The Clinical Research Education Program will be held on April 21 – 23, 2015 at UTHealth’s Cooley Conference Center. The first two days of the course will focus on guidance for good clinical practice, while the third day will be devoted to clinical trial financial management.

Day One will begin with an introduction to clinical research and will continue with presentations on IRB and MHHS review, study initiation, study documentation, and the consent process. The day will also include an interactive session on evaluating special circumstances that may arise during the informed consent process.

Day Two will continue with presentations on subject recruitment and retention, investigational drugs and devices, unanticipated problems, research compliance, and study closure.

Day Three’s topics will include 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 will complete a mock study budget in a hands-on workshop.

Registration for the April 2015 course is now open. Register here.

Please contact Catrina VanAllen for more information (Catrina.M.Coverdale@uth.tmc.edu, 713-500-3578).

ICMJE Requirements for Clinical Trial Registration
Elizabeth Massey Gendel, PhD

You may be familiar with the FDAAA 801 requirements for clinical trial registration at ClinicalTrials.gov, but did you know that ICMJE journals require registration as a condition for publication?

The ICMJE definition of a clinical trial is broader than the FDAAA 801 definition, so even if registration of your study is not required per FDAAA, it may be required by ICMJE journals. The ICMJE definition includes:

- most interventions (not just studies of drugs, biological products, or devices as with FDAAA)
- studies with or without a control (not just controlled trials as with FDAAA)
- trials of all phases (phase 1 and feasibility studies are not excluded as with FDAAA)

As a result, if you plan to publish in an ICMJE journal and if your study meets the ICMJE definition of a clinical trial, it is recommended that you register the study at ClinicalTrials.gov.

Please contact Elizabeth Massey Gendel for more information (Elizabeth.M.Gendel@uth.tmc.edu, 713-500-3587).
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: February 24, 2015
Time: 11:30am – 1:00pm
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: April 21 – 23, 2015
Time: 9:00am – 4:30pm
Location: Cooley University Life Center
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: February 26, 2015
Time: 1:30pm – 4:00pm
Location: UCT 1155
Parking will be validated.
Registration is required. Register here.

Clinical Research Billing
Objective: This training will cover the new clinical research billing policy, which was created to meet new CMS requirements for clinical study Medicare claims. The training is mandatory for all clinical research PIs and staff, and it will also be available online through TRC. Registration is required, and information will be provided in a future notice.
Dates, Time, and Locations:
March 9, 2015; 9:00am – 12:00pm; MSB B.100
March 17, 2015; 1:00pm – 4:00pm; MSB G.100
March 19, 2015; 9:00am – 12:00pm; MSB G.100
March 24, 2015; 12:45pm – 4:15pm; SOD 4320

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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