Clinical Research Education

The Clinical Research Education Course was held on Oct 22-24, 2013 in the Cooley Conference Center.

Day 1 and 2 focused on good clinical practice guidance for conducting clinical research. After an introduction to IRBs, hospital review and institutional compliance, the afternoon was all about informed consent. The next day the speakers focused on initiating and conducting a clinical research study, study documentation and investigational test article accountability. There were several workshops and activities, one of the most entertaining being a role playing activity on informed consent. There were requests for more workshops for future sessions of the course.

Day 3 of the course focused on clinical trial financial management. Topics covered included discussion of basic financial principles, negotiating contracts and an overview of UT Financial Systems. In the afternoon, the focus was on clinical research budgeting and billing including a hands on workshop for a mock study budget.

“The Research Education Course was a fantastic experience from start to finish. I was able to finally put a face with a lot of the names I see cc’ed on e-mails. The instructors provided great insight and shared the wealth of their experiences. The Cooley Center itself was a great location that was both quiet and state of the art. And the logistics of the conference were flawless – there was plenty of food, drinks, breaks, candy snacks at the table, and parking was no hassle. Attending all three days allowed me to learn much, meet new people in the research community, and the spiral binding for the presenter materials takes up much less space on the bookshelf than a bulky binder. During the game of Jeopardy at the close of day two, it was definitely a highlight to watch the teams competing to see who knew the most about the Belmont Report. [The CTRC] put on one of the most useful (and entertaining) continuing education courses I have attended as a professional. I think the Research Education Course is a great resource for anyone involved in research and comes highly recommended by me.” – Daniel O’Neil, Office of Sponsored Projects.

If you have suggestions for our Fall 2013 session or feedback on our Spring 2013 session, we would love to hear from you, please send your comments to clinicaltrials@uth.tmc.edu.

Registration for the Spring 2014 course will open soon. Lookout for announcements on the CTRC website.
Clinical Research Unit at Memorial Hermann Hospital

Dr. Michael Fallon – Medical Director
Kathy Franco BSN RN, CCRC – Manager
Theresa Dancsak MSN RN - Assistant Manager
Cristina Dyke, BA – Administrative Services Officer I
Monika Ruscheinsky, MS, CPhT – Lab Manager
Cary Warner, MS, CCRC - Regulatory Specialist

*To avoid protocol deviations please be aware of the university’s holiday calendar when scheduling your patients*

Helpful Hints and Contacts for Improved study visits at the CRU

As a part of the METRC study the CRU has learned the following regulatory helpful hints when having multiple similar studies with most of study team remaining the same for each study

1: Many parts of the IRB application can be “copied” and “pasted” from an existing approved study to a new application. In fact, there is a choice in iRIS to “COPY STUDY” and this creates a duplicate draft application that can then be edited for the study specific information. We have used the CPHS approved consent form from the first study as a template for the others.

2: When adding a new study staff member to these studies it is possible to use an “apply to multiple” option in iRIS and this creates a personnel change request for each of the selected studies.

3: Many parts of the regulatory binder (CVs, CITI training, medical license, laboratory certificates) can be saved in one location and a note to file can be placed in each regulatory binder to reference the centralized location of these items. This conserves a great deal of space.

4: We’ve also recently converted many pieces of the regulatory binders to an electronic file (copies of protocol/IB/blank CRFs/CPHS correspondence). This was done with the approval of the study sponsor and CPHS.

For additional information regarding the METRC study, please contact Matt Galpin, Cary Warner, or Robert Hudson at 713-704-4137.

Study Spotlight

The Major Extremity Trauma Research Consortium (METRC) is an effort of approximately 25 military and civilian institutions working together to conduct research giving great diversity and statistical power to the study. The UT Houston site is under the leadership of Principle Investigator Joshua Gary, M.D. Dr. Gary is an Assistant Professor of Orthopaedic Surgery at The University of Texas Medical School at Houston. His area of specialty care is orthopaedic trauma, including pelvic and acetabular fractures, complex fractures and dislocations, malunion and nonunion surgery. Dr. Gary has authored numerous peer-reviewed scientific articles and has presented research at multiple national and international meetings.

METRC is currently composed of seven studies, each focusing on a different form of orthopaedic trauma, “FIX-It”, “BIOBURDEN”, “Registry”, “OUTLET”, “TCCS”, “The Pain Study”, and “The Acetabular Fractures Study”. UT Houston leads the nation in enrollment in three of the seven studies that are being conducted. METRC is funded by the Department of Defense with many of the studies originating directly from treatment and care of our military men and women, translating into civilian care for high impact trauma.
Representatives from the Center for Clinical Investigations (CCI) will continue discussion concerning subject billing and Medicare Coverage Analysis will be discussed at the Regulatory Team Meeting. The Operations meeting will begin to cover Memorial Hermann Credentialing and CRU/MHH registration changes. Anyone is welcome to attend these meetings.

**Finance Team meetings:** UTPB 1100:55 from 2 to 3 pm every third Monday.
**Regulatory Team meetings:** UTPB 1100:55 from 2 to 3 pm every second Monday.
**Clinical Research Operations Team meetings:** UTPB 1100:55 from 2 to 3 pm every fourth Monday.

Attention Research Coordinators: As of June 1, 2013, the UTHealth payment address has changed!

Please make the necessary revisions to all invoices, and make sure all of your sponsors on each of your trials are aware of the new payment address. After December 31, 2013 **all payments sent to the old lockbox address will be returned to the sender** and will therefore be substantially delayed in posting to your project accounts. The new address is:

P.O. Box 301418, Dallas, TX, 75303-1418.

Please feel free to contact paf@uth.tmc.edu if you have any questions.

**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 February 12, 2014 with a registration deadline on December 20, 2013. You can find more information [here](#).

**CCRC certification**: The next test date for a Certified Clinical Research Coordinator is February 27 – March 22, 2014 and application deadline is December 2, 2013 for “early-bird”registration and February 4, 2014 for final registration. 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.
**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.
**Dates:** April 22, 23, and 24, 2014.
**Time:** 8 am to 4 pm
**Location:** Cooley University Life Center.
Registration is required.

**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:** December 3, 2013.
**Time:** 8 am to 1 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.
**Dates:** November 21, 01:30 pm – 04:00 pm
**Location:** UCT 1160 (subject to change).
Register [here](#).

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**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/cctr](http://www.uthouston.edu/cctr) for more information.

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