Mandatory Coverage Analysis Begins September 1st

Clinical Research Finance Team

Beginning September 1, 2014, a Coverage Analysis will be required for all studies that have billable charges. This is to ensure that UTHealth and its researchers are following the regulations for research billing compliance. 1,2,3,4

Additionally, as of September 1st, if a study’s completed Coverage Analysis has not been reviewed by the Clinical Research Finance (CRF) team, the contract will not be fully executed.

Not all studies will require a Coverage Analysis, and to determine whether an analysis is required, study teams should complete a “Billing Risk Questionnaire.” This form will eventually be added to iRIS, but until then it can be found on the CRF team’s webpage here.

If a Coverage Analysis is not required for a study, the “Billing Risk Questionnaire” should be submitted to the CRF team as documentation of the reason the Coverage Analysis has not been completed and is not needed. The CRF team will review the questionnaire and, if necessary, notify the department contact(s) to proceed with completion of the Coverage Analysis documents.

All completed Coverage Analysis materials should be submitted to the CRF team for review at CRF@uth.tmc.edu. Once the review is complete, the CRF team will email the PI/study team and the contract specialist. If there are any questions or issues, the CRF team will work with the study team until all matters are resolved and the Coverage Analysis is deemed complete. The CRF review will:

- Ensure that the pre-approval process is completed for device studies and that the qualifying/deeming process is completed for drug and biologic studies
- Ensure that a billing grid is completed
- Ensure that all services in the protocol are listed on the billing grid and are delineated as to which payer will be responsible for payment of that service at that time point
- Ensure that justification is provided for all services delineated as routine costs (standard of care)

Information regarding Coverage Analysis, including procedures and forms, as well as helpful hints and resources, can be found on the CRF team’s website here.

If you were unable to attend one of the CRF Coverage Analysis training sessions in August of 2014 or have any questions regarding Coverage Analysis, please contact the CRF team at CRF@uth.tmc.edu.

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2 Novitas – www.novitas-solutions.com
Coordinator 102 is a mentorship initiative for research coordinators and research nurses, and it focuses on clinical trial management according to good clinical practice (GCP) guidelines and regulations. The program is directed by the Center for Clinical Investigations. It is slated for November 2014 through April 2015, with specific dates and a location to be announced later.

Why Was the Program Developed?
Newly hired coordinators have a variety of backgrounds—some have research coordination experience, but many don’t. Thus, a need exists for in-depth training. In 2013, UTHealth’s Clinical Research Unit (CRU) developed a pilot program to meet this need, and as a result of its success, it is now open to UTHealth employees as the Coordinator 102 program. This new program builds on the existing basic Clinical Research Education Course and offers training beyond what is possible in the 3 days of the basic course.

Furthermore, some coordinators join research teams that have several other coordinators and even a program manager, but other coordinators are alone in their research team without a built-in support system. The mentoring aspect of the Coordinator 102 program can help to fill this gap.

What Does the Program Offer?
Monthly seminars on topics in clinical trial management will be presented over a period of 6 months. Topics include: regulations governing human subjects research, study start up, clinical trial finance, the consent process, regulatory binder and source documentation, and study conduct and close out.

The mentoring component offers a more tailored approach to job training. Participants will be paired with a mentor, who will offer guidance over the 6-month period of the course. Mentors will answer questions and provide feedback, as well as direct mentees to the appropriate contacts and resources for different clinical trial management processes.

Eligibility
Coordinator 102 is open only to individuals who are currently employed by UTHealth as a research coordinator, research nurse, or research assistant. Prerequisites are the basic Clinical Research Education Course, CITI Human Subjects Training, and CITI GCP Training.

Applications
All application materials should be submitted electronically by October 15, 2014. Applications will open soon via the CTRC website.

Only 6 candidates will be selected for the program at this time, and preference will be given to candidates who are already working as clinical trial coordinators and who have little or no clinical trial management experience.

Contact
Please contact Catrina Coverdale for questions, suggestions, and feedback at 713-500-3578 or catrina.m.coverdale@uth.tmc.edu
Monitoring Services Are Now Available
Kathy Franco, RN, BSN, CCRC - CRU Nurse Manager

The International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP) define monitoring as an act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and applicable regulatory requirements.

In industry-sponsored trials monitoring is the sponsor’s responsibility, and in multi-center federally funded trials it is the coordinating center’s responsibility. However, in investigator-initiated trials it is the principal investigator’s (sponsor-investigator’s) responsibility.

Some sponsor-investigators at UTHealth have fulfilled their responsibility for monitoring by contracting with commercial research companies. Others have hired individuals within their team to monitor trials. There have been several requests for other monitoring options, and we are very happy to announce that monitoring services are now available at UTHealth.

Monitoring services will be conducted by Cary Warner. Cary is a certified clinical research coordinator and has worked as a research coordinator for more than 20 years. Previously, she was a research coordinator and regulatory specialist with the Clinical Research Unit (CRU) at UTHealth for over 7 years, and prior to that, she was with The University of Texas Health Science Center at San Antonio.

The cost of monitoring will depend on the complexity of the trial and the frequency and extent of monitoring. The CRU will evaluate the monitoring plan and offer an estimate based on the hourly rate of $65 an hour.

To request monitoring services, please contact Kathy Franco, RN, BSN, CCRC at Kathy.D.Franco@uth.tmc.edu or 713-500-4147.

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 November 1, 2014 with a registration deadline of September 19, 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:** August 26, 2014; September 23, 2014
**Time:** 11:30 am – 1:00 pm
**Location:** MSB 2.135

*Lunch provided to 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. Day 1 and 2 focus on clinical trial management, and day 3 focuses on clinical trial finance and contracting.

**Date:** October 14 – 16, 2014
**Time:** 8:00 am – 4:00 pm
**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 involving human subjects to UTHealth’s CPHS.

**Date:** September 17, 2014
**Time:** 1:30 pm – 4:00 pm
**Location:** UCT 1160

*Parking will be validated.*
Registration is required. Register [here](#).

**SPA Training Course**

**Objective:** The SPA Training Course is a biannual, three-day educational course taught by both departmental and central research administrators. This course will provide hands on experience and expert knowledge of subjects ranging from proposal submission to award closeout.

**Date:** October 21 – 23, 2014
**Time:** 9:00 am – 4:00 pm
**Location:** TMC Library (Jessie Jones Library)

Registration is required. Register [here](#).

Registration for the October 2014 CLINICAL RESEARCH EDUCATION COURSE is now open.

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

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