A Pilot Study on the Effectiveness of the "Navigating Clinical Research" Training Course
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Background: The mission of the HRPP is to support, facilitate, and promote the ethical and safe conduct of research with human subjects at our health system; however, ensuring that investigators are familiar with all of the intricacies when conducting research at an institution presents a challenge. The challenge arises when novice investigators are unfamiliar with the process of conducting research, while experienced investigators may be unfamiliar with the changing process and responsibilities. In an effort to provide the research community with professional guidance and support prior-to and during the conduct of human subjects research, our institute, which is a division of the health system, developed a one-day fully comprehensive class on navigating clinical research.

Study Details: "Navigating Clinical Research" is an interactive class providing both experienced and novice investigators with the comprehensive tools and guidance needed to be compliant; as well as scientifically, operationally, and fiscally responsible while conducting research in the health system. The class is offered quarterly and topics include:

- Clinical research in the health system and identifying research resources;
- Clinical research funding;
- An introduction to the IRB, including a description of policies and regulations pertaining to human subjects research; IRB submission and reporting requirements; consenting research participants, as well as considerations when obtaining consent from populations with special considerations;
- Fundamentals of conducting research with an overview of good clinical practice;
- Navigating the regulatory environment and protecting research subject privacy and security;
- Conducting quality research, including how to ensure study data accuracy, integrity, and quality (ALCOA), and quality assurance; and
- The fundamentals of research billing, including Medicare coverage, mapping the billing process to ensure compliance, and policies and procedures.

Findings: Since the inception of the course in March 2013, we have collected evaluation and survey data using a standardized Likert scale to formally assess the reception and efficacy of the course among researchers and their staff. Preliminary results show that the course was well-received and effectively conveyed critical information in a simple and appealing format. Further analysis of data from this quarter is currently ongoing. Although the course has been tailored for investigators at our health system, the course model could be applied to other institutions as a method to provide
comprehensive fundamentals training specific to their institution when conducting human subjects research.