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

Clinical Research Training Concerns

The Joint Task Force on Clinical Trial Competency (JTF) Eight Competency Domains

Revised CTO Education Curriculum Using JTF Competency Domains

I. Scientific Concepts and Research Design
   1. Components of a Research Protocol
   2. Clinical Scientific Review Committee (CSRC)

II. Ethical and Participant Safety Considerations
   1. CITI (Biomedical Research); CITI Good Clinical Practice (GCP); HIPAA
   2. Informed Consent Process
   3. Audits and Data Safety Monitoring Committee (DSMC)

III. Medicines Development and Regulation
   1. Regulatory Processes

IV. Clinical Trials Operations (GCPs)
   1. SIV/Study Implementation
   2. Conduct of a Study
   3. Medication Accountability
   4. Subject Safety

V. Study and Site Management
   1. Tools Involving Research
   2. IHIS
   3. OCDC/JARO

VI. Data Management and Informatics
   1. Data Management

VII. Leadership and Professionalism
   1. Leadership and Professionalism

VIII. Communication and Teamwork
   1. Departments Outside of the CTO
   2. Multi-Institution Program

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

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
- Revised CTO CRC/CRA Education Curriculum
- Developed RCO Education Curriculum
- Developed In-Person and Online Trainings
- In Progress: Revamping of team preceptor program
- In Development: Annual refreshers, hands on-labs