Clinical Research Foundations Mentoring Program

Program Purpose and Objectives:

The **Clinical Research Foundations Mentoring Program** is one of the core structures that supports the Clinical Research Foundations Training Program. The purpose of this mentoring program is to facilitate the overall development of the employee by providing a ***resource*** and ***networking*** environment that will promote the concepts and skills necessary for new clinical research mentees to be successful in their role. The objectives of the Clinical Research Foundations Mentoring program are as follows:

1) Retention, Engagement, and Empower – Support and retain talented staff by empowering them through training
2) Succession Planning – Creation of a trained talent pool that can become future leaders
3) Development of Professional Learning – Standardized program that is recognized at UTSW
4) Create Culture of Continuous Learning – Through three distinct levels: Foundations, Skilled, and Advanced
5) Career Growth and Development – Through networking opportunities and hands on training

Program Participants:

Mentees

Mentees in the Foundations Level of the Mentoring Program will be:

- Either a new hire or newly transferred to a designated Clinical Research role for less than 30 calendar days. These roles are outlined here
- Signed up for the **"Clinical Research Foundations" training** through the **CITI training platform**

As of 2024, the CRF Mentoring Program will be open only to newly hired or transferred employees at UTSW. **Participation in the Clinical Research Foundations Mentoring Program is a required component of the Clinical Research Foundations Training Program** and must be completed by individuals onboarding in a Clinical Research designated role. A list of these roles can be found here. If you have any questions about the enrollment process and/or criteria, please email us.

Mentors

Mentors are **strongly** urged to complete the **"Clinical Research Foundations" (CRF) training** through the **CITI training platform**. This is suggested since mentors will be paired with research professionals completing the Clinical Research Foundations training, *and the mentees will be instructed to reach out to their mentors for any questions about the CRF content while they are completing it*.

Mentors in the Foundations Level of the Mentoring Program will be:

- Active in a Clinical Research role for ≥ 3 years. Note: experience at other institutions will be considered in the total time count
- Ideally have completed the **"Clinical Research Foundations" training** through the **CITI training platform** or planning to complete the training prior to being assigned to a mentee
- Able to commit to the time needed to participate in the program. The program is expected to take anywhere from three to four months to complete.

Modules

Participants in the foundations level of the mentoring program will cover the following topics through six modules. Each module is focused on specific knowledge objectives and activities as follows:

Module 1: Introduction to Mentoring Program and Establish Goals	
Knowledge Objectives	Activities
• Recognize the benefits served through mentoring and prepare for a successful experience	• Meet and Greet discussion and sign the Code of Mentorship
• Review SMART goal structure and create a goal	• Implement a SMART goal
• Outline a plan for future meetings	• Mentor review program handouts and resources with mentee
	• Review Clinical Research Foundations (CRF) CITI progress
Module 2: Data System Management at UTSW	
Knowledge Objectives	Activities
• Understand how effective data collection, management, and quality are the foundation for all clinical research activities	• Talk about the research process, focusing on the data
• Identify and understand processes that assure data quality. Recognize the importance of data security	• Review Electronic Data Capture (EDC) systems access, ensure that research account has been set up, including access to REDCap and VELOS. Examine hospital's Electronic Medical Record (EMR) system, using a study protocol to identify where the information can be located for a patient on study
• Identify data that contains Protected Health Information (PHI) or restricted information	• Review and practice identifying PHI
Module 3: Study Protocols and Informed Consent	
Knowledge Objectives	Activities
• Identify the major components of a study protocol	• Review a protocol currently assigned to the mentee
• Recognize the importance of conducting informed consent per Good Clinical Practice standards	• Shadow the mentor during an informed consent discussion
• Be able to describe in plain language the risks and benefits of participating in a research study to a potential patient	• Review the informed consent for one of the most complicated studies that the mentee is assigned to. The mentee will practice performing informed consent with the mentor
	• Review SMART goal, check in on progress, discuss strategies to see the goal to success
Module 4: Adverse Events and Reporting	
Knowledge Objectives	Activities
• Be familiar with the concept of unanticipated/adverse events and understand where to locate UTSW resources for reporting, including timelines	• Review different situations that need to be reported. Practice organizing information for a reportable event submission in the eIRB system
• Review Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)	• Review an AE tracking log for an existing study and compare it to the protocol. Discuss reasons why these AEs were necessary to put into the log
• Comprehend the significance of reporting based on government regulations	• Practice how to interview a subject when an unanticipated event has occurred and gather enough data for reporting purposes
Module 5: Project Management of Clinical Research	
Knowledge Objectives	Activities
• Possess a basic understanding of how the clinical research management systems work together at UTSW for subjects on study	• Review role and job description to determine appropriate scope of practice

• Be familiar with Scope of Practice when implementing research activities	• Take the most "complicated" protocol that is currently assigned to the mentee and review what steps would be needed to coordinate the visit
• Apply the above-referenced knowledge or understand the steps toward successfully scheduling a subject's research visit	• Practice entering a study visit in the EMR, including how to request a lab draw, schedule special services (e.g., a CT scan, etc.) as applicable for the department
Module 6: Ethical Conduct of Research	
Knowledge Objectives	Activities
• Apply lessons learned from previous modules to recognize the best course of action to take when faced with a challenging situation	• Review a series of ethical situations and discuss what would be the best course of action
• Be aware of resources and when to reach out for assistance	• Discuss the current resources available for situations that a mentee may need while independently working
• Review the successful resolution of the SMART goal or discuss a plan to finish it outside of the program	• Either close the formal mentorship partnership or arrange to meet informally moving forward

Code of Mentorship

Both the mentor and mentee will be required to sign a **Code of Mentorship** agreement during Module 1. The **Code of Mentorship** agreement is to help the mentee and mentor mutually agree to guidelines that will be the foundation of their relationship as well as to codify ways of increasing the likelihood of achieving success within the program. The expectation is that it will promote a successful Mentor-Mentee relationship that fosters:

- Shared passion, personal compatibility, and shared goals
- Open communication, clearly understood expectations, dedication, and commitment on both sides
- Mutual respect and commitment to practicing good clinical research

Individual Objectives

Upon completion of the **Foundations Level of the Mentoring Program**, the mentee will be able to:

1. Critically evaluate and practice skillets related to clinical trial sites and study management processes by covering major areas of clinical research activities that the mentee will likely encounter within their first year.
2. Review additional concepts and practices from other areas of UT Southwestern Medical Center.
3. Obtain the foundational skillsets to provide more structured and timely updates to their primary PI at future meetings due to self-awareness regarding their integral involvement in clinical research activities.
4. Implement a SMART goal based upon the mentee's needs in relation to the components of clinical trial site and study management that benefit both the department and the mentee's personal career growth and development.

Benefits

There are numerous benefits to participating in the Mentoring program for both the mentor and mentee, some of which include but are not limited to:

- Learn the workplace culture in clinical research
- Networking opportunities
- Accelerate and strengthen skills development
- Become recognized as a participant in the Clinical Research Foundations level of the Clinical Research Training Program with a Certificate of Completion

For further details about the Clinical Research Foundations Mentoring Program, please visit our website or contact the Office of Clinical Research Education Team.