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TIPS FOR FDA AUDITS
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Inspections required by the FDA are eminent at one time or another in your career in clinical research. An audit may be required because of an issue at the site or may be required because the site has a stellar reputation for high enrollment and for every reason in between those two.

First Tip: Don’t Panic.

When you are contacted by the FDA for an audit, respond promptly and schedule the inspection. Take time to breathe, alert the study team, and schedule an inspection that allows enough time to prepare and be readily available. The time for preparation may mean several days but delaying any further may cause concern to the inspector and appear that you are delaying the inspection.

“Do not think you must handle this inspection in silence”

Second Tip: Alert Helpful Resources.

Every institution that conducts clinical trials has wonderful people that specialize in research compliance or regulatory affairs and here at UTHealth, we have the CCI and CTRC as well! Contact these offices to help in sharing this burden of preparation. Do not think you must handle this inspection in silence or under a shroud of shame, these inspections happen to all of those in the clinical research community for various reasons.

Third Tip: Take Notes.

The inspector will make observations and record notes. When you see or hear of this, jot it down in a list. These observations or “citations” will be included in your follow up letter and will need to be resolved. Why not start early? When you take your own notes, you are able to start immediately and resolve the issues you know.

Do not hesitate to ask the inspector to go over the citations or explain those you find confusing in the exit interview. Be polite and non-argumentitive during this time and remember that nothing said to the inspector at any time during the entire visit is considered “off the record”.

Fourth Tip: Don’t Panic.

The FDA is on your side. We all work for the benefit of research and safely conducting research on human subjects. Focus on quality improvement at your site and do not dwell on the past. Learn from it. Take the entire visit as a learning experience and know that help is always available, you need only ask. For more tips on FDA Audits visit the CTRC website.
UPCOMING TRAINING

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management and network with research administrators and staff from various research groups within UTHealth.
Dates: Every 4th Tuesday of the month
Time: 11:30 a.m. – 1 p.m.
Location: MSB 2.135
Lunch provided to the first 40 participants
Registration is not required.
More information here.

Clinical Research Education
Objective – Promoting excellence in clinical trial management for research nurses, study coordinators and other research staff. Day 1 focuses on clinical trial finances and contracting, day 2 and 3 focus on clinical trial conduct.
Time: 8 am to 4 pm
Location: Cooley University Life Center.
Registration will be opened in Summer 2013.

Orientation for Clinical Research Staff
Objective – This educational program is designed to be a general overview of clinical trial research at UTHealth. This five hour program will cover basics of CPHS (UTHealth IRB) review and approval process, Memorial Hermann Hospital review and approval process, clinical trial financial management, and clinical trial management.
Dates: August 6 and December 3, 2013.
Time: 8 am to 1 pm
Location: UTPB 1100:55
Registration is required. Register here.

iRIS Training
Objective: Hands on training in the iRIS system to submit research protocols involving human subjects to the IRB.
Dates: Jun 6 and Jun 26, 2013.
Location: UCT 1160 (subject to change)

About Clinical Trials Resource Center
It is the mission of the Clinical Trials Resource Center to provide a single portal of expertise, and best practices for the study team to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Visit www.uthouston.edu/ctr for more information.

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