Pursuant to HOOP Policy 214, Clinical Research Finance (CRF) will oversee a monitoring program for clinical research billing and research study expenses. CRF monitors studies on a for cause basis, by random selection, or by request.

What is the monitoring process?

Once a study is identified for monitoring, CRF will contact the Principal Investigator (PI) and study team to schedule an “interview” meeting. During the interview, CRF will ask pertinent questions regarding how department/service units are notified that a patient is on a research study. CRF will review processes for study patient registration, patient charging, and charge reconciliation.

Prior to the interview, CRF will request the study patient log. CRF will choose a sample size from the log of patients to review.

CRF will review the following documents during the monitoring process and may request that some or all of these documents be provided by the study team:

- Study Protocol
- Informed Consent
- Coverage Analysis
- Budget
- Contract
- Patient Log
- Patient Standard of Care Claims/Payments (if applicable)
- EG Account (if applicable)
- MHH Account (if applicable)
- Sponsor Invoices/Payments
- Additional Support Items as necessary

CRF will review the documents for billing compliance and accuracy and will provide a report of the results to the PI and study team.

A close out interview will be conducted after the review to discuss the results, any recommendations and process improvements, as well as any further steps that may be needed.

Contact: CRF@uthouston.edu

John Valenta Joins the Clinical Research Finance Team

Please welcome John Valenta, MS to the Clinical Research Finance team. John is currently a graduate student at UTHealth’s School of Public Health studying management, policy, and community health. He earned his Bachelor and Masters of Science in Genetics from Texas A&M University and has worked for the last two years on UTHealth’s Sponsored Projects Administration Contracts Team. In his new position, John will assist with reviewing coverage analysis for clinical research. Welcome, John!
What is a Clinical Research Navigator?

Each of the Texas Regional CTSA Consortium (TRCC) institutions has named an individual from their campus to serve as a Clinical Research Navigator (CRN). These “ambassadors” are the liaisons between local research teams participating in Clinical Trials Xpress (CTX) studies and the CTX central operations team. Working in tandem with investigators and their research staff, the Navigators shepherd local study start-up processes to accelerate protocol implementation timelines. Together with Debra Canter, who on February 29th will join CTX as its Network Operations Navigator, the institution-based Navigators are instrumental in communicating CTX initiatives, mapping campus process workflows, and streamlining activities toward launching the CTX network study opportunities.

Who is the Clinical Research Navigator for UTHealth?

Stephanie M. Hulsey, RN, BSN, CCRN graduated from Baylor University with a BA in Psychology and Philosophy. She previously worked as a Research Coordinator at the Memorial Hermann Clinical Innovation and Research Institute. Stephanie then attended The UT Health Science Center at Houston to obtain a Bachelor of Science in Nursing. Upon graduation, she began her nursing career at Texas Children’s Hospital in Pediatric ICU. After gaining valuable experience, she joined the CRU as a Research Nurse in April of 2015. She also functions as the CRU Unit Educator and was selected to serve as the CTX Navigator at UTHealth.

For more information about the Clinical Trials Xpress initiative, please see our article in the November/December issue of The Clinical Coordinator.

Upcoming Certification Testing Dates

CCRP certification: For those interested in becoming a Certified Clinical Research Professional, the next exam in Houston is at Methodist Hospital on May 7, 2016 with a registration deadline of March 25, 2016. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in September and October of 2016. Applications are due by August 15, 2016, and you can find more information here.
UPDATES FROM THE BIOBANK by Mary Hall, MBA, PhD

Biobank and School of Nursing Faculty Participate in
Taiwan and US Agency for International Cooperation Program

The Center for Clinical and Translational Sciences (CCTS) Biobank director, Jennifer Sanner, PhD, RN, Assistant Professor, Nursing Systems, together with Teng-Yuan (Erica) Yu, PhD, RN, Assistant Dean, Undergraduate Programs and Assistant Professor of Clinical Nursing – Acute and Continuing Care at The University of Texas Health Science Center at Houston (UTHealth) School of Nursing, are part of an international cooperation program between the US and Taiwan. They are collaborating with principle investigator, Min-Huey Chung, PhD, RN, Associate Professor, Graduate Institute of Nursing at Taipei Medical University in Taiwan. Their grant collaboration, which is part of the Taiwan and US Agency for International Cooperation Program, is focusing on genetic analysis of racial differences in cardiovascular disease and involves the CCTS Biobank.

Biobank Activity Increases in 2015!

The CCTS Biobank's number of samples shared and number of study participants whose data were shared increased markedly from 2014 to 2015 (see graph). Also, the Biobank received more inquiries from researchers in 2015 (n=30) relative to 2014 (n=20) and gained four new contributing investigators who have agreed to contribute samples and/or data (visit our “Contributors” page at: https://www.uth.edu/biobank/contributing-investigators.htm).

Led by Eric Boerwinkle, PhD, senior director, and Jennifer Sanner, PhD, RN, director, the UTHealth CCTS Biobank is working toward another great year of collaborative efforts and facilitating research within and beyond the UTHealth community in 2016!

For further information about the UTHealth CCTS Biobank, visit the Biobank website at: https://www.uth.edu/biobank/.

To query samples and submit a request for samples and/or data, use the Sample Location and Enhanced Distribution (SLED) online system, which can be found on the Biobank website and directly at: https://biobank.uth.tmc.edu/BBCIS/.

Or, contact the CCTS Biobank program manager, Mary Hall, at: UTHealth_CCTS_Biobank@uth.tmc.edu or 713-500-2092.
**Upcoming Training**

**Clinical Research Finance Lunch and Learn**

**Objective:** Provide staff members guidance on research financial topics (e.g., budgeting, billing, and coverage analysis). Also, a forum to introduce or update financial matters and to present questions or concerns for discussion in an open setting with peers.

**Date:** March 9, 2016 (Research Billing/Coverage Analysis)
**Time:** 11:30 am – 12:30 pm
**Location:** MSB 2.135

*Feel free to bring your lunch.*
Registration is not required

**Clinical Research Budgeting and Billing Training**

**Objective:** A hands-on workshop that will cover the processes for billing, coverage analysis, building a research budget, and reconciliation.

**Date:** April 26, 2016
**Time:** 1:00 pm – 4:30 pm
**Location:** MSB B.410

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

**Study Coordinator Monthly Forum**

**Objective:** Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.

More information [here](#)

**Date:** March 22, 2016 (Topic: ClinCard)
**Time:** 11:30 am – 1:00 pm
**Location:** MSB 2.135

*Lunch provided for the first 40 participants.*
Registration is not required.

**Orientation for Clinical Research Staff**

**Objective:** Educate new clinical research personnel on clinical trial management, as well as IRB review and Memorial Hermann study start up processes. The program will lead into the Study Coordinator Forum.

**Date:** April 26, 2016
**Time:** 9:00 am – 11:30 pm
**Location:** MSB G.100

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:** March 10, 2016
**Time:** 1:30 am – 4:00 pm
**Location:** UCT 1155 (Parking will be validated)

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 [https://www.uth.edu/ctrc/](https://www.uth.edu/ctrc/) for more information.

**Sujatha Sridhar, MBBS, MCE**
Director
713-500-3622

**Catrina VanAllen, MBA, CCRP**
Senior Research Compliance Specialist
713-500-3578

**Rosemary Tran, BS**
Graduate Assistant
713-500-3551

**Elizabeth Massey Gendel, PhD**
Regulatory Specialist
713-500-3587

**Jane K. Lee, MPH**
Intern
713-500-3551