*Category: Training & Quality Assurance – Completed Project*

**How to Be a Principal Investigator: A Practical Training Program for Investigators**

R. Kingsford, D. Pitt, S. Low, L. Weaver, J. Moehle, A. Cohen, T. Werner;

Huntsman Cancer Institute, University of Utah

**1. Background**

Principal investigators complete rigorous medical training and online self-guided training in human subjects protection (HSP) and good clinical practice (GCP). These mandatory trainings focus mainly on the history of HSP and general concepts in GCP. The practical skills required to be a successful investigator are not included in academic training courses.

**2. Goals**

Our goal was to train new investigators in best practices for conducting clinical research. The planning committee identified six competence domains to inform the content for the training:

1) Roles and responsibilities of the investigator

2) Federal and international regulations regarding research

3) Institutional processes and regulations

4) Informed consent, adverse event assessment, and source documentation

5) Roles and responsibilities of research staff

6) Resources available to investigators in their clinical areas

**3. Solutions and Methods**

We formed a planning committee of seven people, including experienced principal investigators, research personnel, compliance officers, and research administrators. The committee planned and conducted a half-day seminar entitled “How to be a Principal Investigator.” The initial pilot seminar included junior and senior faculty from 10 internal medicine divisions, pediatrics, and nursing. The planning committee designed pre-, post-, and 3-month surveys to gauge understanding and retention. Self-assessed quantitative cumulative scores showed improvement in understanding that persisted for 3 months. Given the success of the initial intervention, the training is now mandatory for all Department of Medicine investigators. The seminar includes eight lectures, two panel discussions, an interactive case study, and a resource handout. We used the survey again to gauge understanding and garner feedback from the investigators. The planning committee has provided several different sessions of the seminar on different days and different times of the day in order to accommodate schedules.

**4. Outcomes and Future Directions**

Across the six competence domains, the average cumulative investigator understanding score was 25.95 of a possible 30 following the seminar. Qualitative investigator feedback has been generally positive. Investigators from other departments such as the Department of Surgery for whom the training was not mandated have attended and found the content to be beneficial. Several investigators indicated that they liked the interactive nature of the seminar. We find that interdisciplinary and interdepartmental collaboration on content and identification of speakers continues to generate new ideas for future partnership.

Using feedback generated from the survey, the planning committee will explore format options such as an interactive online training.

The committee is exploring a combined session including trial coordination staff and investigators, based on a suggestion from the surveys.

We will continue to evaluate and modify content in response to institutional needs, as well as national and international updates in regulations and institutional needs.