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The Clinical Coordinator

Clinical Research News You Can Use…

CITI COI Training is not Required Because COI is Covered in Mandatory UTHealth Training

In an effort to minimize the burden of ongoing training requirements, UTHealth's CPHS would like to point out that taking the CITI Conflict of Interest (COI) course is neither required nor necessary. All employees take the mandatory online UTHealth training each spring, and this online UTHealth training includes a COI module that satisfies UTHealth (and CPHS) policies. Taking the CITI COI course is a duplication of effort and not necessary.

ICMJE Will Require Data Sharing Statements Starting Next Year

In January of 2016, the International Committee of Medical Journal Editors (ICMJE) released a proposal for sharing deidentified individual participant data from clinical trials (proposal at this link). ICMJE recognizes that there are currently significant challenges to sharing this data, and on June 6, 2017 ICMJE announced that they will not yet mandate data sharing but will in the meantime require data sharing *statements*. Requirements for these statements are described by the editorial at this link and, briefly, are as follows:

1. As of July 1, 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement. Required components of this statement and examples are found in the editorial at the above link.

2. Clinical trials that begin enrolling participants on or after January 1, 2019 must include a data sharing plan in the ClinicalTrials.gov record. ClinicalTrials.gov offers fields that allow this requirement to be met.

UTHealth Good Clinical Practice (GCP) Corner

Topic: Records & Reports

1. What should data that are reported on the Case Report Form (CRF) be consistent with and derived from?
2. What should happen if there is inconsistency between the data on the CRF and the source documents?
3. Any change or correction to a CRF should be dated and initialed and should not obscure the original entry.
4. What type of documents individually and collectively permit evaluation of the conduct of research and the quality of data produced?
5. What are some examples of essential documents?

Answers: 1. Source Documents. **2.** Documentation should be made to explain the discrepancy. **3.** True. **4.** Essential Documents. 5. IRB-Approved Protocols and Informed Consent Documents, Signed Consent Forms, Investigator Brochure, IRB Approval Letter, Source Documents, Case Report Forms, Unanticipated Problem Reports, Adverse Event (AE) Reports, Drug Accountability Logs, Monitoring Visit Reports, Audit Reports, Study Participants Master Contact Log.

Upcoming Training

iRIS Training

Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth's CPHS and AWC.
Date: June 28, July 20, and August 16, 2017
Time: 1:30 pm – 4:00 pm
Location: UCT 1155 (parking will be validated)
Free. Registration is required. Register here.

Orientation for Clinical Research Staff

Objective: General overview of clinical trial research at UTHealth, including study start up processes and clinical trial management.
Date: June 20, 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.

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: July 12, 2017
Topic: CTX 100-day Wait Less Challenge
(presented by Patricia Winger)
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Lunch provided for the first 40 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: August 9, 2017
Topic: FDA Presentation
Time: 11:30 am – 1:00 pm
Location: MSB 3.001
Lunch provided for the first 50 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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