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The Clinical Coordinator

Clinical Research News You Can Use…

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FDA Talk on Inspections

One does not typically describe a talk on FDA matters as "fun," but all attendees would probably agree that Alanna Mussawwir-Bias delivered a highly engaging (and fun!) talk to the Houston clinical research community at the August 9, 2017 Clinical Coordinator Forum.

Mussawwir-Bias distinguished between FDA regulation and FDA guidance, as above

FDA's Alanna Mussawwir-Bias (center) with attendees

At the Forum, Alanna discussed FDA inspections and how to prepare for them, as well as enforcement actions. She also described the responsibilities of clinical investigators and offered tips for a successful study.

Alanna is a Supervisory Consumer Safety Officer (SCSO) in the Office of Bioresearch Monitoring (BIMO) of FDA's Office of Regulatory Affairs (ORA). She and her team are responsible for BIMO inspections in the ORA BIMO Division II Dallas region, which includes Houston.

If you missed the talk, Alanna has graciously shared her slides. You may contact CTRC at clinicaltrials@uth.tmc.edu to request her presentation.

New Clinical Trial Requirements for NIH Grants and Contracts

NIH is rolling out a series of changes that affect NIH-funded clinical trials. Changes that will apply to January 25, 2018 due dates and beyond include the requirements to use a **clinical trial-specific FOA for clinical trials**, a **single IRB for multi-site studies**, and the **new Human Subjects and Clinical Trial Information form**. These changes and more are described at: https://grants.nih.gov/policy/clinical-trials.htm.

April Vanderslice Completes Clinical Research Internship Program

April Vanderslice, CIP

Please join us in congratulating April Vanderslice, CIP (Certified IRB Professional) for completing the Clinical Research Internship Program! During the year-long program, April was mentored by Matthew Galpin, CCRC, who was one of the first clinical research coordinators to complete this program in 2014 and who went on to implement the program in the Department of Orthopedic Surgery.

There is a great need for this program because newly hired coordinators have a variety of backgrounds (some have research coordination experience, but many don't), and coordinators usually don't receive formal training for their jobs. The program was initially developed by Kathy Franco, Director of the Clinical Research Unit (CRU), to offer in-depth training beyond what is possible in the 3 days of UTHealth's basic Clinical Research Education Course.

The Clinical Research Internship Program defines various domains of knowledge that are critical for coordinating clinical trials, including human subjects protection, informed consent, study management, regulatory affairs, clinical practice, clinical lab practice, care coordination and continuity, and scientific inquiry. Throughout the year-long program, participants are guided by an experienced mentor through activities associated with each of these domains, and competency in each area must be demonstrated in order to complete the program.

April has a background in human subjects protection—she is a certified IRB professional (CIP) and has over 20 years of experience as an IRB administrator, beginning at UTMB as a departmental IRB coordinator and then later joining UTMB's IRB as a coordinator, eventually becoming the senior manager of the IRB. In 2016, April transitioned from reviewing clinical research to performing and managing clinical research when she joined UTHealth's Department of Orthopedic Surgery as a research coordinator. With her change in roles, April was a great fit for the program.

Matthew stated, "I was honored to have completed this program under the guidance of Kathy Franco when I first started in research, and I found that the content and structure were fundamentally critical—yet, prior to the implementation of this program, there was no place to gain that knowledge in a structured manner. I have used Kathy's experience and guidance as my mentor to continue this internship and many other aspects of training for all kinds of research staff, specifically new coordinators with no experience."

Matthew added, "April really broke the mold. In my experience, there has always been a disconnect between coordinators, PIs, and IRB personnel—each group often wondering what the other was thinking. It is not often that you find someone who is so well versed in the regulatory and IRB processes and who also wants to be a coordinator. UT Orthopedic Surgery sees tremendous value in April's ability to close that gap, and she has done an amazing job in the transition."

Congratulations, April!

Let's Welcome Benson and Michael to the CRU!

Benson Mathai, MHA is a new Research Coordinator in UTHealth's Clinical Research Unit (CRU). Benson graduated from the University of Houston – Clear Lake with his Bachelors of Science in Healthcare Administration in 2008 and Masters in Healthcare Administration in 2015. Prior to joining the CRU team, Benson worked at MD Anderson Cancer Center for 9 years in clinical research

Michael Tran, BSN, RN is the newest member of UTHealth's Clinical Research Unit, joining the team as a Research Nurse. Michael graduated from UTHealth's School of Nursing (SON) in 2013. Before joining the CRU, he worked at Ben Taub Hospital in the Neurosurgical ICU.

Congratulations, Benson and Michael, and good luck on your new positions at UTHealth!

Deborah Osafehinti Joins CTRC

We are pleased to welcome Deborah Osafehinti, MBChB to the Clinical Trials Resource Center (CTRC). Deborah is currently an MPH student majoring in epidemiology at the UT School of Public Health. She earned a Bachelor of Medicine and Bachelor of Surgery degree from the Obafemi Awolowo University, Nigeria and practiced as a clinician for four years before coming to the United States in 2015. Prior to joining CTRC, she worked as a graduate research assistant at the Center for Clinical and Translational Sciences (CCTS), UTHealth where she was involved in data management and quality control. She is joining CTRC as a graduate assistant. Welcome, Deborah!

The next Clinical Research Education Course is October 17-19, 2017.

Find more details and register at:

https://www.uth.edu/ctrc/training/clinical-research-education.htm

FEATURED STUDY

HPV-Associated Cancer in Men

Virtually all cervical cancers, most oropharyngeal and anal cancers, and a major proportion of penile, vaginal, and vulvar cancers are attributable to oncogenic types of human papillomavirus (HPV). Cervical cancer screening is a regular part of annual well-woman visits; however, there is no screening strategy for non-cervical HPV-associated cancers and, thus, no screening for men. Considering that approximately half of anal cancers and >80% of oropharyngeal cancers occur in men and that the annual U.S. incidence of oropharyngeal cancer in men now outnumbers that of cervical cancer in women, a screening strategy for risk of HPV-related cancers in men is needed.

The development of a screening tool, however, first requires the identification of cohorts with an elevated cancer risk and who are thus most likely to benefit from the screening. The **HPV-related Oropharyngeal and Uncommon cancers Screening Trial of meN (HOUSTON) study** led by PI Erich Sturgis, MD, MPH of MDACC and Co-I Kunal Jain, MD of UTHealth aims to take this initial step.

Previous studies have shown that a potential strategy for identifying people at extreme risk of HPV-associated cancer is to assay for antibodies to HPV type 16 E antigens, and the HOUSTON study will employ this assay to estimate the incidence of HPV-associated oropharyngeal, anal, and penile cancer in men ages 50 – 59. The data from the HOUSTON study will ultimately enable risk stratification, early detection, and screening strategies for HPV-associated cancers in men.

UTHealth's Clinical Research Unit (CRU) is assisting with recruitment and execution of the study. Recruitment is occurring through the ENT clinic at Memorial Hermann Medical Plaza, health fairs, locations around TMC, as well as the survivorship clinic at MDACC.

For more information, see the ClinicalTrials.gov record NCT02897427 at this link.

Meagan Olivares, BS and Michael Tran, BSN, RN recruiting for the HOUSTON study

UTHealth Good Clinical Practice (GCP) Corner

Tips for a Successful Study – TRUE or FALSE?

1. Know and FOLLOW the protocol.
2. Clarify any ambiguity or discrepancy in the protocol prior to study initiation.
3. Keep all records (i.e., sponsor memos, IRB memos, subject letters emails memos).
4. Keep all test article accountability records (i.e., shipping receipts, enrollment logs, dispensing logs).
5. Know your IRB requirements for reporting.
6. Know the sponsor's AE/SAE reporting requirements.
7. The study team is ultimately responsible for the conduct of the study.

Answers: 1. True. **2.** True. **3.** True. **4.** True. **5.** True. **6.** True. **7.** False (correct answer – PI).

NIH Certificates of Confidentiality

NIH issues Certificates of Confidentiality, and the purpose is to protect the privacy of subjects who participate in NIH-funded research in which sensitive information is collected or used. Recently, NIH has updated their policy on Certificates in order to enhance privacy protections.

In the past, Certificates were issued only at the request of investigators; however, under the new policy, researchers will no longer have to apply for a Certificate of Confidentiality. Instead, Certificates are automatically granted to recipients of NIH-funded grants, cooperative agreements, and contracts in which identifiable, sensitive information (as defined by NIH) is used or collected.

Additionally, under the new policy, disclosure of the participant information is no longer up to the discretion of the researcher. Rather, disclosure is only permitted under the following circumstances:

1. if required by federal, state, or local laws, such as for reporting communicable diseases;
2. if participant has given permission for the disclosure; or
3. for the purposes of research that is compliant with human subjects regulations.

Read the new NIH policy: NOT-OD-17-109.

UTHealth Good Clinical Practice (GCP) Corner

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 October 28, 2017 with a registration deadline of September 15, 2017. 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 2018. Applications are due by December 1, 2017, and you can find more information here.

Upcoming Training

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: September 28, 2017
Time: 1:30 pm – 4:00 pm
Location: UCT 1155 (parking will be validated)
Registration is required. Register here.

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: October 11, 2017
Topic:: UT BIG SERVICES: Design and Execution of Research Projects (REDCAP) (presented by Susan Guerrero, CISSP, PMP of SBMI)
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Lunch provided for the first 40 participants.
Registration is not required.

Clinical Research Education Program

Objective: Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. This three day program focuses on clinical trial management, good clinical practice, and efficient trial conduct.
Date: October 17 – 19, 2017
Time: 8:30 am – 4:30 pm
Location: Cooley University Life Center
Register here.

Orientation for Clinical Research Staff

Objective: General overview of clinical trial research at UTHealth, including study start up processes and clinical trial management.
Date: December 6, 2017
Time: 8:30 am – 3:30 pm
Location: UCT 1505C (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 1840. Please visit https://www.uth.edu/ctrc/ for more information.

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