvement Team (RQIT) to conduct internal not-for-cause quality review of selected studies, reviewing all documentation associated with the conduct of the selected research study protocol. The studies for quality review are selected at random, or a Research Department, Investigator, or the health system’s HRPP may request the review of a specific study. All quality findings are confidential peer-review information. A quality review tool is used to evaluate the research and regulatory process. The quality review focuses primarily on the following areas: (a) the consent process; (b) regulatory documentation; (c) investigational drug/device tracking; and (d) research related activities and Billing Compliance. A summary report is created and sent to the research department indicating a score based on the significance and quality of compliant findings. Any study receiving an “Unsatisfactory” score is subject to a re-visit by the review team to ensure that any corrective action has been implemented. The principal investigator is responsible for responding to the report within 30 days of receipt. In 2013, the RQIT review tool was converted from a paper format to an electronic format allowing the review team the ability to enter their findings directly into the electronic tool. This eliminates paper records to retain and store, and creates a more systematic tool from which data can be retrieved. Based on feedback from the RQIT reviews, common findings were compiled into a “Helpful Hints for Managing Research Studies.” This document now accompanies all new study approvals sent from the IRB to the individual research departments.