The Critical Need for Consistent Training for Clinical Research Professionals

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Clinical Research Training Concerns

- No formal consistent training
- No regulations controlling training
- On-the job training
- Some certification and advanced degree programs available but not consistent
- No universally accepted measure of competency across the profession

Original CTO Education Curriculum

- CITI (Biomedical Research), **CITI Good Clinical Practice** (GCP), HIPAA
- Tools Involving Research
- IHIS
- Components of a Research Protocol
- Departments Outside of the CTO
- SIV/Study Initiation

- Multi-Institution Program
- Regulatory Processes
- Informed Consent Process
- Conduct of a Study
- Medication Accountability
- Subject Safety
- Audits and DSMC
- CSRC
- Data Management
- OCDC/JARO

Original CTO Education Curriculum Concerns

- Flow of information not always logical
- Some information out of date
- Much of training was delivered through manuals and documents
- Not role specific
- Modules did not always clearly specify the action to be taken
- Possible inconsistencies in training from team to team

The Ohio State University Comprehensive Cancer Center, James Cancer Hospital & Solove Research Institute

Revised CTO Education Curriculum Using The Joint Task Force on Clinical Trial **JTF Competency Domains Competency (JTF) Eight Competency Domains** I. Scien Resear SCIENTIFIC CONCEPTS AND RESEARCH DESIG 8 II. Ethic ETHICAL AND analysis of clinical trials PARTICIPANT SAFETY Safety COMMUNICATION CONSIDERATIONS AND TEAMWORK ises care of patients spects of human subject Encompasses all eler protection, and safety in the of communication with 4 onduct of a clinical trial the site and between th site and sponsor, CRO, a regulators. Understan III. Med of teamwork skills MEDICINES necessary for conductin and Re **DEVELOPMENT AND** a clinical trial REGULATION of how drugs, devices, an IV. Clin biologicals are develope and regulated Operati **LEADERSHIP AND** PROFESSIONALISM incompasses the principle and practice of leadershi **CLINICAL TRIALS** V. Stud clinical research **OPERATIONS (GCPs)** Manage anagement and GCP npliance; safety anagement (adverse event entification and reporting VI. Data DATA MANAGEMENT AND INFORMATICS AND INFORMATICS Encompasses how data are acquired tmarket surveillance, and Informa harmacovigilance), and andling of investigation ind managed during a clinical trial, ncluding source data, data entry, queries TUDY AND SITI VII. Lea uality control, and correction and the MANAGEMENT concept of a locked database Profess at the site level to run a study (financial and personnel aspects). Includes site and st operations (not encompa VIII. Co gulatory/GCPs **Teamw**

Uses for Eight Competency Domains Framework:

- Developing job requirements
- Assessing job candidates
- Matching employees/contractors with assignments
- Planning training to support career paths
- Assessing investigator qualifications
- Designing conference agendas and training programs
- Choosing training and education events to attend.

Implementation of Revised CTO Education Curriculum and Onboarding

- Revised Manager and Employee Onboarding Checklists Revised CTO New Staff Orientation Developed RCO Education Curriculum Developed In-Person and Online Trainings
- Revised CTO CRC/CRA Education Curriculum • In Progress: Revamping of team preceptor program • In Development: Annual refreshers, hands on-labs

The James

THE OHIO STATE UNIVERSITY COMPREHENSIVE CANCER CENTER

tific Concepts and ch Design	1. 2.	Components of a Research Protocol Clinical Scientific Review Committee (CSRC)
al and Participant Considerations	1. 2. 3.	CITI (Biomedical Research); CITI Good Clinical Practice (GCP); HIPAA Informed Consent Process Audits and Data Safety Monitoring Committee (DSMC)
icines Development gulation	1.	Regulatory Processes
ical Trials ions (GCPs)	1. 2. 3. 4.	SIV/Study Implementation Conduct of a Study Medication Accountability Subject Safety
y and Site ement	1. 2. 3.	Tools Involving Research IHIS OCDC/JARO
a Management and atics	1.	Data Management
dership and sionalism	1.	Leadership and Professionalism
mmunication and ork	1. 2.	Departments Outside of the CTO Multi-Institution Program