Volume 16, Issue 5
July 2019

The Clinical Coordinator

Clinical Research News You Can Use

INSIDE THIS ISSUE

START, UTHealth's new Grants and Contracts Management System

START, UTHealth's new Grants and Contracts Management System, will go live on 9/2/2019.

UTHealth | START

Key Dates

7/29/19 Mandatory training begins.
9/2/19 START goes live.
10/2/19 All agreements submitted to SPA on or after October 2, 2019 must be submitted via UTHealth START.
10/5/19 All proposals submitted for deadlines on or after October 5, 2019 must be submitted via UTHealth START.

To Access START, All Users Must Attend Mandatory Training

Registration for START training is currently open. Different sessions are offered, tailored to user role.

Training Sessions Offered

- Study Coordinators/Clinical Trial Administrators: 2-day session
- Faculty: ½-day session. System introduction and navigation; Dashboard; Starting a Proposal; Submitting a Contract to SPA; Routing and Approvals; Financial view of projects; SPIN overview (funding opportunity database)
- Department Grants & Contracts Administrators: 3-day session. DMOs who function as G&C administrators should attend this course
- DMOs/Chairs/Associate Deans: ½-day session. System introduction and navigation; Dashboard; Routing and Approvals; Financial view of projects; Reports; SPIN overview (funding opportunity database)

To Register for START Training

- Log into Learn2Succeed at this link
- Click "Course Catalog" in the menu on the left
- Click "Sponsored Projects Administration"
- Click to select a session according to your role (note that multiple dates are offered per role), after which you will be taken to a second window titled "Enrollment Information"
    - To find course location: In the second window titled "Enrollment Information," click the hyperlink in the "Name" section under the "Session Information" heading, which will take you to a third window—scroll down to bottom of this third window to view course location address and room number.
- To enroll: In the second window titled "Enrollment Information", click enroll in the upper right corner.

For details on START, see SPA's webpage at this link.

Jasmine Rosario Joins CPHS as IRB Coordinator for Panel 2

Jasmine Rosario is the newest member of the CPHS team, serving as IRB Coordinator for Panel 2. Jasmine started with UTHealth in June 2019. She is new to the Houston area. Jasmine, who is originally from New York, worked as an IRB coordinator at Memorial Sloan Kettering Cancer Center (MSKCC), where she worked for 9 years. During the last 7 years, she has worked at Baylor Scott & White (BSW). During her final two years at BSW, she worked as a Regulatory Specialist. Outside of work, Jasmine stays really busy with her 3 kids ages, 18, 12, and 3. Her oldest daughter started at PVAMU in July 2019, where she plays in the band.

Welcome, Jasmine! We're so happy to have you as a part of UTHealth!

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Suhail Qureshi Joins CRF as Manager of Institutional Wide Clinical Research and Finance Administration

Suhail Qureshi, MD, MHA comes with more than 13 years of experience in clinical research, finance, and administration from MD Anderson Cancer Center. Suhail is a medical graduate from King Edward Medical University in Lahore, Pakistan, and he recently received his Masters of Healthcare administration degree from Walden University.

Suhail started his career at MD Anderson Cancer Center as research assistant in the department of cardiology. In collaboration with the department of Stem Cell and Cellular Therapy, he coauthored more than 18 medical publications.

Suhail transitioned into the department of Stem Cell and Cellular therapy to work for the data management research division and was the lead member to participate in the Data Management Competency program.

Suhail later joined the department of Clinical Research Finance at MD Anderson Cancer Center, where he and his team managed financial aspects of clinical trials administration, including coverage analysis development, internal budget, grants, contract, and clinical research billing review.

Welcome, Suhail! We look forward to working with you!

REMIINDER: Central Invoicing for Administrative Start Up Fees, IRB Fee Invoicing

Effective July 1st, 2019, the IRB will no longer perform collection activities for unpaid invoices. CPHS will continue to invoice the sponsor directly for IRB fees; however, CPHS will no longer be responsible for following up with sponsors if payment is not received. Departments are now responsible for monitoring applicable financial project accounts for payment receipt and for performing collection activities if necessary. IRB fees will be automatically debited from study project FMS account 120 days after invoice has been sent to the sponsor. SPA will provide assistance to departments experiencing payment issues. Please contact SPA with any payments >120 days past due to request assistance with collection activities.

Effective July 1st, 2019, administrative start up fees will be invoiced centrally for all industry-initiated clinical studies. See the process chart at this link, as well as FAQs at this link. The PI and/or Department is responsible for ensuring terms related to administrative startup costs are clearly incorporated within the Clinical Trial Agreement, as well as the budget—note that if the administrative start up fees are not clearly defined within the contract, they cannot be invoiced.

Each Clinical Trial Agreement will generate an IRB fee invoice and an Administrative Startup invoice. It is the department's responsibility to provide SPA with the names of the financial staff whom they would like to be cc'd when the invoices are sent to sponsor. The most efficient approach would be to simply cc applicable financial staff upon initial submission of the contract to SPA.

For details, see SPA's webpage at this link.

Test your knowledge of Good Clinical Practice (GCP)! Answers are found below.

1. A _____is a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor for each trial subject.
2. A source document is any document where the data are first recorded.
3. Data reported on the case report form (CRF) that are derived from source documents should be consistent with the source documents or the discrepancies should be explained.
4. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry.

Answers:
1. Case Report Form (CRF), **2.** True, **3.** True, **4.** True

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 and Time: 8/1/19 and 8/27/19, 1:30 – 4:00pm
Location: UCT 1155 (parking will be validated)
Registration is required. Register here.

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management. More information here.
Date: August 28, 2019
Topic: TBD
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Lunch will be provided for the first 40 participants.
Registration is not required.

Orientation for Clinical Research Staff

Objective: General overview of clinical research at UTHealth, including study start up processes and clinical trial management.
Date: August 6, 2019
Time: 8:30 am – 2:30 pm
Location: UCT 1505C (UCT parking will be validated)
Lunch will be provided.
Registration is required. Register here.

TMC – SoCRA METS

Objective: Monthly training and educational event for clinical research professionals from TMC member institutions.
Date: August 7, 2019
T**ime:** 3:30 pm – 4:30 pm
Topic: FDA GCP and ICH GCP
Speaker: Dalal Murai, COO, GXP Quality Systems
Location: Third Coast Restaurant, 6th Floor Room II, 6550 Bertner Avenue
Registration is required. Register here.

IRB Office Hours

If you would like help submitting an iRIS application or writing a protocol or consent form, or if you want to learn more about IRB reciprocity agreements, then consider taking advantage of IRB office hours.
MSB hours: 2nd and 4th Thursdays from 1:00 pm – 4:00 pm at MSB B.640
SOD hours: 1st Thursdays from 1:00 pm – 4:00 pm at SOD 4416 (Research Office conference room).
An appointment is not necessary

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 suite 1840. Please visit https://www.uth.edu/ctrc/ for more information.

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We would love to hear from you.
Please send your comments, suggestions and feedback to clinicaltrials@uth.tmc.edu