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The Clinical Coordinator

Clinical Research News You Can Use…

CRF – Case Billing Requests & One-On-One Training

The Clinical Research Finance Team (CRF) in Sponsored Projects Administration (SPA) now handles clinical Research Case Billing setups. If a research patient needs a new case to be set up, or if an existing case needs to be extended, then complete the case billing request form, and email it to CRF@uth.tmc.edu. A stand-alone case billing request form can be found on the SPA Forms website at this link: https://go.uth.edu/spa.

The CRF Team is happy to provide in-depth, one-on-one training to assist department administrators with budget development and coverage analysis for clinical trials. If you would like to schedule a one-on-one training, please email CRF@uth.tmc.edu or call CRF's main line at 713-500-3073.

NIH and FDA Release a Clinical Trial Protocol Template

The NIH and FDA have released a clinical trial protocol template, as announced by the NIH Notice at this link. A Word version of the template is found at this link. The template contains instructional and example text, and it follows the International Conference on Harmonisation (ICH) E6 (R2) Good Clinical Practice guidelines. NIH and FDA designed this template specifically for phase 2 and 3 clinical trials that require an IND or IDE, but it can be used as a resource for any trial.

The NIH has also released a secure, web-based e-Protocol Writing Tool (found at this link), which uses the new protocol template described above. The tool allows multiple people to work on a single protocol, and it can assist in progress tracking and document version control. In the future, the tool will include instructional and sample text for behavioral and phase 1 trials, as well as other enhanced functionality.

UTHealth's Clinical Trials Resource Center (CTRC) provides 2 protocol templates for download at this link.

Test your knowledge of Good Clinical Practice (GCP) - TRUE or FALSE?

1 ***Source Data*** are all of the pieces of information in the original records about a clinical trial's clinical findings, observations, or activities that are necessary for the reconstruction and evaluation of the trial.
2. ***Source Documents*** are the original documents (or certified copies of the records) where source data are contained.
3. Examples of ***Source Documents*** are hospital records, clinic/office charts, lab reports, radiology reports, subject diaries, pharmacy dispensing records, and surgical reports.

Answers: 1. True. **2.** True. **3.** True.

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: May 18, June 8, and June 28, 2017
Time: 1:30 pm – 4:00 pm
Location: UCT 1155 (parking will be validated)
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: June 14, 2017
Topic: UT CRF: Coverage Analysis and Budget Dev. (John Valenta & Kyle Jernigan)
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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