The Critical Need for Consistent Training for Clinical Research Professionals

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1. Background

Clinical research training has not kept pace with growth in the field. No formal regulations exist that provide the training requirements for research professionals; therefore, training typically lacks consistency. While some academic institutions have begun offering advanced degrees in clinical research, there is still no universally accepted measure of competency across the profession.

2. Goals

Organizations around the world acknowledge the need for consistent clinical research training and the lack thereof. The Joint Task Force (JTF) on Clinical Trial Competency assembled in 2013 to bring uniformity to clinical research training. The JTF consolidated training input from numerous organizations into the eight competency domains shown in the figure below. Organizations can use these tools to develop specific clinical research training programs. Wider implementation of such programs can help establish consistent professional expectations in clinical research.

Competency Domains for the Clinical Research Professional

1. **SCIENTIFIC CONCEPTS AND RESEARCH DESIGN** — Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials

2. **ETHICAL AND PARTICIPANT SAFETY CONSIDERATIONS** — Encompasses care of patients; aspects of human subject protection, and safety in the conduct of a clinical trial

3. **INVESTIGATIONAL PRODUCTS DEVELOPMENT AND REGULATION** — Encompasses knowledge of how investigational products are developed and regulated

4. **CLINICAL STUDY OPERATIONS (GCPs)** — Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, postmarket surveillance, and pharmacovigilance), and handling of investigational product

5. **STUDY AND SITE MANAGEMENT** — Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)

6. **DATA MANAGEMENT AND INFORMATICS** — Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database

7. **LEADERSHIP AND PROFESSIONALISM** — Encompasses the principles and practice of leadership and professionalism in clinical research

8. **COMMUNICATION AND TEAMWORK** — Encompasses all elements of communication within the site and between the site and sponsor, CRO and regulators. Understanding of teamwork skills necessary for conducting a clinical trial

3. Solutions and Methods

The Ohio State University Comprehensive Cancer Center (OSUCCC) Clinical Trials Office (CTO) Education Curriculum was written in 2014 to standardize training for all teams and individuals within the CTO. The JTF clinical research competency tool was used to revamp the CTO Education Curriculum and training program to align training content with the eight JTF Competency Domains for the various roles within the CTO. A more robust in-person training program has also been developed to provide CTO staff more detailed consistent training.

Using the revised CTO Education Curriculum as a guide, the following training methods for CTO staff was implemented:

- **On-boarding**: Separate on-boarding checklists for managers and staff ensure effective integration of new staff;
- **Orientation**: The CTO New Staff Orientation delivers overviews of internal and external areas and explanations of the relationships of these areas;
- **In-person training**: Staff attend standard, interactive in-person training regarding topics such as Informed Consent Process, Adverse Event and Deviation Documentation, Serious Adverse Event Reporting, Research Chart Organization, Data Collection, etc.;
- **Assignment of a preceptor**: Each new employee is assigned a preceptor from their team to provide in-depth training regarding team and protocol items; and
- **Continuing Education Opportunities**: Individuals with various research expertise present at regular CTO Education webinars. The training team also provides ongoing training for any new or revised CTO processes and procedures.

4. Outcomes and Future Directions

The outcomes of a vigorous training plan provide the following benefits:

- Interactive trainings allow for more engaged learning for staff members;
- Role-specific curricula provide tailored, detailed training for each research role;
- Staff are more comfortable with their position and feel that they can perform their jobs at a higher level;
- Improved audit results;
- Increased overall morale;
- Streamlined training overseen by the Training Team leads to all teams conducting research consistently, alleviating ambiguity regarding policies; and
- All research subjects receive the same appropriate research oversight.

A well-defined training program aligned with the JTF competency tool leads to more competent and satisfied staff which leads to reduced turn-over and better service. It is not enough to provide training about a research topic once in one format; multi-modal training – in-person, hands-on labs, written resources, annual refreshers, and routine reminders – are proving to be more effective in providing continual education for clinical research professionals.