The HCCA Research Compliance Conference was held during the first week of June 2015, with five UTHealth employees in attendance.

One conference session in particular was pertinent to study teams—“Heed the Warnings: Using FDA Warning Letters to Stay Audit Ready,” delivered by Kristin West, JD, MS, Associate Vice President and Director of the Office of Research Compliance at Emory University. In her talk, Kristin discussed the top findings from FDA warning letters. The FDA posts all warning letters here, and some of the most common violations are discussed below.

**Protocol Noncompliance**

The most common citation is protocol noncompliance, that is, the failure to conduct a study in accordance with the investigational plan.

*Examples include:* missing safety labs, no documentation of the reasons a participant missed a test or a visit, failure to ensure eligibility criteria were met, and making changes to the protocol without first obtaining IRB approval.

**Inadequate Case Histories**

The second most frequent finding is the failure to maintain adequate and accurate case histories with respect to data or informed consent.

*Examples include:* failure to complete case report forms, failure to maintain source documentation that supports the data in case report forms, failure to document the review of lab results, failure to properly document informed consent, lost records, and failure to document the timely review of adverse events.

**Informed Consent Violations**

Another common and serious citation is the failure to obtain informed consent in accordance with 21 CFR Part 50 from each human subject prior to administering study drug or conducting study-related tests.

*Examples include:* no consent before administration of the test article, missing consent forms, participants did not sign and date consent, most recent IRB-approved consent was not used, re-consent was not obtained or not obtained in a timely manner, consent did not contain required elements, inappropriate time period between consent signature and the first study procedure, and improper consent of non-English speaking subjects.

**The Take Home Message**

Many citations could have been avoided by keeping good documentation. If it’s not documented, then it didn’t happen!

To ensure that your team’s records are audit ready, you may contact CTRC to request a routine, not-for-cause monitoring visit: [clinicaltrials@uth.tmc.edu](mailto:clinicaltrials@uth.tmc.edu).
Upcoming Training

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.
Date: July 28, 2015
Time: 11:30 am – 1:00 pm
Location: MSB 2.135
Lunch provided for the first 40 participants.
Registration is not required. Information here.

Clinical Research Education Program
Objective: Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. Days 1 and 2 focus on clinical trial management, and day 3 focuses on clinical trial finance and contracting.
Date: October 2015
Time: 8:30 am – 4:30 pm
Location: Cooley University Life Center
Registration will open soon.

Orientation for Clinical Research Staff
Objective: Educate new clinical research personnel on clinical trial management, as well as the IRB review and Memorial Hermann study start up processes. The program will lead into the Study Coordinator Forum.
Date: August 25, 2015
Time: 8:15 am – 11:30 pm
Location: MSB 2.104B
Registration is required. Register here.

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: July 1, 2015
Time: 1:30 pm – 4:00 pm
Location: UCT 1160
Parking will be validated.
Registration is required. Register here.

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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