Clinical Research News You Can Use...

INSIDE THIS ISSUE
Commercial IRBs 1
The Clinical Trials Xpress 2
New CRU Staff 3
Upcoming Certification Testing Dates 3
Upcoming Training 4
About the CTRC 4

More Commercial IRB Options for Industry-Sponsored Trials

Clinical Trials Resource Center

UTHealth investigators have had the option to rely on Chesapeake IRB since 2012. Now, three additional commercial IRBs are available for the review of industry-sponsored, multi-center clinical trials: Western IRB (WIRB), Quorum Review IRB (Quorum), and the Biomedical Research Alliance of New York IRB (BRANY). All are AAHRPP accredited.

Procedures for Relying on a Commercial IRB

The procedures for relying on Western, Quorum, or BRANY IRBs will be the same as those for Chesapeake. The first step is to receive permission from UTHealth’s CPHS, which is sought via an iRIS application. iRIS will soon be modified to offer Western, Quorum, and BRANY as choices in the panel for “Permission to Rely on Other IRBs,” but in the meantime, select “Other” and enter the name of the IRB in the text box. Additionally, upload the sponsor protocol and sponsor consent to iRIS, and, if the trial will be performed at MHHS, complete the MHHS application form.

Once you have received written permission from UTHealth’s CPHS via iRIS, you may submit an application to the commercial IRB. The commercial IRBs will maintain oversight until study closure and will be responsible for continuing review, change requests, and problem reporting.

All communication regarding the research must be directed to a commercial IRB representative; however, researchers may contact the CPHS office for assistance or clarification.

Fees

The commercial IRBs’ fee schedules will be posted in iRIS in the “Operating Procedures” section under “My Assistant.” Study teams are strongly encouraged to speak with the sponsor representative to make arrangements to pay the commercial IRBs directly. In addition to the commercial IRB review fees, CPHS will invoice the sponsor directly for an administrative fee for maintaining compliance oversight at UT Houston ($1300 for initial review and no charge for continuing reviews).

The CTRC website will soon be updated to provide guidance for using these commercial IRBs, but until then, if you have questions contact CTRC at clinicaltrials@uth.tmc.edu.

Western IRB

Representatives from Western IRB (WIRB) spoke at the Research Coordinator Forum on May 26, 2015. They discussed procedures for submission and demonstrated WIRB’s electronic system Connexus. Before submitting an application to WIRB, or if you have questions, concerns, or suggestions regarding the WIRB review process, please contact Jacob Johnson, Institutions Account Manager at 360-570-1310 or jhjohnson@wirb.com. WIRB also provides “A Guide for Researchers” document.
Launch of an Innovative Clinical Trials Network Model, the Clinical Trials Xpress

Adapted from an Announcement from The University of Texas System

The University of Texas System, in collaboration with the Texas Regional CTSA Consortium (TRCC), is pleased to announce the launch of an innovative clinical trials network model—the Clinical Trials Xpress.

This model, which responds to an increasing national mandate for greater collaboration and operational efficiency, aims to accelerate the pace of multi-institutional clinical trials. To accomplish this, the Clinical Trials Xpress will provide UT investigators and industry partners access to streamlined and cost effective study implementation processes.

Key components of the network model include:

- A robust, investigator- and informatics-driven study feasibility process
- Rapid study start-up facilitated through master clinical trial agreements
- Negotiation of common clinical trial budgets and shared Medicare coverage analysis
- Use of the UT IRB Reciprocity Agreement or accredited central IRBs to eliminate redundant reviews at each Institution
- Collection and reporting of performance metrics to assess, refine, and report the efficiency and effectiveness of the network model
- Marketing of the network capacity for multi-site clinical trials to industry partners and other potential funding partners

The Clinical Trials Xpress network will act through a central coordinating office located in the Texas Medical Center. This central office will work closely with institutional clinical trials offices and other relevant campus offices at participating institutions.

The network is currently governed by the TRCC Executive Committee, which will review, evaluate, and prioritize industry-sponsored and/or investigator-initiated clinical trial protocol concepts for inclusion in the network.

Founding Clinical Trial Xpress institutions include the five UT System CTSA Institutions:

- The University of Texas Health Science Center at Houston
- The University of Texas MD Anderson Cancer Center
- The University of Texas Medical Branch at Galveston
- The University of Texas Health Science Center at San Antonio
- The University of Texas Southwestern Medical Center

As the network matures, other UT institutions and partners will be invited to participate.

The Clinical Trials Xpress network opens up a promising new opportunity to accelerate the translation of new discoveries into clinical care and enhance the reputation of the UT System and its Institutions as world-class leaders in clinical research.

For more information, contact Patty Winger at pattywinger@ccrsconsultants.com.
Let’s Welcome New Members of the CRU!

Clinical Research Unit

Hayley Balkin graduated from The University of Texas Medical Branch at Galveston with a Bachelor of Science in Nursing. She worked for Memorial Hermann TMC in 2013 in MICU and TSICU. She then transferred to outpatient GI and worked in a clinic from 2014 to early 2015. She started working in the CRU as a Research Nurse in March 2015.

Stephanie M. Hulsey, RN, BSN, CCRN graduated from Baylor University with a Bachelor of Arts in Psychology and Philosophy. She previously worked as a Research Coordinator for Dr. Elizabeth Noser and the Memorial Hermann Clinical Innovation and Research Institute. Stephanie then attended The University of Texas 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 working there for several years, she joined the CRU as a Research Nurse in April.

Shannon Winton graduated from San Jacinto College in 2006 with an Associate of Science in Nursing. Her recent experience includes utilization review for both the Department of Aging and Disability Services and the Texas Health and Human Services Commission. She also has worked in Trauma ICU at the University Hospital in San Antonio, TX and has background in emergency medicine and outpatient surgery. She is currently working in the CRU as a Research Nurse and Study Coordinator.

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 August 8, 2015 with a registration deadline of June 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.
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:** June 23, 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](#).

**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:** June 11, 2015  
**Time:** 1:30 pm – 4:00 pm  
**Location:** UCT 1160  
*Parking will be validated.* Registration is required. Register [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:** October 2015  
**Time:** 8:30 am – 4:30 pm  
**Location:** Cooley University Life Center  
Registration will open soon.

**Center for Clinical Investigation (CCI) Meeting**  
**Objective:** Aid clinical research while reducing 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:** June 8, 2015  
**Time:** 2:00 pm – 3:00 pm  
**Location:** UTPB 1100.55  
Registration is not required.

---

**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, BS, CCRP**  
Senior Research Compliance Specialist  
713-500-3578

**Ngozi Okafor, MPH**  
Graduate Assistant  
713-500-3551

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

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