Implementing a Research Compliance Training Program within a Community Health Center
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Problem Stated: Like many small research institutions, we struggled to balance the need to implement a training program to ensure federal and state regulatory compliance with the desire to expand the program to support investigators in adopting best practices for the efficient, compliant, and ethical conduct of research. Our goal was to expand the current training program utilizing existing staff and resources to: 1. Support researchers to achieve the highest standard of regulatory compliance through education on good clinical practices (GCPs), research compliance, and other key topics, and 2. Inform the research community of lessons learned from noncompliance and unanticipated problems reported to the IRB.

Description of Program: To meet this challenge, we worked with the Directors of the health institute to utilize the established monthly staff meetings to reserve six dates for regulatory compliance trainings in 2013. We provided four pre-planned trainings: Financial Conflict of Interest, Confidentiality and Data Security, HIPAA and Research, and Responsible Conduct of Research. Two meeting dates were reserved to provide training on lessons learned. One training provided a refresher on the informed consent process and the other was used to present a new policy, Reporting Participant Complaints, both developed in response to events reported to the IRB. Working with the IRB, we created a new mandatory training for Principal Investigators on their roles and responsibilities. The training was provided multiple times to ensure all investigators attended. In addition, new investigators are required to meet with the Compliance Manager to complete the training. Through this training, investigators are encouraged to invite the Compliance Manager to study operational meetings to provide targeted trainings on topics ranging from source documentation to IRB reporting. Finally, the Compliance Manager established monthly IRB office hours that researchers use to discuss issues related to their study or upcoming IRB submissions.

Conclusion: We have found success in adopting a training model that is flexible, integrated, and responsive to both regulatory requirements and the local research context. The new training model significantly increased the number of all staff trainings provided (six in 2013/three in 2012) and provided other educational opportunities to increase awareness of research compliance. Other institutions seeking to expand their compliance training program may find this model useful.