The Development of a Competency-Based Training Program

**Introduction**

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 (Figure 1).

**Figure 1. Issues Addressed**

- Confusion
- Knowledge Gaps
- Inconsistent Evaluation Criteria
- Subjective Quality Measures
- Power by Quantity-Based
- Subjective Quality Measures

**Solutions/Methods**

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. Central to this initiative was ensuring consistency with nationally accepted SC core competencies while tailoring the program to LCCC-specific expectations. (Figure 2).

**Figure 2. Goals of a Competency-Based Training Program**

- Goals to Develop a Competency-Based Training Program
  - Consistent with nationally accepted SC Core Competencies
  - Tailored to Site-Specific Expectations
  - Structured Process
  - Objective Measures
    - Reduce Risks
    - Ensure Quality of Training
    - Provide Opportunity for Practice
  - Comprehensive Program
  - Address Gaps
  - Provide Opportunities
  - Expedite Training

**Figure 3. Core Competency Domains**

- In-Person Consenting
- Non-English-Speaking Consenting
- Remote Consenting
- Prescreening Subjects
- Eligibility Verification
- Registration and Randomization
- Scheduling
- Lab Kit Management
- Protocol Compliance and Completion
- Informed Consent
- Study Visit Conduct
- Adverse Events Assessment
- SAE Reporting
- Concomitant Medications Review
- Clinical Research Progress Notes
- Drug Accountability
- Research Charts
- Redaction
- EDC Systems
- Data Entry and Query Resolution

**Figure 4. Core Competency Topics**

**Figure 5. Core Competency Assessment**

**Results**

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 (Figure 3).

These domains consist of 23 topics for training (Figure 4). 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 trainee in their assessment (Figure 5). The clinical trainer team leads, 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.

Fifteen SCs have participated in the training program, of which eleven are actively in the program (Figures 6 and 7). 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.

**Conclusions**

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.