The Clinical Coordinator

Clinical Research News You Can Use...

INSIDE THIS ISSUE

Clinical Trial Management System 1
IRB Submissions – Insider tips 2
New CTRC Staff 3
New CCI staff 3
New HIPAA Omnibus Rule 3
Upcoming Training 4
About CTRC 4

CLINICAL TRIAL MANAGEMENT SYSTEM
Sujatha Sridhar, MBBS, MCE

UT Houston is participating in a UT System shared services project to implement a clinical trial management system (CTMS).

We are currently in the joint discovery process with UTHSC San Antonio, UT Medical Branch and UT Tyler and Velos. Velos eResearch has the capability to connect financial, administrative and clinical research activities to hopefully integrate some of the processes we are currently doing manually.

Velos eResearch offers flexible form creation and reporting capabilities. Over the next few months, a core team will be working with researchers and research staff involved in clinical trials throughout the University to document our clinical trial budgeting and billing process.

The timelines to implementation are not final, but it is anticipated that the CTMS will go live at UT Houston in Fall 2014. It is our understanding that the CTMS system will interface with our electronic IRB system iRIS. There are plans to interface with the Financial Management System to get automatic updates of payments.

Budgeting – The Velos CTMS will help with the clinical trial budgeting process. Currently at UT Houston we use templates for building budgets. We also have UT Houston clinical services price lists available on the CTRC website. The budgeting template has built in formulas to calculate effort for various members of the research team. The CTMS has the capability to pull all these various pieces together in one place to help us build budgets for clinical trials.

The clinical trials resource center has started to conduct Medicare coverage analysis on a few studies in collaboration with MHH Center for Research Innovation. We will be ramping up this process gradually. The Velos CTMS would be helpful in solidifying the Medicare coverage analysis process.

Billing – The Velos CTMS has the capability to create invoices for milestone payments based on research subject visits. With a feed from FMS, research staff will be able to track payments received from the sponsor to help with reconciliation.

Jodi Ogden, Assistant Vice President, Sponsored Projects Administration is leading the project at UT Houston and Angela Weatherhill, Senior Manager, Systems Analysis and Programming is the Project Manager.

The CTRC team will keep you updated of the progress at our monthly study coordinator forum meetings as well as through the newsletter.
Here are some tips to help you maximize the time you spend within iRIS and reduce the chances of you receiving the dreaded ‘Returned for Corrections’.

**Tip #1 Work Smart! Make use of the “User Profile” functionality in iRIS** - CV and CITI training certificates only have to be entered in one central location in iRIS thereby removing the need to attach research training documents to every new study. If all the study team members have an updated profile, you do not have to submit human subjects training certificate and CV for each new protocol.

**Tip #2 Include the HIPAA authorization into the informed consent** - When creating a consent document for your new study, use the CPHS template that contains the HIPAA authorization form. If HIPAA authorization is part of the consent document, then you do not need to submit a separate HIPAA authorization form each year at the time of Continuing Review. If you have a separate consent and HIPAA authorization form on your existing study and want to combine your documents, here is a simple way to update the consent form: In iRIS, create a new version of the approved consent and then check out the document to your desktop. Next, go to the CPHS website and open the consent template with the HIPAA form. Highlight and copy the HIPAA portion of the form and paste into the desktop consent document. Edit the HIPAA portion and check your consent form back into iRIS. Create a Study Miscellaneous submission form, attach the updated informed consent and submit to CPHS.

**Tip #3 Review the previous continuing review submissions before you start the current one** - A good habit to develop at the time of continuing review is to look at the submissions from the years prior especially at the enrollment numbers. CPHS will return your submission if the demographic breakdown of subjects is missing; so if your study does NOT collect this, be sure to tell us upfront. If your study has a DSMB, the most recent report is due at this time.

**Tip #4 Provide a rationale for every change request** - For every change request submitted to CPHS the site must provide a rationale for the change. Submissions are routinely returned because this information is missing. Usually the Sponsor provides a document outlining the changes and the rationale (if they do not provide one, ask!). The Sponsor also informs the site what documents are impacted by the change (i.e., a revised protocol, updated Investigator brochure, revised CRFs) If the change involves an increased risk to the subject, describe it in detail. For investigator initiated changes, CPHS will request for a revised protocol.

**Tip #4 Make your own template for Protocol Deviations** - Protocol deviations happen and they must be reported. CPHS evaluates a deviation to determine if the deviation is serious or non-serious and if the deviation is ongoing or a single event. Be sure to include details of the deviation and how the deviation was handled by the site. Deviations can often be reduced simply by re-education of study team members.
NEW FACES

We are pleased to welcome Catrina Coverdale to the Clinical Trials Resource Center. Catrina has earned a bachelor of science degree in biochemistry and microbiology from Texas State University. Catrina is a certified clinical research professional and has about 8 years experience working in the clinical research field. Catrina will be responsible for coordinating all the training programs organized by the Clinical Trials Resource Center. Catrina will also participate in the post approval monitoring program and other projects as part of the human subjects quality improvement program. Welcome Catrina!

We are also pleased to welcome back Arlene White-Brisco. Arlene is a research administration professional with over 17 years of experience. For the past six years, Arlene has held various research administrator positions within the Texas Medical Center, which include an IRB coordinator for UTHealth and a Senior Regulatory Affairs Coordinator for the Department of Pediatrics Hematology & Oncology at Baylor College of Medicine. Arlene has come back to UTHealth to serve as the Regulatory Specialist for Internal Medicine. In this position, she will be assisting with regulatory affairs administration for clinical research within Internal Medicine. Welcome Arlene and Tammy!

HIPAA OMNIBUS FINAL RULE

The new HIPAA Omnibus Final Rule allows researchers to combine conditioned and unconditioned authorizations as long as the authorization clearly differentiates between them. For example, a single authorization may include a condition that the research participant must provide authorization to participate in a clinical trial while allowing the participant to decline participating in a genetic substudy for the same research study.

The previous interpretation of HIPPA regulations by HHS prohibited authorization for use and disclosure of PHI for unspecified future research. In the new rule, HHS allows authorization to describe that PHI may be used or disclosed for future research. The effective date for this rule is March 26, 2013 and the compliance date is September 23, 2013. More information on the final rule can be found in the federal register. The templates for the combined consent and authorization document is available on the CPHS website.
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 23 – 25.
Time: 8 am to 4 pm
Location: Denton Cooley Conference Center.
Registration is required. Register here.

Let’s Talk Research Ethics
Objectives – Paula Knudson facilitates discussions that explore how ethical principles factor into CPHS decision making process and conduct of human subjects research.
Dates: Every 2nd Thursday of the month.
Time: 12 pm to 1:30 pm
Location: MSB 2.104B
Lunch provided to the first 15 participants
Registration is not required.
More information here.

iRIS Training
Objective: Hands on training in the iRIS system to submit research protocols involving human subjects to the IRB.
Dates & Times:
Wed, 3/13/13: 1:30 – 4:00 pm
Location: UCT 1160 (subject to change)
Registration is required. Register here.
Parking will be validated.

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/ctrc for more information.

Sujatha Sridhar, MBBS
Director
713-500-3622

Thea Troetscher, RN
Regulatory Specialist
713-500-3583

Marilyn Perry, CCRP
Regulatory Specialist
713-500-3587

Catrina Coverdale, BS, CCRP
Training Coordinator
713-500-3578

Ngozi Okafor, MPH
Graduate Assistant
713-500-3622