The CPHS Executive Committee initiated an HRPP quality improvement program in 2010 to identify strategies to reduce regulatory burdens not only for researchers, but also for CPHS members and IRB staff, while enhancing human research protections. As part of our effort to improve the transparency of CPHS activities, I’m pleased to present the third annual CPHS Faculty Report. This document provides metrics describing CPHS activities in 2012, including workload and time to approval data. We also include an analysis of feedback we have received on our CPHS Faculty Survey.

CPHS saw the number of new applications increase from 755 in 2011 to 886 new applications in 2012. The time to approval includes the time taken by the CPHS staff to process applications, time taken by the CPHS members to review and also the time taken by investigators to respond to deficiencies, queries and stipulations. We looked at the 158 initial submissions approved at a convened meeting in 2012. Only 26% of the applications were accepted as submitted. About 37% were returned by the pre-screening process once and the rest were returned for correction more than once. These submissions were returned mainly because of missing signatures and incomplete application packets.

The median time to approval for exempt applications (submission to final approval) was reduced from 26 days in 2009 to 21 days in 2012. The time to approval for initial submissions reviewed at a full board meeting was also reduced from 106 days in 2009 to 90 days in 2010 and further reduced to 76 days in 2012.

Several new quality improvement projects were initiated in 2012. Starting February 2012, UTHealth allowed investigators to choose to submit multicenter industry sponsored trials to Chesapeake IRB. CPHS also initiated the new department review process for initial submissions from the Medical School that are eligible for review at a full board meeting. The department review process will supplement the research ethics review by CPHS.

The CPHS Executive Committee continues to monitor the CPHS review process to improve the quality and efficiency of our human research protection program. To read the entire report visit CPHS Faculty Report. Please send your comments, concerns and feedback to clinicaltrials@uth.tmc.edu.
The Clinical Research Education Course was held on April 23 – 26, 2013 in the new UTHealth conference facility. Day 1 of the course focused on clinical trial financial management. Topics covered included discussion of basic financial principles, negotiating contracts and an overview of UT Financial Systems. In the afternoon, the focus was on clinical research budgeting and billing.

Elida Salazar, a research coordinator working in Pediatrics-Genetics said, “Janet Sherry and Angie Holliday were great. I liked how they emphasized that organization is important. I also enjoyed listening to Maria Lopez’s presentation. She shared anecdotes that will help me as I work on my research.” Angie Rivera, a research coordinator with Surgery agreed with Elida. She added, “Amanda Ferguson’s advice to know when to remain silent when negotiating is something that will help me not only in work but also in my life.”

Day 2 and 3 were focused on good clinical practice guidance for conducting clinical research. After an introduction to IRBs, hospital review and institutional compliance, the afternoon was all about informed consent. The next day the speakers focused on initiating and conducting a clinical research study, study documentation and investigational test article accountability. There were several workshops and activities, one of the most entertaining being a role playing activity on informed consent. There were requests for more workshops for future sessions of the course.

There were 43 total participants, some of them attended all the three days while others attended just the first day or the last two days. Most of the participants were new to the research field. There were 22 participants who had less than one year experience, 13 had one to five years’ experience while 8 participants had more than 5 years’ experience. Of the 43 participants, 20 were study coordinators, 7 were research nurses and 8 were research administrators.

Tammy Johnson, Assistant Nurse Manager, Internal Medicine is an experienced research nurse who joined UTHealth a few months ago. Tammy was an active participant at the course. We asked Tammy for feedback about the course. Tammy said, “I was so impressed with the seminar. It’s a difficult job to accommodate that many people for 3 days and still have them leave happy. I think this course is essential for those new to research at UTHealth, as it provides specifics on conducting research within the University and our partners. The day on budgeting and billing is a “must have” for anyone involved in the financial aspect of research.”

If you have suggestions for our Fall 2013 session or feedback on our Spring 2013 session, we would love to hear from you, please send your comments to clinicaltrials@uth.tmc.edu.

Registration for the Fall 2013 course will open soon. Lookout for announcements on the CTRC website.
NEW FACES

We are pleased to welcome four new staff at the Clinical Research Unit (CRU). Mary Pierce was born in the Bronx and graduated as a Registered Nurse in 1976. She relocated to Texas in 1982 to work at UTMB but did not make the move to Houston until after Hurricane Alicia in 1983. She took a position at St. Luke’s Episcopal Hospital and continued from 1983 – 2011. Mary now has Bachelor of Liberal Studies, Bachelor of Science in Nursing, and her Masters in Business Administration. Her nursing experience is in Cardiology ICU and the Cathlab along with 17.5 years of experience as a research nurse. Mary joined the CRU in January 2013 as an RN.

Alice Morgan was born in Toronto, Canada and graduated from nursing school in 1979. She also graduated with a Bachelor of Liberal Studies. Her professional experience includes: emergency room, spina bifida, pediatric endocrinology, hospice, and clinical research. She has two published abstracts and still finds time to volunteer in multiple activities in our community. Alice joined the CRU in January 2013 as an RN.

Robert D. Hudson has a Bachelor of Science in Biology from the University of Houston. He formerly worked as a research assistant at the UT Houston Department of Molecular Biology. His hobbies consist of road cycling, fishing, and volunteering at the community animal shelter. Robert joined the CRU in March 2013 as a Research Technician I.

Sheryl L. Fue is a graduate from Cypress Falls High School and is currently attending Lone Star College for her Bachelor’s degree. She enjoys family, friends, and adores her 6 year old daughter. Sheryl joined the CRU in March 2013 as the Clinic Coordinator.
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.
Time: 8 am to 4 pm
Location: Cooley University Life Center.
Registration will be open in Summer 2013.

iRIS Training
Objective: Hands on training in the iRIS system to submit research protocols involving human subjects to the IRB.

Location: UCT 1160 (subject to change)
Registration is required. Register here.
Parking will be validated.

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.

Clinical Research Orientation
Objective – This educational program is designed to be a general overview of clinical trial research at UTHealth. This five hour program will cover basics of CPHS (UTHealth IRB) review and approval process, Memorial Hermann Hospital review and approval process, clinical trial financial management, and clinical trial management.
Time: 8 am to 1 pm
Location: UTPB 1100:55
Registration is required. Register here.

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/ctr for more information.

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