**Penalties for ClinicalTrials.gov**

**Noncompliance Anticipated in 2016**

**Clinical Trials Resource Center**

**FDA will soon enforce compliance.** Registration of applicable clinical trials and reporting of their results is required by federal law. FDA states that those who do not comply can be fined up to $10,000 a day and/or be denied NIH grant money. So far, the FDA has not levied these penalties; however, enforcement is anticipated to begin in 2016 and will likely focus on results reporting. FDA has already begun a pilot process to enforce compliance by sending warning letters to a handful of PIs, including at least one UTHealth PI.

**Why now?** In November of 2014, DHHS issued a Notice of Proposed Rulemaking (NPRM), which proposes changes to the current requirements for submitting data to ClinicalTrials.gov. In the spring of 2016, this NPRM will be finalized and, as NIH Director Dr. Francis Collins stated, the updated regulations will give NIH and FDA “a firmer basis for taking enforcement actions.”

**Noncompliance is revealed.** Recently, there has been a growing awareness that researchers are not abiding by the law. In an article titled “Law ignored, patients at risk,” the news source STAT examined research institutions, including The University of Texas Health Science Center at Houston, to see whether they have reported results on time, or at all, to ClinicalTrials.gov. STAT found that most institutions have “flagrantly violated” the federal law. Another study, published in the New England Journal of Medicine, reported that only about 13% of applicable clinical trials reported results on time. The public is also aware of the issue, as reflected by this story on NPR.

**When must results be reported?** The law requires that results be submitted to ClinicalTrials.gov no later than 12 months after the “Primary Completion Date,” which is defined as the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

**You’re not alone! Help is available.** You are strongly encouraged to contact Elizabeth Massey Gendel, PhD (Elizabeth.M.Gendel@uth.tmc.edu, 713-500-3587) for one-on-one assistance with ClinicalTrials.gov registration and results reporting. She has recently attended a workshop led by ClinicalTrials.gov staff and is familiar with what the reviewers are looking for.

**ClinicalTrials.gov offers online resources.** ClinicalTrials.gov offers many resources to assist researchers. Registration resources are found here. Results reporting resources are found here and here.

*Take care of your ClinicalTrials.gov records now before enforcement begins!*
Let’s Welcome New Members of the Clinical Research Unit (CRU)!

**Shelbie Martin**

**Shelbie Martin, BS** graduated in August of 2015 from Texas A&M University with a Bachelor of Science in health. While at Texas A&M University, Shelbie was involved with the university’s branch of Project Sunshine, a non-profit organization that provides free programs and services to children with long-term illnesses, disabilities, and special needs, as well as to their siblings. She recently moved to Houston and is working in Internal Medicine as a Research Assistant.

**Stefani Garcia**

**Stefani Garcia, BS** will be a new research coordinator for the Orthopedic Surgery Department. She was born in Houston but spent most of her life in Colombia. Stefani attended the University of Houston, where she majored in biology and minored in chemistry. At UH, she worked in Dr. Gregg Roman’s laboratory studying Drosophila 5HT1a and 5HT1b genes and characterizing the behavior of several Drosophila species, which inspired her to continue doing research after graduation.

**Diego Moreno**

**Diego Moreno, BA** is the new Patient Access Representative for the Clinical Research Unit (CRU). Diego is a graduate of the University of Houston-Downtown, where he received a Bachelor of Arts in management. Prior to joining the CRU team, Diego worked as an Accounts Payable Assistant at an IT service company. He also worked at J.P. Morgan Chase as a Customer Service Representative. Diego is fluent in both English and Spanish, and he is now your point of contact for any scheduling and/or registration needs in the CRU.

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Estela A. Acosta

Estela A. Acosta, BSN, RN received her nursing degree in December of 2011 from Prairie View A&M University-Houston and is currently working as a Research Nurse/Coordinator at the UTHealth Center for Clinical & Translational Science’s Clinical Research Unit. Acosta is a strong advocate for ethical clinical research and believes in the conquest of life threatening disease. She is a firm research patient advocate, and she believes in an informed consent, that is, explaining the study, the procedures involved, and the risks versus the benefits; giving the patient ample time to make a decision; answering all questions; and informing the patient that participation is voluntary and that there is the option to withdraw from the study at any time. Her current projects include involvement in the development of the new Clinical Research Center at LBJ Hospital. She is managing several Investigational Medical Product research studies at the UTHealth Clinical Research Unit and LBJ Hospital. In addition, she has experience as a Clinical Research Coordinator from 2002 to 2008 in the Division of Infectious Diseases, also at UTHealth. Her special interests in research include kidney disease, HIV, stroke, and cancer. She has held inpatient and outpatient positions as staff nurse and charge nurse at Houston area hospitals and the Harris Health System. She was a part of the SMART (Strategies for Management of Antiretroviral Therapy) Study Group and is listed as a US-based SMART Clinical Site Investigator on page 2295 of the 2006 SMART publication titled “CD4+ Count–Guided Interruption of Antiretroviral Treatment” in the New England Journal of Medicine (vol 355, no 22, pp 2283-96). Acosta hopes that her contributions in research will make a difference in the future of clinical research and in the lives of research participants.

Jane K. Lee Joins EVPARA

We are pleased to welcome Jane K. Lee, MPH to EVPARA. Jane graduated with a Bachelor of Arts in English literature from Texas A&M University, and she went on to receive a Master’s in public health from the UTHealth School of Public Health in Houston, Texas. Currently, Jane is pursuing a law degree from South Texas College of Law. She’s a certified mediator and is active in her law school’s advocacy program. Jane will be an intern to the Office of the Executive Vice President for Academic and Research Affairs, working primarily with the Research Compliance, Education, and Support Services under Dr. Sujatha Sridhar. Welcome, Jane!
Leveraging IRB Reciprocity to Streamline Review of Multi-Center Clinical Trials

The UT System Master IRB Reciprocity Agreement, created to reduce the regulatory burden on researchers and institutions, allows one institution to rely upon another institution’s IRB for the review, approval, and continuing oversight of multi-center human subjects research. This Agreement significantly reduces the duration of study start-up by eliminating redundant IRB activities and is a cornerstone of the Clinical Trials Xpress (CTX) model.

CTX worked with UTHealth IRB leadership and founding network institutions to develop a unique process to engage the IRB reciprocity model. Three key tenets of the process ensure efficiency and convenience for network study teams conducting the same multi-site study:

- UTHealth IRB serves as the “Reviewing IRB” for all network studies,
- CTX coordinates and submits study materials to the IRB for all investigators at Relying Institutions, and
- IRB Approvals and other critical study documents are stored in an online eRegulatory Binder for access by appropriate study site and sponsor personnel.

The mechanics of the CTX-IRB process have been successfully tested through submission of Pfizer’s SPIRE I and II trials on behalf of investigators at UTHealth, UTHSC-San Antonio, and UT Southwestern Medical Center. These phase 3 trials, which explore the effectiveness of a new lipid-lowering treatment, were approved in early January, and all sites are slated for activation later this month.

For more information about the Clinical Trials Xpress initiative, please see our article in the November/December issue of The Clinical Coordinator.

Upcoming Certification Testing Dates

CCRP certification: For those interested in becoming a Certified Clinical Research Professional, the next exam in Houston is at Methodist Hospital on May, 7 2016 with a registration deadline of March 25, 2016. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in February and March of 2016. Applications are due by February 1, 2016, and you can find more information here.
**Bioethics Grand Rounds**

**Title:** The Ethical Basis of Research Regulation: A Return to Foundational Obligations and Responsibilities in Medical Science  
**Speakers:**  
Susan M. Miller, MD, MPH  
John S. Dun, Sr. Research Chair in General Medicine; Houston Methodist Hospital  
Joseph J. Fins, MD, MACP  
E. William Davis, J., MD Professor of Ethics  
Chief, Division of Medical Ethics and Professor of Medicine; Professor of Medical Ethics in Neurology and Medicine in Psychiatry; Weill Cornell Medical College and New York Presbyterian Hospital  
**Date:** January 27, 2016  
**Time:** 5:00 pm – 6:00 pm  
**Location:** Methodist Hospital, Rio Grande Conference Room  
Registration is not required.

**Center for Clinical Investigation (CCI) Meeting**

**Objective:** Aid clinical research and reduce 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:** February 8, 2016  
**Time:** 2:00 pm – 3:00 pm  
**Location:** UTPB 1100.55  
Registration is not required.

**Clinical Research Finance Lunch and Learn**

**Objective:** Provide staff members guidance on research financial topics (e.g., budgeting, billing, and coverage analysis). Also, a forum to introduce or update financial matters and to present questions or concerns for discussion in an open setting with peers.  
**Date:** February 10, 2016  
**Time:** 11:30 am – 12:30pm  
**Location:** MSB 2.135  
*Feel free to bring your lunch.*  
Registration is not required.

**Study Coordinator Monthly Forum**

**Objective:** Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth. More information [here](#).  
**Date:** February 23, 2016 (Topic: Consent Process for Special Circumstances)  
**Time:** 11:30 am – 1:00 pm  
**Location:** MSB 2.135  
*Lunch provided for the first 40 participants.*  
Registration is not required.

**Orientation for Clinical Research Staff**

**Objective:** Educate new clinical research personnel on clinical trial management, as well as IRB review and Memorial Hermann study start up processes. The program will lead into the Study Coordinator Forum.  
**Date:** February 23, 2016  
**Time:** 8:15 am – 11:30 pm  
**Location:** MSB 2.104B  
Registration is required. Register [here](#).

**Clinical Research Budgeting and Billing Training**

**Objective:** A hands-on workshop that will cover the processes for billing, coverage analysis, building a research budget, and reconciliation.  
**Date:** February 23, 2016  
**Time:** 1:00 pm – 3:30 pm  
**Location:** MSB G.100  
Registration is required. Register [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:** February 17, 2016  
**Time:** 9:30 am – 12:00 pm  
**Location:** UCT 1155  
*Parking will be validated.*  
Registration is required. Register [here](#).
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/ for more information.

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