IRB RECIPROCITY WITH BCM

CPHS has recently entered into a reciprocity agreement with Baylor College of Medicine IRB. If you are collaborating with researchers from Baylor College of Medicine on a human subjects research protocol, you used to have to seek approval from both BCM IRB and UT Houston CPHS. With this new agreement, only one IRB review may suffice.

If you wish to rely on BCM IRB for an upcoming research study, seek permission to rely via iRIS. If your collaborator from BCM would like to rely on the UT Houston CPHS, your collaborator should seek permission to rely. More information on the process can be found on the CPHS website.

CHANGE IN CHESAPEAKE APPROVAL PROCESS

Staff at Chesapeake IRB make sure that the consent form contains UT Houston approved language for research related injuries. Any changes to this language must be approved by the CPHS office. For some research studies, negotiation with the sponsor for inclusion of the CPHS approved injury language has taken some time.

Instead of waiting until the injury language is approved by the sponsor, Chesapeake IRB will now issue approval letter for the research study along with a consent form that contains the UT Health approved subject injury language. Any changes to this language will then need to be submitted as a change request to Chesapeake IRB. More information on applying to Chesapeake IRB here.

NEW FDA GUIDANCE

FDA has recently published a draft guidance document – “IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed.”

This guidance document clarifies IRB responsibilities with respect to:

1. Review of Qualifications of clinical investigators who conduct FDA-regulated research including review of publically available information from FDA about a clinical investigator’s inspectional history.
2. Review of adequacy of the research site.
3. Determination of whether an IND or IDE is required for an FDA-regulated investigation.

For more information visit FDA website.

CONGRATULATIONS!

Congratulations to Sylvia Romo for being promoted to Senior IRB Coordinator. Sylvia has been working with the CPHS office since 2004. In addition to being the coordinator for Panel 1, Sylvia has been instrumental in training new IRB coordinators within the IRB office. Sylvia has also contributed towards continuing education for research coordinators.

Sylvia will relinquish her role as IRB coordinator and take on new responsibilities in reviewing exempt applications, training and assisting researchers and research staff with their IRB submissions. We wish her the very best in her new role.
FOND FAREWELL

Our training coordinator, Linda Gilbert, recently retired after serving UTHealth for over 20 years. In the four years that Linda worked with us in the Clinical Trials Resource Center, she played the role of Events Coordinator and made sure that all our training events ran like clockwork. She was always concerned about the comfort of participants, even warning them that conference rooms may get a bit chilly and reminding them to bring a sweater. She made sure that participants had a great environment for learning.

She noted the various dietary restrictions that some of the regular meeting goers had and took the extra effort to order special food for them.

Linda was always the first to arrive at work every morning and greeted everyone cheerfully. Her holiday decorations were legend, and her scented candles helped create a soothing work environment. And, inspite of not having a sweet tooth, she was well known for always having a tray filled with ‘good’ candy on her desk. We will miss her very much. We wish her the best in her retired life.

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:
Tue, 2/19/13: 1:30 – 4:00 pm
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.

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