IRB Fee Billing
Effective Sep 1, 2013
Many of you communicated your concerns about the IRB fee billing process. For the past several months Cristina Dyke Budget Analyst with the Clinical Research Unit has been working to make the billing process simpler for research staff. Several changes are being implemented starting Sep 1, 2013.
- The IRB fee will not be linked to the contract size.
- The IRB fee will include the IDC within the cost.

Initial Review: $2600 ($2000 + 30% IDC)
Continuing Review: $650 ($500 + 30% IDC)

For protocols submitted to Chesapeake IRB, CPHS fees will be $1300 for initial review and no charge for continuing reviews. The IRB application will be amended within the next few weeks to include a field for sponsor IRB billing contact. Cristina Dyke will invoice the sponsor directly for the IRB fee.

We hope this will help make the IRB fee billing process simpler for you. If you have any questions or concerns do write to us at clinicaltrials@uth.tmc.edu.

NEW RELEASE OF iRIS SYSTEM
Implemented July 13, 2013
A new release of the iRIS system was implemented over the weekend of July 13, 2013. iMedRIS Data Corporation is the vendor that created and supports the iRIS system. They put out new releases of the software periodically that include both fixes to existing problems as well as new features. This latest release was very important to implement because it is the precursor for us to be able to implement a module to accommodate Animal Research here at UTHealth (hopefully later this year). Details on all the new features in this release can be found in the “Operating Instructions” under “My Assistant” in iRIS. Highlights of the new features include:
- There is now a “modern view” versus “classic view” for displaying items on your home page.
- Information about Human Subjects Education is now available on the “person lookup” for iRIS when pulling people into a study.
- Improvements have been made to the “workflow tracking” and “Correspondence” areas.
- Improvements have been made to the “Review Response” submission form that is attached to returned submissions.
- Completed submissions will remain on the “Submissions in Process” tab until they are finalized by all boards (e.g. Memorial Hermann).

If you have questions or are having any difficulties with the new release of iRIS, please call Barbara Legate at 713-500-3470.
Dr. Michael Fallon – Medical Director  
Kathy Franco RN BSN, CCRC – Manager  
Theresa Dancsak RN, MSN - Assistant Manager  
Cristina Dyke – Budget Analyst  

The Clinical Research Unit (CRU) currently has 100 active trials, 4 of which are new NIH funded multicenter trials in Pediatric, GI and Orthopedic Trauma Surgery.

**Did You Know?**

The CRU offers UT researchers an optimal on-campus resource and expanded capabilities for conducting clinical investigations, while serving as an environment for training health professionals in clinical research. The CRU, located on the 3rd floor of the Robertson Pavilion in Memorial Hermann Hospital, is devoted entirely to the implementation and conduction of clinical research.

The CRU team is comprised of 8 clinical research nurses with a variety of clinical backgrounds, 3 experienced study coordinators, 2 lab specialists and 3 administrative members. All of our staff members, most of whom are cross-trained with coordinating and lab experience, work closely together to offer expertise and deliver the best clinical research support to the UT and Memorial Hermann research community.

The CRU provides access to specialty core services, such as:

- Consulting support in early stages of protocol development
- In-patient and out-patient clinic space
- Nursing and/or coordinator services
- Regulatory monitoring
- Lab services including cell reconstitution and Nitrogen storage
- Research training
- CRU staff can be sent to clinical areas in the hospital such as the ICUs, ER, ORs, clinical units, ambulatory clinics or diagnostic facilities such as imaging suites.
- Administrative services also include budget development, parking validation, meal tickets, and Petty Cash services. Fees vary based upon protocol needs. To request a copy of our budget and fees please contact Kathy Franco RN BSN, CCRC by phone at 713-704-4137, or via e-mail at Kathy.D.Franco@uth.tmc.edu.

**What is new in the CRU?**

The CRU now has a simplified patient registration process. We invite you to use our new CRU Patient Registration Form. Once the registration form is completed you can fax it to 713-704-6417 and/or email it to CRUScheduling@uth.tmc.edu. Appointments may also be requested by calling our Patient Appointment Center at 713-704-4137 any time between 7:00 a.m. and 5:00 p.m. To request a copy of the CRU Patient Registration Form you can contact Sheryl Fue via e-mail at Sheryl.L.Fue@uth.tmc.edu.

***The CRU invites investigators, research staff, and sponsors to tour the unit. To schedule a tour, contact Kathy Franco RN BSN, CCRC by phone at 713-704-4137, or via e-mail at Kathy.D.Franco@uth.tmc.edu***
NEW FACES and CHANGING PLACES

Cynthia Roth has lived in Houston for nearly 40 years. She attended University of Houston obtaining a Bachelor of Arts degree in Journalism and Marketing. She has over 25 years’ experience in professional services for multiple industries including consulting, architecture/engineering and real estate. She is active in animal welfare and was a co-founder of Houston Area Doberman Rescue where she continues today as its president. Cindy’s family including a twin sister resides in Houston. Her current position at UTHealth is a Senior Sponsored Projects Specialist in the Office of Sponsored Projects. Welcome Cynthia!

Daniel O’Neal completed his undergraduate studies at Southern Methodist University in Dallas before moving to Houston in 2007 to complete both his J.D. and LL.M graduate degrees. In his free time, he volunteers in the community by providing pro bono legal assistance in certain civil matters to indigent HIV/AIDS patients; and in non-legal capacities with entities such as the Food Bank and Planned Parenthood. Daniel’s current position at UTHealth is as a Sponsored Projects Specialist in the Office of Sponsored Projects. Welcome to UTHealth Science Center at Houston!

Amanda Ferguson has worked at UTHealth since February 2011, previously in the Office of Sponsored Projects. Prior to joining UTHealth, Amanda worked in compliance for The Methodist Hospital System and in the Medical-Legal Partnership at the University of Kansas Medical Center. Amanda received a Bachelor’s of Business Administration from the University of Nebraska-Lincoln and her Juris Doctor from the University of Kansas. She is a member of the Health Law Section of the State Bar of Texas. She has now joined the Office of Institutional Compliance as a Compliance Coordinator. Congratulations and good luck on your new position within our institution!

William Mitchell graduated from Texas A&M with a Master of Public Service and Administration degree in May 2011. He joined the UTHealth Office of Sponsored Projects team two years ago as a Sponsored Project Specialist on the Contracts team. William is now the Supervisor for Systems and Reporting in the Office of Sponsored Projects. Congratulations and good luck on your new position within our institution!

CERTIFICATION FOR CLINICAL RESEARCH PROFESSIONALS

CCRP certification: For those of you interested in becoming a certified research professional, the next test date at The Methodist Hospital in Houston, TX is November 2, 2013 with a registration deadline on September 20, 2013. More information here. CRC certification: The next test date for certified Clinical Research Coordinator is September 5 – 21, 2013 and application deadline is August 7, 2013. More information here.
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 is required. Register here.

Orientation for Clinical Research Staff

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.
Dates: August 6 and December 3, 2013.
Time: 8 am to 1 pm
Location: UTPB 1100:55
Registration is required. Register here.

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)

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.

Sujatha Sridhar, MBBS
Director
713-500-3622

Thea Troetscher, RN
Regulatory Specialist
713-500-3583

Marilyn Perry, CCRP
Regulatory Specialist
713-500-3587

Catrina Coverdale, BS, CCRP
Training Coordinator
713-500-3578

Ngozi Okafor, MPH
Graduate Assistant
713-500-3551