The CCTS Biobank

Mary Hall, PhD

UTHealth investigators may be able to shorten their time to discovery and translation by requesting clinical and genomic samples and data for their research from the UTHealth CCTS Biobank.

The CCTS Biobank is a decentralized program that facilitates sharing of human subject samples and data with qualified researchers. By using a federated model of sharing, samples and data in the Biobank collection actually remain in the possession of each contributing researcher until a qualified investigator, with an IRB-approved study, submits a request and the contributor approves the collaboration.

The Biobank collection consists of various sample types from healthy subjects as well as individuals having cardiovascular disease, autoimmune disorders, cancer, and stroke. Sample types include plasma, serum, buffy coat, red blood cells, peripheral blood mononuclear cells, saliva, and DNA as well as related clinical and genomic data collected and generated by investigators within the Texas Medical Center. Contributing investigators have agreed to share samples and data based upon scientific merit, inventory availability, and correlation with their scientific studies. All samples and data in the Biobank have been consented for secondary use.

Whether you are an early stage investigator or a seasoned principal investigator, the CCTS Biobank can be a valuable resource for samples and data for preliminary studies for grant proposals or clinical discovery and translational research. For more information, please visit the UTHealth CCTS Biobank website at: https://www.uth.edu/biobank/

To query samples and to submit a request for samples, use the sample location and enhanced distribution (SLED) online search application which can be found on the website or directly at: https://biobank.uth.tmc.edu/BBCIS/

If you would like further information about requesting samples and/or data from the Biobank or are interested in becoming a contributing investigator, please do not hesitate to contact the CCTS Biobank Program Coordinator, Mary Hall, at: UTHelath_CCTS_Biobank@uth.tmc.edu or 713-500-2092.
Clinical Research Billing Information Sessions

Clinical Research Finance

The Clinical Research Finance (CRF) team has met with clinical DMOs throughout the University to assist with implementation of clinical research billing. Through this process the team has developed resources for research and clinical staff.

In order to share the resources and provide clarification, the Clinical Research Finance team is offering three new information sessions intended to assist with the implementation of HOOP 214: Clinical Research Billing (CRB). The CRF Team will provide resources for communication with various clinics and hospitals. Departments will have the opportunity to choose tools that will integrate well with their business models.

The sessions will cover:
1. Implementation plans for each department
2. Tools for research coordinators and clinic staff
3. Clarification of CMS requirements
4. Audience Q&A

Scheduled sessions:
- Tuesday, August 4, 2015: 3:00 pm – 4:30 pm in MSB 2.103
- Wednesday, August 19, 2015: 1:00 pm – 2:30 pm in MSB B.500
- Thursday, August 27, 2015: 1:00 pm – 2:30 pm in MSB 2.135

Follow this link to register.

Let’s Welcome Michelle Acas-Hyun to the Clinical Research Finance Team

Clinical Research Finance

Michelle Acas-Hyun has recently joined the Clinical Research Finance team. In her new role, Michelle will serve as a Clinical Research Financial Analyst, and her duties include conducting reviews for billing risk, initializing the process for coverage analysis, performing clinical research billing data analysis, and acting as REDCap project manager.

Michelle has been with UTHealth for two years. Previously, she worked on the Grants Team in Sponsored Projects Administration (SPA). She also has experience working with clinical research studies.

Welcome, Michelle!

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 7, 2015 with a registration deadline of September 26, 2015. 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 2015. Applications are due by August 15, and you can find more information here.
Successful FDA Inspection of Dr Samia Khalil’s Study Site

Clinical Trials Resource Center

This July, Dr. Samia Khalil and Dr. Emad Sorial underwent a successful FDA inspection of their site for the study titled, “A multi-center, randomized, open-label, parallel, active-comparator, multiple dose trial to determine the efficacy, safety, and pharmacokinetics of intravenous ibuprofen in pediatric patients” (NCT01002573). The site was chosen for inspection by the FDA due to high enrollment.

No significant findings were documented on site; therefore, the issuance of a 483 is not expected (an FDA 483 form documents and communicates any concerns discovered during an inspection by the FDA). The keys to their success were good research documentation and frequent monitoring visits.

In preparation for the FDA audit, the sponsor visited the study team a few months ago. Additionally, the Clinical Trials Resource Center (CTRC) monitored the study by reviewing the regulatory binder, consent documents, and subject binders. CTRC also coached the study team on what to expect during the FDA inspection.

If you anticipate a visit by the FDA, be sure to contact CTRC at clinicaltrials@uth.tmc.edu.

To ensure that your team’s records are audit ready, you may contact CTRC to request a routine, not-for-cause monitoring visit: clinicaltrials@uth.tmc.edu.

Congratulations to the Khalil team!

Good to Know - How is Legal Guardianship Verified?

Clinical Trials Resource Center

During the FDA audit of the Khalil study site, the FDA inspector asked the study team how legal guardianship is verified during the consent and assent process in pediatric cases. At MHHS, legal guardianship is reviewed at the time of admission (or following admission if the patient came through the Emergency Room) by a hospital-employed social worker—the adult must present documentation of legal guardianship.

For more information, contact CTRC at clinicaltrials@uth.tmc.edu.

UT System’s ClinicalTrials Xpress in the News

See this link for a feature on UT System’s Clinical Trials Xpress by News Medical.

For more information about the Clinical Trials Xpress, contact Patty Winger at pattywinger@ccrsconsultants.com.
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 25, 2015
Time: 11:30 am – 1:00 pm
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. This three day program focuses on clinical trial management, good clinical practice, and efficient trial conduct.
Date: October 20 – 22, 2015
Time: 8:30 am – 4:30 pm
Location: Cooley University Life Center
Register here.

Center for Clinical Investigation (CCI) Meeting
Objective: Aid clinical research and reduce the burden on individual teams by identifying best practices, streamlining clinical research management processes, and providing education, training, and support to clinical research staff.
Date: August 10, 2015
Time: 2:00 pm – 3:00 pm
Location: UTPB 1100.55
Registration is not required.

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: TBA
Time: 1:30 pm – 4:00 pm
Location: UCT 1160
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/ctrcl/ for more information.

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