# The Development of a Competency-Based Training Program

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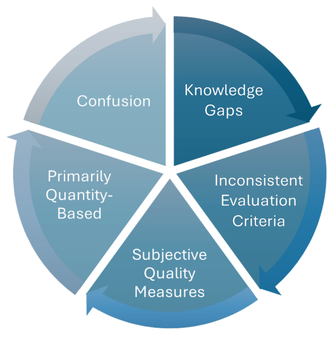
## Introduction

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**).

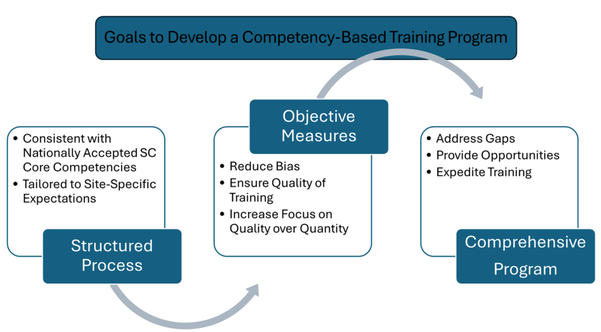
### Figure 1. Issues Addressed




## Solutions/Methods

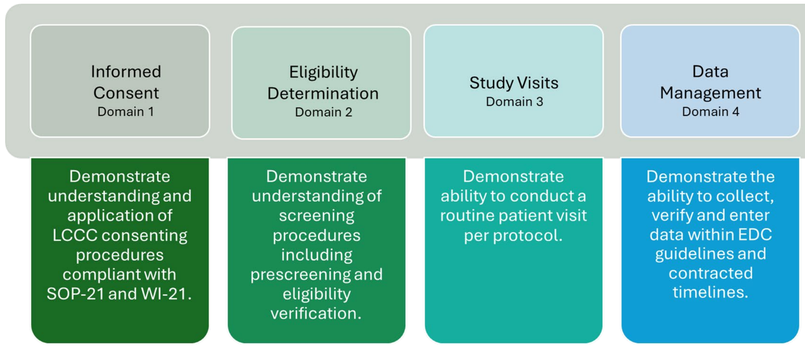
To address these challenges, LCCC needed to develop a competency-based training program. The goals of this project were to establish a structured process for determining a trainee’s transition to independence and to provide objective measures to reduce bias and ensure the quality of training. This program 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. (**Figure 2**).

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




## Solutions/Methods

### Figure 3. Core Competency Domains




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 trainer in their assessment (**Figure 5**). 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.

### Figure 4. Core Competency Topics

| Topic | Domain |
|---|---|
| In-Person Consenting | 1 |
| Non-English-Speaking Consenting | 1 |
| Remote Consenting | 1 |
| Prescreening Subjects | 2 |
| Eligibility Verification | 2 |
| Registration and Randomization | 2 |
| Scheduling | 3 |
| Lab Kit Management | 3 |
| Protocol Comprehension and Compliance | 3 |
| Study Visit Preparation | 3 |
| Study Visit Conduct | 3 |
| Adverse Events Assessment | 3 |
| SAE Reporting | 3 |
| Concomitant Medications Review | 3 |
| Clinical Research Progress Notes | 3 |
| Drug Accountability | 3 |
| Research Charts | 4 |
| Redaction | 4 |
| EDC Systems | 4 |
| Data Entry and Query Resolution | 4 |

### Figure 5. Core Competency Assessment

**Competency Assessment: Study Visit Conduct**

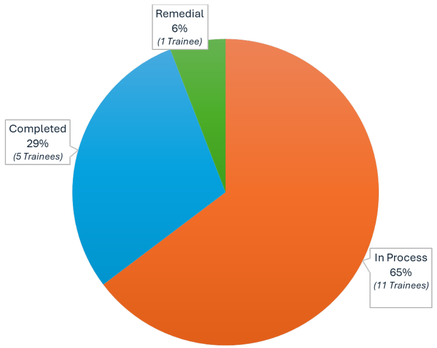
**Rating Scale:**

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| Unacceptable | Needs Improvement | Meets Expectations | Exceeds Expectations | Outstanding |

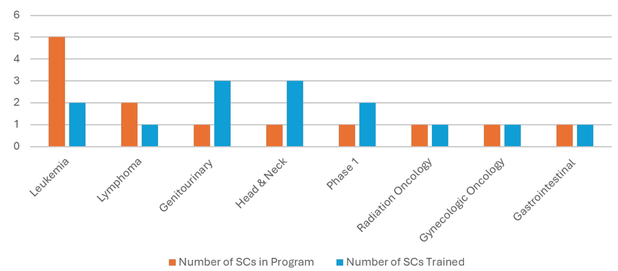
| Assessed Name: | |
|---|---|
| **Assessment Category** | **Score** |
| **Adverse Events & Medical History Review:** | |
| Reviews ongoing adverse events (AEs) and medical history with the patient | |
| Captures any intervention for new, existing, and worsening events and decide if this is allowed per protocol | |
| Grades AEs using the correct CTCAE version, reviews the protocol for any holding parameters, correctly interprets any parameters and communicates modifications to the provider and other applicable parties (i.e., infusion, IDS, TPF) | |
| Review attribution for new or worsening AEs with the treating physician | |
| **Concomitant Medications Review:** | |
| Interviews patient and captures new concomitant medications and medication changes (i.e., dosage) | |
| Captures start and stop dates, dosage, route, frequency, and indication | |
| Confirms that the patient is not taking any prohibited medication per protocol and standard of care (SOC) | |
| **Clear for Treatment:** | |
| Documents labs on lab flowsheet and follows second check process | |
| Ensures that treating physician agrees to clear to treat | |
| Clears patient in EPIC and releases proper orders (i.e., Study Coordinator, Clear to Treat, oral medication) | |
| **Overall Score:** | |

| **Assessor – Assessment** | |
|---|---|
| **Have all the components of the assessment been achieved?** ☐**YES** ☐**NO** | |
| **Comments:** | |
| **Assessor Name:** | |
| **Signature:** | **Date:** |

### Figure 6. Program Participation




### Figure 7. Program Progress by Disease Group




## Results

Fourteen 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.

## Contact

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