

The Development of a Competency-Based Training Program

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1. Background

The University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) Clinical Trials Office (CTO) has historically used the term “independence” to signify a study coordinator’s (SC) transition from training to autonomous execution of role responsibilities. However, this term lacked definition, leading to inconsistencies across the office. Additionally, despite numerous training resources, the absence of an official training program led to confusion during onboarding and training. Training requirements were primarily quantity-based with subjective quality measures, posing risks such as knowledge gaps and inconsistent evaluation criteria.

2. Goals

To address these challenges, LCCC needed to develop a competency-based training program. The goals of this project were to establish a structured process for determining a trainee’s transition to independence and to provide objective measures to reduce bias and ensure the quality of training. This program aimed to be comprehensive by assessing for and closing training gaps, eliminating reliance on opportunities organically arising, and allowing experienced SCs to expedite their training. Central to this initiative was ensuring consistency with nationally accepted SC core competencies while tailoring the program to LCCC-specific expectations.

3. Solutions and Methods

After a thorough needs assessment consisting of input from SCs and leadership and a review of the office's training materials and practices, it was decided to focus on the areas of study visits and data management. Competency domains were created to demonstrate: 1) Understanding and application of LCCC consenting procedures compliant with Standard Operating Procedures and Work Instructions, 2) Understanding of screening procedures including prescreening and eligibility verification, 3) Conducting a routine patient visit per protocol, 4) Collecting, verifying, and entering data within Electronic Data Capture guidelines and contractual timelines. These domains consist of 23 topics for training. Requirements are outlined in a rubric format, where each topic is associated with specific activities that need to be completed successfully to demonstrate objective competency. In addition to the rubric, 15 assessments are available in the form of a test, case study, or rating scale to guide the trainer in their assessment. The clinical trainer, team lead, or clinical research manager determines that the SC has performed each topic competently. The manager completes the final sign-off signifying that the SC has demonstrated competency and may act within the SC scope with minimal to no assistance.

4. Outcomes

Eight SCs have participated in the training program, of which three are actively in the program. An additional SC has taken remedial training using relevant components. This program has resulted in a comprehensive, stepwise methodology uncovering weaknesses that were not self-reported and allowing for tailored training. It has provided a transparent route to independence and increases confidence in one’s ability to excel in their role.

5. Lessons Learned and Future Directions

This initiative has fostered a robust and equitable training environment, further underscoring the importance of competency-based methodology. Future directions include adding additional SC competencies, replicating this methodology for other positions, and developing competency-based performance plans and career ladders based on these assessments.