Clinical Research News You Can Use...

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**October’s Clinical Research Education Course**

*Elizabeth Massey Gendel, PhD*

The Clinical Research Education Course was held on October 14-16, 2014 at UTHealth’s Cooley Conference Center. The course offered lectures by UTHealth and Memorial Hermann staff, as well as interactive activities and workshops. About 30 participants attended.

**Days 1 and 2** focused on guidance for good clinical practice. The **first day** began with an overview of research at Memorial Hermann Healthcare System (MHHS) and an introduction to clinical research and continued with presentations on IRB and MHHS review, the Clinical Research Unit, 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, the investigational drug service, investigational devices, unanticipated problems, research compliance and monitoring, and study closure. To cap off the talks on good clinical practice, attendees competed in a game of Jeopardy to win copies of the CFR/ICH Good Clinical Practice 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, negotiation, clinical trial contracts, MHHS’s processes for budgeting and billing of research services, and coverage analysis. To conclude the course, the newly updated **Clinical Trials Budget Tool** was introduced in a hands-on budgeting workshop.

“I really liked the supportive atmosphere,” commented Karina Wlostowska, a Clinical Research Coordinator with the Ironman Sports Medicine Institute at MHHS. She added, “My favorite part of the course was study documentation and organization during the first day, and I will certainly utilize this information in my daily work—bottom line, I would highly recommend this course!”

Adrian Botello, a Research Coordinator at CeTIR stated, “I truly enjoyed the training class. The opportunity to have so many key people in our field sharing their work practices and ideas is just another example of the level of quality that we here at UT Health should strive for. An excellent work ethic is what is being taught in this course. I personally benefited greatly from this experience.”

Registration for the Spring 2015 course will open soon. Look for announcements on the [CTRC website](#).
There have been several changes to the Clinical Trials Budget Tool, so be sure to use the most recent version. The basic format and functionality of the tool remain the same—the changes simply streamline the process by reducing duplicate entry. Changes are described below.

**Step 3a – Device, Drug:** The questions for qualifying clinical trials and device studies have been added to the budget tool as Step 3a. The heading box will autopopulate from the effort tab. Only answer the questions that apply to the study; for instance, device questions will not need to be answered for drug/biologic studies. Submit the completed form, including PI signature, to crf@uth.tmc.edu. Electronic signatures are acceptable. Note that the PDF questionnaires from the CRF website may still be used if preferred.

**Step 3b – CA & EG Account:** The coverage analysis grid and the EG account setup form have been merged into a single document, which eliminates duplicate entry into common fields. The coverage analysis form will now be provided with the HEAT ticket that is used to set up the EG account.

**Step 6 – UTP Charge Document:** The UTP charge document now autofills, which reduces duplicate entry—all of the white fields will feed over from the previous tabs.

For new contracts that are currently in the budget/coverage analysis process, there is no need to change to the new budget tool.

Please contact Heather Cody if you have questions about the form: 713-500-3983 or Heather.Cody@uth.tmc.edu.

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**ClinicalTrials.gov Registration**

*Elizabeth Massey Gendel, PhD*

Studies that are considered to be applicable clinical trials (guidance [here](#)) are required to be registered to ClinicalTrials.gov.

**Why do I need to register my study?**

- It’s required by law ([FDAAA 801](#))
- It’s required for journal publication ([ICMJE](#))
- It’s required by UTH (HOOP 168)
- It’s mandatory for Medicare claims* ([CMS Change Request 8401, MLN Matters SE1344](#))

*Beginning January 2015, it will be mandatory to report a ClinicalTrials.gov NCT number on Medicare claims for items/services provided in clinical trials that are qualified for coverage. Note that MHHS approval of any qualifying trial is contingent upon registration to ClinicalTrials.gov."

For help in determining whether your study requires registration or for help with any aspect of ClinicalTrials.gov registration and results submission, please contact Elizabeth Massey Gendel: 713-500-3587 or Elizabeth.M.Gendel@uth.tmc.edu.
The Clinical Research Unit (CRU) is expanding its offerings to the research community. Due to the fact that the Medical School’s petty cash office has closed, the CRU is now offering this service to all researchers.

This petty cash service may be used to pay research participants for small dollar transactions ($100 or less). The CRU handles the entire process—the only thing the coordinator or PI needs to do is pick up the money and sign the affidavit.

There is a onetime set-up fee to use this service ($25 for NIH studies and $50 for industry-sponsored studies) and a per-visit fee ($11.25 for NIH studies and $16.25 for industry-sponsored studies).

If you are interested in signing up for this service, please contact Cristina Dyke with your request: 713-704-5803 or Myriam.C.Dyke@uth.tmc.edu.

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**Upcoming Certification Testing Dates**

**CCRP certification:** For those of you interested in becoming a Certified Clinical Research Professional, the next test date in Houston, TX is at The Methodist Hospital on January 17, 2015 with a registration deadline of December 5, 2014. You can find more information [here](#).

**CCRC certification:** The next exam dates for certification as a Clinical Research Coordinator (CRC) are in March 2015. Applications will open October 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 administrators and staff from various research groups within UTHealth.
Date: October 28, 2014; November 25, 2014
Time: 11:30 am – 1:00 pm
Location: MSB 2.135
Lunch provided for the first 45 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: April 21 – 23, 2015
Time: 8:00 am – 4:00 pm
Location: Cooley University Life Center
Registration is required and will open soon.

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: November 6, 2014
Time: 1:30 pm – 4:00 pm
Location: UCT 1160
Parking will be validated.
Registration is required. Register here.

Grants 101
Objective: Provide an overview of the process of preparing and submitting a grant application from UTHealth, as well as the review process by funding agencies. Target audiences are junior investigators and administrative support staff.
Date: January 22 – 23, 2015
Time: 8:30 am – Noon
Location: Cooley University Life Center
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 www.uthouston.edu/ctrc/ for more information.

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