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The Clinical Coordinator

Clinical Research News You Can Use…

Orientation for Clinical Research Staff

Research coordinators usually do not receive formal training for their jobs, which is an issue considering the central role they play in the successful completion of clinical research. UTHealth's coordinator education programs aim to fill this gap. The cornerstone of these programs is a formal 3-day clinical research education (CRE) course, which is a comprehensive introduction to good clinical practice (GCP) and clinical trial management. This 3-day CRE course is offered once a year in October. To supplement this yearly course and allow more frequent opportunities for training, a condensed version, the orientation program for clinical research staff, is offered once every 2 months.

The clinical research staff orientation began in 2013 and has evolved to a 1-day educational program that provides an overview of clinical research conduct at UTHealth. The orientation begins with an introduction to various resources available at UTHealth to help clinical research staff. Next, representatives from UTHealth's IRB office and the Memorial Hermann Healthcare System (MHHS) Clinical Innovation and Research Institute (CIRI) office talk about their respective review and approval processes for research projects, as well as share tips for successful submissions and quick turnaround times. Sponsored Projects Administration (SPA) staff also present on grants and contracts submission and review processes and share resources available for clinical trial coverage analysis and budget development. Further, an experienced research nurse or coordinator covers the basics of clinical trial management throughout the lifecycle of a clinical research study, with special emphasis on best practices in clinical trial management. Finally, the services of the Clinical Research Unit (CRU) are discussed, and regulatory issues such as ClinicalTrials.gov, INDs, and IDEs are outlined.

While the orientation program is geared towards research staff who are new to clinical research at UTHealth, experienced research staff are welcome to attend. Participation in this orientation program is not mandatory, but it's highly encouraged. The next clinical research staff orientation is scheduled for April 18, 2017 from 9 am to 3 pm at UCT 1505C. Breakfast and lunch will be provided, and parking will be validated. If you'd like to participate, please register here.

Test your knowledge about Good Clinical Practice (GCP)! Answers are found below.

1. What is a "major" versus a "minor" protocol deviation?
2. Whose responsibility is it to assess whether a protocol deviation is major or minor?
3. What is the timeframe for reporting a major protocol deviation to CPHS?
4. What information should be included in the major protocol deviation report to CPHS?
5. How are minor protocol deviations documented and reported?

Answers: 1. Major deviations impact patient safety (minor deviations do not). **2.** PI. **3.** Within 7 days of PI's first knowledge. **4.** Details of deviation and corrective action plan. **5.** Keep a deviation log, and submit it at continuing review. [**For more information** (i.e., how-to for deviation reports and corrective action plans), see the protocol deviation policy at this link.]

Upcoming Training

Orientation for Clinical Research Staff

Objective: General overview of clinical trial research at UTHealth, including study start up processes and clinical trial management.
Date: April 18, 2017
Time: 9:00 am – 3:00 pm
Location: UCT 1505C (UCT parking will be validated)
Breakfast and lunch provided.
Free. Registration is required. Register here.

Methodist Hospital Educational Series

Date: April 18, 2017
Topic: Coordinating a Multicenter PI-Initiated Trial (Raquel R. Bunge, RN, BSN, CCRC, Clinical Trials Manager, Academic Office of Clinical Trials, HMRI)
Time: 12:00 pm – 1:00 pm
Location: Houston Methodist Hospital Fondren 100 Conference Room
Light refreshments may be served, and you are welcome to bring a snack.
Free. Registration is not required. CE may be available.

Western IRB Open Forum

Objective: To assist with the Western IRB application process.
Date: April 21, 2017
Time: 9:00 am – 11:00 am
Location: MSB 3.001
Breakfast provided for first 25 participants.
Free. Registration is not required.

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management, and network with administrators and staff from various research groups within UTHealth. More information here.
Date: May 10, 2017
Topic: Protocol Deviation and CAPA (Audrey Williams & Carolyn McKinney)
Time: 11:30 am – 1:00 pm
Location: MSB B.605
Lunch provided for the first 40 participants.
Free. Registration is not required.

About the Clinical Trials Resource Center

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Please visit https://www.uth.edu/ctrc/ for more information.

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