UT Southwestern Medical Center

Office of Clinical Research

Clinical Research Foundations Training Program

Mission

The **UT Southwestern Clinical Research Foundations Training Curriculum** is designed to provide comprehensive education to all clinical research personnel at point of hire and to ensure research personnel have a consistent foundational understanding of the requirements to successfully deliver clinical research.

Program Design

The Clinical Research Foundations training curriculum is structured around eight major components, identified by a joint task force team based at Harvard University (https://mrctcenter.org/clinical-trial-competency/), which are designed to address all clinical research competency domains. These include:

1. Scientific concepts and basic research design
2. Ethical and participant safety considerations
3. Medicine development and regulation
4. Clinical trial operations
5. Study and site management
6. Data management and informatics
7. Leadership and professionalism
8. Communication and teamwork

The program is online and self-paced to allow researchers to complete their training around additional research onboarding needs.

Reference

The **Clinical Research Handbook** has been created to accompany this course. It outlines all aspects of the curriculum in further detail and provides an additional comprehensive resource for researchers.

Program Participants

Completion of the Clinical Research Foundations Training Program is **mandatory for individuals who are new to research at UT Southwestern**, and upon completion, researchers will receive a certificate of completion from the Office of Clinical Research.

Researchers who are new to clinical research at UT Southwestern and hired into the below job titles will be required to take the training:

Job Code	Job Title	Job Code	Job Title
2501	CLIN RESCH ASSIST I	4362	MGR RESCH PRGMS
2502	CLIN RESCH ASSIST II	4379	PROJECT MANAGER CLINICAL RESEARCH
2503	CLIN RESCH ASSIST LEAD	1037	RESCH RN
2504	CLIN RESCH COORD I	1035	RESCH RN SR

Job Code	Job Title	Job Code	Job Title
2505	CLIN RESCH COORD II	2508	SUPERVISOR RESEARCH NURSE
2506	CLIN RESCH COORD LEAD	2509	MANAGER RESEARCH NURSE
2507	SUPV CLIN RESCH	9713	ADVANCED PRACTICE RESEARCH NURSE
4367	MGR CLIN RESCH		

Although this training is required for new research hires, all staff are welcome to access and view the materials to reinforce their own learning and understanding.

Individuals who wish to view ad-hoc modules can do so via the Clinical Research Foundations Training website.

Clinical Research Foundations Courses

Scientific Principles of Clinical Research

Objective: Learners will be able to differentiate medical care from clinical research, define different types of research and the objectives of each, and discuss why it's important to disseminate research results.

	Units	Topic Areas	Competency Domains	Running Time
1	Principles in Research	Define clinical research, trial phases, key concepts of research	1, 8	35:51 min
2	Key Concepts of Clinical Research	Science of clinical research, research hypothesis, experiment planning	1, 8	35:26 min
3	Methods of Research (Part 1)	Observational study design and operations	1, 4, 8	26:33 min
4	Methods of Research (Part 2)	Interventional study design, operations, and components of a research publication	1, 4, 8	26:02 min

Introduction to Clinical Research at UT Southwestern Medical Center and Affiliates

Objective: Introduce clinical research staff to the Offices and Committees that interface with Clinical Research at UT Southwestern and Affiliate Hospitals.

	Units	Topic Areas	Competency Domains	Running Time
1	Leadership welcome and departments	Understanding of research structure at UT Southwestern Medical Center	7, 8	23:15 min
2	Research Committees	Outline and understand committees involved in clinical research approvals	4, 5, 7	32:18 min
3	Other Approvals and Resource Offices	Outline and understand other approvals and offices involved in clinical research	4, 5, 7	21:44 min
4	Performance Site Approvals	Outline and understand the role, importance and process required for performance site approvals	4, 5, 7	20:01 min
5	Resources	Outline and understand institutional resources available to support clinical research	7, 8	34:50 min

Required CITI Modules

Objective: Provides clinical research professionals with basic and thorough training tailored to the researcher's critical role in the conduct of clinical trials. Each module contains detailed content, images, supplemental materials (such as case studies), and a quiz. Modules vary in length, and learners may require different amounts of time to complete them based on their familiarity and knowledge of the topic. However, they can complete them at their own pace. Modules are each designed to take about 30 to 45 minutes to complete, which means the entire CITI course could take about 8-12 hours to complete.

	Units	Topic Areas	Competency Domains
1	Clinical Research Coordinator Responsibilities (ID 16576)	Study Documentation and Binders, IC Process and avoiding Undue Influence, CRFs and Data Capture, Study Closeout	2, 4, 5, 7
2	Funding, Financial Management, and Budgeting (ID 16752)	Types of Funding, Pre and Post Award Processes, CTA and Coverage Analysis, Routine vs Research Costs, Budget Preparation	2, 5
3	Informed Consent (ID 16758)	HHS vs FDA, ICH and GCP, Designing the ICF, Recruitment materials, Consent Process, PI vs CRC responsibilities	2,3
4	Planning Research (ID 16751)	History of Clinical Trials, Drug and Device Development, Clinical Trial design and Phases, Study Sponsor, Protocol Components and Feasibility, Study Team Roles and responsibilities, Site Feasibility and Review	1, 2, 3, 4, 5, 8
5	Principal Investigator (PI) Responsibilities (ID 16755)	PI responsibilities, AE reporting, Study Documentation, Site Visits and Monitoring, FDA/IRB Inspection, Authorship and Publication	3, 4, 5, 8
6	Protocol Review and Approvals (ID 16754)	Understanding other committees, DSMBs, Radiation / IBCs, Investigational Drug Services	4
7	Site Management, Quality Assurance, and Public Information (ID 16759)	Lab storage and set up, Records retention, POC testing, Training, Management Structure, Research Integrity and Misconduct, Confidentiality	4, 7
8	Sponsor Responsibilities (ID 16757)	Sponsor IND / IDE Responsibilities, Sponsor DOA, Sponsor Documents and Monitoring, Sponsor Risk Reporting, Sponsor Safety Reporting	3, 4, 8
9	Working with the Institutional Review Board (IRB) (ID 16753)	Purpose of IRB, Interactions with IRB, Types of review and documents required, Reportable Events / Compliance / Deviations /Safety Monitoring, Study Closeout	4
10	Project Management for Clinical Trials (ID 17864)	Project Management, Processes and Workflows, leading a team, Managing/Assessing Risk, Communication, Management Styles	2, 3, 5, 7, 8
11	Preventing and Identifying Misconduct and Noncompliance (ID 17865)	Research Definitions, Research Misconduct, Detecting Fraud, Misconduct and Noncompliance, Prevention strategies, Data integrity and Monitoring, CAPA plans	4, 7
12	Training and Mentoring (ID 17866)	CRC onboarding, Creating Training Plans, Mentoring	8
13	Financial Management of Clinical Trials (ID 17867)	Identifying Costs, Subject Reimbursement, CMS, Preventing False Claims, Budgets	5
14	Subject Recruitment and Retention (ID 17868)	Recruitment Regulations, Recruitment Plan, Timeline and Enrollment goals, Recruitment techniques, Cultural Competency / Understanding Barriers, Vulnerable Populations, Retention.	2, 5, 7
15	Statistics and Data Management of Clinical Trials (ID 17869)	Basic Statistics, Sample Size, Clinical Trial Stats Design, Randomization and Blinding, Interim Analysis, Data Management and Informatics, Risk Based Monitoring for Data	4, 6
16	Specialty Areas and Regulatory Requirements (ID 17870)	Electronic Systems, Electronic Signatures, Biologics, GMP, Shipping and receiving hazardous goods	1, 3