UT Southwestern Medical Center

Document ID: SOP-OCR-CLINICAL RESEARCH TRAINING
Title: Clinical Research Foundations Training for Onboarding Study Personnel
Revision: 1.0
Last Revision Date: 30th April 2024

Approval Signatures

Process Owner Approval			
Name	Title	Signature	Date
Bhanu Pappu	Associate Vice President, Clinical Research Services		30th April 2024

Document Revision History

Rev	Date	By	Revision Summary
1.0	30th April 2024	Lucy Palmer, PhD, Sandra Morones, RN, BSN, MSPH,	First version

UT Southwestern Medical Center

Table of Contents

UT Southwestern Medical Center

Clinical Research Foundations Training for Onboarding Study Personnel

1.0 Purpose

This standard operating procedure describes procedures for assigning and completing clinical research training requirements for personnel working in clinical research that is conducted at UT Southwestern Medical Center (UTSW).

2.0 Scope

This procedure applies to clinical researchers newly hired by UTSW, transferring from a non-clinical research role to a research role, and/or as mandated by department and institutional heads. This requirement to standardize education and training is part of a joint effort between the Human Research Protection Program (HRPP) and the Office of Clinical Research (OCR) to ensure that all Individuals involved in clinical research are equipped with basic skills necessary for their positions. The program was created with support from the HRPP, OCR, and the Clinical and Translational Science Award (CTSA) Program.

3.0 Definitions and Abbreviations

3.1. Abbreviations

APP – Advanced Practice Provider

CITI – Collaborative Institutional Training Initiative

CHH – Children's Health

CRF – Clinical Research Foundations

CUH – Clements University Hospital

GME – Graduate Medical Education

HR – Human Resources

HRPP – Human Research Protection Program

MSO – Medical Staff Office

NP – Nurse Practitioner

OCR – Office of Clinical Research

PA – Physician Assistant

RN – Registered Nurse

4.0 Clinical Research Foundations Training Background

4.1. General

4.1.1. Standardized clinical research training is required for all clinical research-designated individuals by the OCR to ensure that personnel are introduced to the concepts and skills necessary to be successful in their role. Standardized training also introduces staff to the major UTSW departments, groups, and committees that these staff may be interacting with during their normal day to day operations in clinical research not only at UTSW, but also at UTSW's affiliated institutions.

4.1.2. Individuals who are either newly hired to UTSW or who transfer internally from a non-research designated job code to a clinical research-designated job code at UTSW are required to enroll in the Clinical Research Foundations (CRF) course within the Collaborative Institutional Training Initiative (CITI) platform. **The content of the CRF CITI training curriculum is further outlined in Section 4.2**.

4.1.3. Clinical-research designated job codes that will be required to take the CRF CITI training curriculum have been pre-determined and approved jointly by the Assistant Vice President for Human Research Administration, HRPP, as well as the Associate Vice President, Clinical Research Services within the OCR. **The final list of clinical-research designated job codes, including the process for future updates as necessary, is further outlined in Section 4.3**.

4.1.4. The OCR will work with UTSW's Human Resources (HR) to receive a weekly report of new hires and internal transfers to UTSW. The OCR will then follow a standardized process to determine who is required to complete the CRF CITI training curriculum.

4.1.5. Once an individual has been identified as required to take the CRF CITI training curriculum, they will be contacted by the OCR via email with a Welcome message that includes all relevant information necessary to enroll in the CRF CITI course.

4.1.6. Individuals who are designated as required to enroll in the CRF CITI training program will follow a standardized curriculum to enroll in the appropriate program.

4.1.7. Licensed professionals, although they may engage in clinical research activities as part of their duties within UTSW and affiliated hospitals, are not required to complete the CRF CITI course curriculum. Temporary workers are also excluded from the CRF CITI course curriculum requirement. **Additional information on this topic is further outlined in Section 4.6**.

4.1.8. Departments and/or affiliated institutions have the latitude to assign CRF CITI curriculum as needed to other applicable individuals that may benefit from this training. Moreover, individual departments and/or affiliated institutions can additionally assign their own supplemental and institution-specific training at their discretion. If a department and/or affiliated institution chooses to assign the CRF CITI curriculum to their employees, they will be responsible for assigning the CRF CITI curriculum, determining their own deadline for successful completion, and monitoring completion. The OCR will not be responsible for monitoring these individuals.

4.1.9. Individuals can also independently choose to enroll in the CRF CITI course to complete the training at their own discretion. The OCR will be able to view their successful completion within the CITI program but will not be responsible for tracking these individuals. Moreover, the OCR will not be responsible for following up with these individuals for incomplete CRF CITI completion.

4.1.10. Individuals can access and view the full suite of video contents contained within the CRF CITI course on the Clinical Research Foundations website, housed at Clinical Research Foundations Training: Human Research Protection Program - UT Southwestern, Dallas, Texas. Accessing and viewing these videos on the HRPP website is considered an open and available resource to all staff and does not count toward CRF CITI completion. If an individual wishes to be credited with CRF CITI completion on their CITI record, they must enroll within the CRF course on the CITI platform and complete all the modules with an 80% minimum passing grade.

4.1.11. CRF CITI training through the OCR is not designed to replace specific departmental, clinic or hospital-based policies on staff conduct or training. Moreover, the CRF CITI Training does not replace any study-specific training required by sponsors. **Researchers will be expected to fulfill all study-specific, departmental, clinic or hospital training requirements in addition to the OCR CRF CITI training requirements prior to the conduct of clinical research procedures. It is the responsibility of the Department to ensure these additional training requirements are fulfilled.**

4.2. Content of the Clinical Research Foundations training curriculum

4.2.1. The CRF training curriculum consists of (1) Organization-Specific modules as well as (2) content modules created by CITI. The Organization-Specific modules as well as content modules created by CITI comprise the entirety of the current CRF training curriculum.

4.2.1.1. **Organization-Specific modules**: these are modules that were designed and produced by UTSW. The total recording time is approximately 4 hours. The following are designated as required viewing, including completed quizzes (as applicable), to demonstrate successful completion of the CITI course:

- Leadership Welcome and Major Departments (ID 21058)
- Scientific Principles of Clinical Research (ID 21056)
- Introduction to Clinical Research at UT Southwestern Medical Center and Affiliates (ID 21059)

4.2.1.2. CITI created content - These content modules created by CITI consist of both basic as well as advanced level topics. The total time to view all the materials and complete the quizzes (as applicable) is anywhere from 4 to 8 hours, depending on the learner. The following are designated as required viewing, including completed quizzes (as applicable), to demonstrate successful completion of the CITI course:

- Project Management for Clinical Trials (ID 17864)
- Preventing and Identifying Misconduct and Noncompliance (ID 17865)
- Training and Mentoring (ID 17866)
- Financial Management of Clinical Trials (ID 17867)
- Subject Recruitment and Retention (ID 17868)
- Statistics and Data Management of Clinical Trials (ID 17869)
- CRC: Overview (ID 16682)
- Planning Research (ID 16751)
- Funding, Financial Management, and Budgeting (ID 16752)
- Working with the Institutional Review Board (IRB) (ID 16753)
- Protocol Review and Approvals (ID 16754)
- Principal Investigator (PI) Responsibilities (ID 16755)
- Clinical Research Coordinator (CRC) Responsibilities (ID 16756)
- Sponsor Responsibilities (ID 16757)
- Informed Consent (ID 16758)
- Site Management, Quality Assurance, and Public Information (ID 16759)
- CRC Resources (ID 16774)

4.2.2. All the above courses must be reviewed, and all quizzes completed (as applicable) with an overall average 80% passing score, to receive certification from CITI that demonstrates successful completion of the course.

4.2.3. CITI has also created modules that are designated as electives. Individuals may choose to review this content, but it is not required to fulfill the CRF CITI training curriculum requirement. Moreover, review and completion of these courses do not count toward the overall average passing score: Further details of elective courses can be found below:

- Specialty Areas and Regulatory Requirements (ID 17870)
- Overview of the Clinical Trial Agreement (CTA) (ID 17356)
- Understanding the Terms of the Clinical Trial Agreement (CTA) (ID 17357)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA) (ID 17358)
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites (ID 17359)

4.3. Clinical Research Designated Job Codes

4.3.1. Individuals who are either new to UT Southwestern or transfer internally from a non-research designated job code to a clinical research-designated job code will be required to take CRF CITI training as part of their onboarding process to their new role.

4.3.2. The following job codes are recognized as clinical research job codes:

Table 1. Clinical Research Job Codes

Job Code	Job Title
2501	CLIN RESCH ASSIST I
2502	CLIN RESCH ASSIST II
2503	CLIN RESCH ASSIST LEAD
2504	CLIN RESCH COORD I
2505	CLIN RESCH COORD II
2506	CLIN RESCH COORD LEAD
2507	SUPV CLIN RESCH
4367	MGR CLIN RESCH
4362	MGR RESCH PRGMS
4379	PROJECT MANAGER CLINICAL RESEARCH
1037	RESCH RN
1035	RESCH RN SR
2508	SUPERVISOR RESEARCH NURSE
2509	MANAGER RESEARCH NURSE
9713	ADVANCED PRACTICE RESEARCH NURSE

4.3.3. Any updates to the pre-determined clinical research job code designations will be considered on a case-by-case basis between the Assistant Vice President for Human Research Administration, HRPP, as well as the Associate Vice President, Clinical Research Services within the OCR.

4.3.4. Once a new job code is approved for inclusion to the clinical research job codes list, this SOP as well as the Clinical Research Foundations website will be updated with this pertinent information: Clinical Research Foundations: Human Research Protection Program - UT Southwestern, Dallas, Texas.

4.4. Process to Identify Clinical Research Staff Eligible for Training

4.4.1. A weekly report from Human Resources (HR) will be sent to the OCR containing individuals in the job titles outlined in 4.3.2. This Excel spreadsheet will capture all UTSW employees (1) with an effective start date within the past week, or (2) that started under a clinical research-designated job code (see Table 1 in Section 4.3). For point (2), these will include individuals that transferred from a non-clinical research designated job code to a clinical research designated job code.

4.5. Outreach and enrollment into the training curriculum

4.5.1. Once an individual has been identified as required to take the CRF CITI training curriculum (per Section 4.4), they will be contacted by the OCR via email with a Welcome email message within 5 days of date of hire.

4.5.2. Individuals are required to complete the CRF training within 30 days from receipt of the OCR Welcome email.

4.5.3. Individuals will need to enroll on the CRF course through the CITI training platform and complete the training. Course completion will only be valid if completed through the CITI portal. Further details and a tip sheet for using the CITI for CRF completion can be found here.

4.6. Exclusions from CRF CITI Training

4.6.1. Individuals who are credentialed through the Medical Staff Office (MSO), Graduate Medical Education (GME), or Registered Nurse (RN) Ambulatory training programs are not required to enroll in the CRF CITI course curriculum through the OCR. A list of licensed job titles that this situation should cover can be found below:

Table 2: Exempt Categories from CRF CITI Training

Responsible Office	Exempt Research Personnel
Medical Staff Office (MSO)	MDs (currently practicing with USA license to practice), Advanced Practice Providers (APPs) (including Physician Assistants (PAs) and Nurse Practitioners (NPs)

Graduate Medical Education (GME)	MD Residents (currently training and practicing at UTSW/CHH/Parkland Hospital with USA license to practice)
Registered Nurse (RN) Ambulatory Training	Ambulatory RNs and Apheresis Nurses currently trained at Clements University Hospital (CUH) or associated clinics.

4.6.2. Employees transferring from a current clinical research job title or hired under a legacy clinical research job code (e.g., 4377 – Research Study Coordinator, 4413 – Research Assistant II, etc.) may not be required to complete the training if these employees demonstrate current clinical research experience and scope of work at UTSW.

4.6.3. Temporary workers who are employed by departments to assist the department on a temporary or contractual basis may be required to complete the CRF CITI course training requirements, as part of their research credentialing requirements. This will be determined by the OCR Research Credentialing team as part of their review. Department heads will also have the latitude to require CRF CITI course training for their temporary workers as part of their existing departmental policies.

4.6.4. If an employee does not fall within one of the above designations and is unsure whether they are required to take the CRF CITI course curriculum, they can reach out to the OCR at OCR@UTSouthwestern.edu to confirm whether CRF CITI training is required.

4.6.5. Any individuals who do not fall within Table 1 or Table 2, whether for inclusion or exclusion, may also be flagged for further review by the OCR while reviewing the weekly download from HR. If necessary, the employee's current supervisor will be contacted by the OCR for additional information. These individuals will then be reviewed on a case-by-case basis by OCR leadership to determine whether CRF CITI course training is required. If training is determined to be necessary, then the OCR will send the Welcome email message (see Section 4.5).

4.6.6. On occasion, an employee and/or employee's direct supervisor may feel that the employee should not be required to participate in the mandatory CRF CITI training despite being mandated by the OCR (see Section 4.5). If so, they can appeal the mandatory requirement via email to OCR@UTSouthwestern.edu. The OCR will review appeals on a case-by-case basis.

5.0 Confirmation of Course Completion and Escalation Procedures

5.1. General

5.1.1. Evidence of successful completion of the CRF course within CITI must be demonstrated no later than 30 calendar days from receipt of the Welcome email message from the OCR.

5.1.2. The OCR will confirm that the newly hired or newly transferred staff has enrolled to the appropriate CRF CITI course within 7 calendar days from the date of the Welcome email message. If the

employee has not enrolled in the CRF CITI course within 7 calendar days, a First Reminder email will be sent to the employee and their direct supervisor.

5.1.3. If the individual has not successfully completed the CRF CITI training within 5 calendar days of the final 30 calendar day deadline, the OCR will email the employee and the employee's direct supervisor to remind them of this upcoming deadline.

5.1.4. Final confirmation of successful completion of the CRF CITI course completion by the 30-calendar day deadline will be performed by the OCR. If the CRF course is not completed by the 30-calendar day deadline, then the Department Chair and Department Administrator will be directly contacted, and research activities may be limited. **Consequences of non-compliance are outlined in Section 6.**

6.0 Non-Compliance with CRF CITI Training Requirements

6.1. General

6.1.1. If the CRF CITI course is not completed by the 30-calendar day deadline, then the Department Chair and Department Administrator for that employee will be notified of non-compliance.

6.1.2. Non-compliance with the program may result in revoking privileges of an employee's participation in clinical research studies until this training is completed. **The consequences for non-compliance until successful CRF CITI completion are outlined in Section 6.2.**

6.1.3. A grace period may be extended to individuals who are unable to complete their CRF CITI course training requirements in a timely manner due to extenuating circumstances. This grace period request must be initiated by the employee and/or employee's supervisor with proper justification for approval. **The parameters and process for this grace period are further outlined in Section 6.3.**

6.2. Consequences for Non-Compliance until CRF CITI Resolution

6.2.1. The Associate Vice President of Clinical Research Services and OCR leadership will work with the Department Chair, HRPP office and Department Administrator to either suspend or revoke privileges from the employee, including suspension from all research activities. The suspension will remain in place until the CRF CITI training has been satisfactorily completed and confirmed on the CITI website by the OCR.

6.3. Grace Period

6.3.1. Situations may arise that require an extension from the 30-day calendar requirement for CRF CITI course training.

6.3.2. The following situations are recognized by the OCR that may require extensions, but are not limited to:

6.3.2.1. Extended leave of absence due to medical reasons (e.g., illness or injury)

6.3.2.2. Extended leave of absence due to military leave

6.3.2.3. Extended leave of absence due to personal reasons (e.g., pre-approved vacation)

6.3.2.4. Extra training and credentialing requirements as mandated by multiple institutions (e.g., CRC is working at both UTSW and Children's and facing multiple deadlines)

6.3.3. To be granted a grace period, the employee and/or supervisor must email the OCR and request an extension, *preferably in advance of the final deadline*.

6.3.4. Regardless of who reaches out to the OCR requesting a grace period, both the employee and his or her supervisor will receive a confirmation email from the OCR acknowledging the grace period with a defined deadline. This will ensure that all parties are aware of the deadline and program expectations.

6.3.5. If an extension is granted by the OCR, the employees records will be updated with this new deadline date. If the new deadline is not met, then OCR leadership will be contacted to determine next steps and consequences may ensue as outlined in Section 6.2.

7.0 Troubleshooting

7.1. General

7.1.1. General enquiries related to the UT Southwestern CRF CITI course curriculum training process should be directed to the email inbox at OCR@utsouthwestern.edu. A member of the OCR team will respond within 2-3 business days to any queries submitted related to the CRF CITI course.

7.1.2. For issues related to broken hyperlinks or outdated information on the content created by the program, send an email to OCR@utsouthwestern.edu.

7.1.3. For issues related directly to CITI access, tips on completing assigned modules within CITI and/or additional information regarding navigating the CITI website, individuals will be referred to the CITI tip sheet at CITI Instructions (citiprogram.org) or informed to contact CITI at support@citiprogram.org or to 888-529-5929.

8.0 Associated Documents and Resources

8.1. General

8.1.1. The following documents have been prepared to assist clinical researchers complete the CRF CITI course requirements.

- Clinical Research Foundations Curriculum: crf_training_crf_curriculum_2023.pdf (utsouthwestern.edu). This document explains all the components of this training program with brief descriptions for each segment.
- Clinical Research Foundations website main landing page: Clinical Research Foundations: Human Research Protection Program - UT Southwestern, Dallas, Texas
- Clinical Research Training Resources website: Clinical Research Foundations Training: Human Research Protection Program - UT Southwestern, Dallas, Texas
- Frequently Asked Questions website: Frequently Asked Questions: Human Research Protection Program - UT Southwestern, Dallas, Texas

8.1.2. The following documents have been prepared and are offered as additional resources to the participants accessing any aspect of the program:

- Clinical Research Handbook: 01 Introduction.docx (utsouthwestern.edu). This handbook will be updated annually in November, or mid-year if required, and is intended to accompany and complement the CRF CITI course curriculum and to serve as an additional resource.
- The Joint Task Force for Clinical Trial Competency created a core competency framework for clinical research professionals: Home - Joint Task Force for Clinical Trial Competency (mrctcenter.org). This served as the basis for our new education curriculum.
- The OCR have put together an Onboarding Checklist to help clinical researchers navigate getting set up at UT Southwestern Medical Center.