UAB Good Clinical Practices and Study Implementation Education and Training Effort

Training and education – the why?

For years, implementing research has been conducted without structured research implementation education and limited Good Clinical Practice (GCP) training for human subjects research. With the growing complexity in clinical research and the need to the shrinking research dollars, rigorous well educated and trained research staff are essential. In 2014, a Joint Task Force developed competencies that outlined what is needed in research education for all research staff. This task force consisted of academicians and industry representatives to define competencies that would address every aspect of implementing a clinical study within expected GCPs. The education programs we have developed are a first effort at addressing the competencies which are categorized into 9 core domains.1

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What are competencies?

Competencies encompass knowledge, attributes, skills, attitudes, and behaviors necessary for a particular set of tasks or objectives

9 CORE DOMAINS
1. Scientific Concepts and Research Design
2. Ethical Considerations, Patient Care and Safety
3. Medicines Development and Regulation
4. Clinical Trials Operations (GCP’s)
5. Study and Site Management
6. Data Management and Informatics
7. Leadership and Professionalism
8. Communication & Teamwork

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