Clinical research can be a challenging undertaking. Negotiating budgets, enrolling and caring for research subjects, maintaining study documents, interacting with sponsors, managing study finances and closing out a study are complex responsibilities. Investigators, research nurses, study coordinators, regulatory staff, and research administrators all play an integral part in one or more of these activities.

In recognition of these complexities, Dr. Giuseppe Colasurdo, named Dr. Michael Fallon, MD as Champion of Clinical Research and charged him with creating a framework of support for clinical research at the University. In 2012, after meeting with researchers throughout the institution, Dr. Fallon and his team created the Center for Clinical Investigation (CCI) to guide, strengthen, and build clinical research at UTHealth while reducing the burden on individual research teams. The CCI hopes to achieve this goal by identifying best practices, streamlining clinical research processes, and providing education, training, and support. The CCI was officially launched in January 2013 with the creation of interacting teams in the three primary arenas of clinical research: Regulatory Affairs, Clinical Research Services, and Financial Administration. The approach is to:

- Assemble groups composed of those with expertise in each area
- Define current practices and identify successes and challenges
- Identify key issues and work with various administrative groups to address the issues
- Develop best practices and standardize processes
- Develop a working frame and procedures to facilitate clinical research efforts and support research staff
- Educate and train clinical research teams
- Identify partners to build internal and external collaborations
- Prepare for possible clinical trials management system

Each team meets once a month and includes clinical research staff from throughout the university and research partners from the Office of Sponsored Projects, CPHS Office, Clinical Research Unit, Clinical Training and Resource Center, and Memorial Hermann Hospital. Although the initial scope of the CCI is limited to the Department of Internal Medicine as we foster our direction and strategy, we welcome participation from anyone who is involved in clinical research. As the CCI matures and gains momentum, the CCI will develop into a resource for all of UTHealth.

For more information, please contact clinicaltrials@uth.tmc.edu.
ADDITIONAL SAFEGUARDS FOR CHILDREN IN CLINICAL INVESTIGATIONS
Catrina Coverdale, BS, CCRC, Regulatory Specialist

The Food and Drug Administration published an amendment to safeguard children who are enrolled into clinical trials in 2001. The amendment was done to bring the FDA into compliance with the Health and Human services (HHS) providing additional safety guidelines for children enrolled as clinical trial subjects. The rule is being finalized at this time to “comply with the congressional mandate in the Children’s Health Act and because of increases in the enrollment of children in clinical investigations.” This article highlights the updates in the final rule for adopting additional safeguards for these children.

Guardian: The definition of guardian has been modified. In the previous submission, the term “guardian” or “parent” was used when describing the persons legally authorized to consent for and on behalf of a subject and their participation in a trial. It was deemed necessary to amend this definition to “legally authorized representative” so that children participating in research trials are rightfully protected by law. The term “permission” was adopted into the the finalized interim rule for an additional safeguard for enrolled children.

IRB assessment: It is now mandated that the IRB assess the level of risk for children to be participants in a clinical trial. OHRP has guidance to this review process and is available on their web page at OHRP Homepage.

REVIEW OF DEPARTMENTAL REVIEW PROCESS

On Jan 1, 2013, CPHS launched the new departmental review process. In talking with researchers and research staff, we realize that there is still some confusion on when this review is required.

At the present time, this new requirement is effective only for research conducted by Medical School faculty. You do not have to go through the departmental review process if you are planning to submit an application for exemption. If your research protocol poses no greater than minimal risk to participants and includes procedures that can be found on this list it may be reviewed by the expedited procedure. CPHS does not require a formal department review for research that may be reviewed by the expedited procedure. (please note - your department may require this).

For all other research from the Medical School, i.e. research that does not meet the criteria for exemption or review by the expedited procedure, please ensure that you go through the department review process. CPHS allowed each department in the Medical School to set up the process that would work best for the department. If you do not know the process in your department, please contact your department chair or contact the CPHS office. CPHS office will return applications that do not have a completed Department Research Review form. If there are comments and suggestions on the form, you are highly encouraged to incorporate the comments and suggestions into the study protocol. Submit this completed form along with all the usual documents via an iRIS initial application. If you do not agree with the comments and suggestions provided by the department review, include some justification along with your iRIS application.

You do NOT have to route for department signature when you submit the initial application within iRIS. For more information visit the CPHS website.
The Center for Clinical and Translational Sciences (CCTS) is in the process of establishing a Clinical Research Unit (CRU) at LBJ Hospital. The CCTS is a joint UTHealth-MD Anderson (MDA) project, funded by the NIH through the Clinical and Translational Sciences Award (CTSA) program. The primary objective of the CTSA grant is to expedite the translation of research findings to patient care and prevention in the community. As such, the CCTS provides services and infrastructure designed to support investigators in the development, implementation, conduct, and dissemination of their research. The CRU, formerly the General Clinical Research Center (GCRC), is one of 12 research training and support components of the CCTS. CRUs provide the infrastructure for research conduct, including clinical space, skilled nursing and study coordinator support, and lab services. In addition, support for research development and protocol navigation through approval processes is available through the CRU and other CCTS components.

The new unit at LBJ will be the fifth CCTS CRU. The other units are located at Memorial Hermann Hospital in the Medical Center, the UT Dental Branch, MD Anderson Cancer Center, and Mercy Hospital in Brownsville, Texas. The objectives of locating a CRU at LBJ are to facilitate T2 research, or the study of clinical trial findings in the patient care setting; facilitate collaborative research among UTHealth, MDA, and clinicians at LBJ; increase research capacity of clinician-investigators at LBJ through CCTS services and support; and last but not least, increase opportunities for clinical trial participation among the largely Hispanic and African American patient population at LBJ and residents of the surrounding community.

Implementation of the LBJ CRU is under the direction of Dr. Ruby Benjamin-Garner, PhD, an epidemiologist in the CCTS. Although clinical space for the unit has not been identified as of yet, Dr. Benjamin-Garner is now located in the Chief of Staff’s office, 1st floor LBJ, and will be available to assist investigators with research design, IRB and Harris Health System applications, and other regulatory issues. Research support services for researchers conducting research at LBJ Hospital.

Good luck to those of you who have the SOCRA certification exam in May! The registration deadline for taking the test in Houston this May was March 22, 2013. For those of you interested in becoming a certified research professional, the next test date at The Methodist Hospital in Houston, TX is August 3, 2013 with a registration deadline on June 21, 2013. Start gathering the necessary documentation for course registration today! Find all the details about the certification as well as exam dates and eligibility at the SoCRA website.
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, 2013
**Time:** 8 am to 4 pm
**Location:** Denton Cooley Conference Center.
Registration is required. Register [here](#).

Orientation Clinical Research Staff
**Objectives** – To provide a quick overview of the clinical research approval process and clinical research management at UTHealth.
**Dates:** June 4, Aug 6 and Dec 3, 2013
**Time:** 8 am to 1:30 pm
**Location:** UTPB 1100:55
*Breakfast provided.*
Registration and 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:**
Tuesday, April 2nd – 1:30 pm – 4:00 pm
Thursday, April 25th – 9:30 am – 12:00 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 CTRC [website](#) for more information.

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