Clinical Research Education Course

The Clinical Research Education Course was held on April 15-17, 2014 in UTHealth’s Cooley Conference Center. The course offered lectures by UTHealth and Memorial Hermann (MHHS) staff, as well as interactive activities and workshops. About 40 participants attended the course.

Days 1 and 2 focused on guidance for good clinical practice guidance. The first day began with an introduction to clinical research and continued with presentations on IRB and MHHS review, study initiation, study documentation, and the consent process. The day ended with an interactive session that allowed attendees to evaluate special circumstances that may arise during the informed consent process. Day 2 continued with presentations on subject recruitment and retention, investigational drugs and devices, unanticipated problems, research compliance, and study closure. To cap off the talks on good clinical practice, attendees competed in a game of Jeopardy to win copies of the 2013 CFR/ICH GCP Reference Guide.

Day 3 of the course focused on clinical trial financial management. Topics included basic financial principles, an overview of UTHealth’s financial systems, negotiating and processing contracts, Medicare coverage analysis, MHHS’s processes for budgeting and billing of research services, and financial reconciliation. To conclude the course, attendees completed a mock study budget in a hands-on workshop.

“The Clinical Research Education course is fantastic,” commented Renee Collins, Senior Sponsored Projects Specialist in OSP. She added, “The CTRC team provided attendees with a vast amount of knowledge and offered additional resources for specific departmental questions and concerns. The course provides you with a renewed passion and commitment for the role that you serve. I would advise any staff member who is involved in clinical research administration to attend this training.”

Mina Fanous, MBBS, Research Assistant in the Department of Radiology stated, “The course has far exceeded my expectations. Topics were covered in just enough detail to give a clear picture of the steps necessary to implement a clinical trial at UTHealth. Additionally, I met wonderful colleagues from different departments. Catrina, Sujatha, and Trae made the atmosphere relaxed and fun, and they were attentive, energetic, and enthusiastic. Very well done!”

Registration for the Fall 2014 course will open soon. Look for announcements on the CTRC website.
UTHealth has developed an internal process for coverage analysis. The initial focus will be on industry-sponsored clinical trials, and **coverage analysis for certain industry-sponsored trials will be mandatory starting June 1, 2014.**

**What is coverage analysis?**
Coverage analysis is a review of all of the procedures listed in the study protocol’s schedule of events to determine which ones are eligible for billing to a third party, such as Medicare. This review is integral to ensuring clinical research billing compliance.

**Who will conduct the coverage analysis?**
UTHealth’s Clinical Trials Resource Center (CTRC) will ensure that a formal coverage analysis is completed when required. CTRC staff will assist the designated members of the research team or department in conducting coverage analysis.

**Does my clinical trial require coverage analysis?**
If the research sponsor is willing to pay for all of the procedures in the study schedule, then a formal coverage analysis is not needed. On the other hand, if some costs are billed to a third party payor, such as Medicare, then a formal coverage analysis is required. CTRC will work with researchers and research staff to assist them in making this determination.

**What is the basic process for coverage analysis?**
When studies are submitted via iRIS for CPHS review, CTRC will identify those that require coverage analysis and will then reach out to the study team to offer assistance. If you’d like to know more about this process or would like to learn how to conduct a coverage analysis for your research study, please contact CTRC at clinicaltrials@uth.tmc.edu.

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**CTRC has a New Member**

We are pleased to welcome **Elizabeth Massey Gendel, PhD** to the Clinical Trials Resource Center (CTRC). Liz attended the University of Saint Thomas in Houston, receiving a Bachelor of Science in Biology, and she went on to work with the Human Genome Project at Baylor College of Medicine. Liz then attended UCLA and received a PhD in Biochemistry and Molecular Biology, after which she joined UTHealth as a postdoctoral scholar in the lab of Danielle Garsin in the Department of Microbiology and Molecular Genetics. To explore life outside of the lab, Liz completed an internship in the Department of Scientific Publications at the Texas Heart Institute. She then took on a role in administration, serving as a Sponsored Projects Specialist in UTHealth’s Office of Sponsored Projects.

In her new position as a Regulatory Specialist in CTRC, Liz will assist with ClinicalTrials.gov administration, IRB submission, the IND and IDE processes, and preparation of *The Clinical Coordinator*. Welcome, Liz!
IRB FEES ARE REQUIRED for the review of initial and continuing review of INDUSTRY SPONSORED protocols. Effective September 2013, the IRB fee is $2600 for initial review and $650 for continuing review. For contracts below $5000, please discuss the possibility of a waiver with the IRB Director.

For protocols submitted to Chesapeake IRB, CPHS administrative fee will be $1300 for initial review and no charge for continuing reviews.

For protocols reviewed by Chesapeake IRB, please make arrangements with the sponsor to pay Chesapeake IRB directly. If the sponsor does not agree to be billed directly by Chesapeake IRB, ensure that the sponsor will pay for all the Chesapeake IRB invoices + a 30% IDC.

To address concerns about IRB fee billing from a variety of individuals, we've established a new IRB fee billing process. IRB fees for initial review, continuing review and administrative fee for initial reviews will be billed directly by the IRB office to the sponsor.

Cristina Dyke, Administrative Services Officer, will generate an invoice based on submissions received by the IRB office. The invoice will be sent to the sponsor contact listed on the application and copied to the study team contacts at UTHealth. The IRB initial application has been revised to include sponsor contact information for IRB billing purposes. For existing research, Cristina will contact the study team to obtain sponsor contact information.

For questions regarding an IRB fee invoice, contact Cristina Dyke. For general comments or suggestions about the new IRB fee billing process, please do not hesitate to contact us.

Upcoming Certification Testing Dates

**CCRP certification:** For those of you interested in becoming a Certified Clinical Research Professional, the next test date at The Methodist Hospital in Houston, TX is July 19, 2014 with a registration deadline of June 6, 2014. You can find more information [here](#).

**CCRC certification:** The next exam dates for certification as a Clinical Research Coordinator are in September 2014. Applications for testing open May 1, 2014, and you can find more information [here](#).
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.
Date: April 22, 2014
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 – This educational program aims to promote excellence in clinical trial management for research nurses, study coordinators and other research staff. Day 1 and 2 focus on clinical trial management and day 3 on clinical trial finances and contracting.
Date: Oct 14-16, 2014.
Time: 8 am to 4 pm
Location: Cooley University Life Center.
Registration will open in Summer.

Orientation for Clinical Research Staff
Objective – This one day program provides an overview of clinical trial research at UTHealth. The first half of the day focuses on CPHS review and approval process, MHH hospital review process and clinical trial management. The afternoon session focuses on clinical trial financial management.
Date: June 24, 2014; Aug 26, 2014
Time: 8 am to 3 pm
Location: MSB 2.104B
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.
Date: April 29, 2014, May 22, 2014
Location: UCT 1160 (subject to change).
Register here.

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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