



Clinical Research News You Can Use

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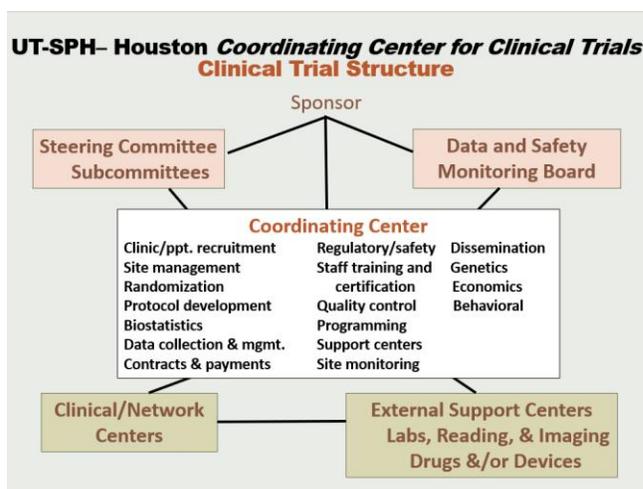
Support for Multicenter Clinical Trials

The **Coordinating Center for Clinical Trials (CCCT)** is one of many centers within UTHealth’s School of Public Health and has 45 plus years’ experience in clinical trial leadership, design, management, execution, analysis, and dissemination (both NIH- and industry-sponsored). The CCCT has played a leadership role in medical research (including cardiovascular disease, eye disease, diabetes mellitus, and sickle cell disease) by **servicing as a coordinating center for 25+ nationwide multicenter clinical trials**, including the landmark ALLHAT trial.

Key personnel include statisticians, physicians, epidemiologists, project managers, information technology personnel, statistical programmers, and safety and regulatory personnel, as well as financial and administrative teams. The group has extensive experience in managing both large- and small-scale multicenter trials and research networks, with proficiency in project management, administration, database development, and analytical support. The entire CCCT team is steadfast and devoted to the highest standards of research, leadership, and dissemination.

Barry Davis, MD, PhD, Director of the CCCT, recently presented at the Research Coordinator Forum on the resources of the Center and is seeking collaboration opportunities with Investigators within the UTHealth that could benefit from the services of a Coordinating Center. **The CCCT assists with the logistical and statistical needs of multicenter trials, freeing up clinician Investigators to focus on the care of participants and the collection of valuable research data.**

If you are considering applying for funding of a multicenter trial or are interested in learning more about collaborations with CCCT, please visit their website at <https://sph.uth.edu/research/centers/ccct/> or email them directly at Barry.R.Davis@uth.tmc.edu or Shelly.L.Sayre@uth.tmc.edu.



FOCUS ON THE CLINICAL RESEARCH UNIT

The **mission** of the Center for Clinical and Translational Sciences (CCTS) Clinical Research Units (CRUs) is to facilitate clinical research by providing investigators with specialized facilities, personnel, and advice. The CRU at Memorial Hermann Hospital System (MHHS)-TMC offers clinic space, 6 outpatient and 4 inpatient rooms, nursing and coordinator services, scheduling of diagnostic tests and procedures, a chart room and physician charting area, consulting support in early stages of protocol development, and lab services, including cell reconstitution and nitrogen storage. For more information, see CRU's website at: <https://www.uth.edu/cru/index.htm>



Candace Hernandez, BS has been a Research Assistant II with UTHealth since August 2018. Candace received a B.S. in Biology from Louisiana State University and has over eight years of research experience. Candace worked at Pennington Biomedical Research Center in Baton Rouge, Louisiana where she served as both a research assistant and laboratory coordinator for in-house and central laboratory clinical trials. She has also had the privilege of providing field support of clinical studies in conjunction with the United States Department of Defense. Candace is an avid reader and baker and is happy to be a part of the Clinical Research Unit at UTHealth



Krystle Oliver, RN, BSN, CRRN, is currently a Clinical Research Nurse with UT Health Clinical Research Unit since July 2018. Overall, she has been with UTHealth since July 2017. She holds a BSN in nursing from Chamberlain College of Nursing, as well as BS in Biology from Abilene Christian University. Her clinical background includes emergency, medical surgical and neurology/rehabilitation and outpatient adult/pediatric neurology. She also holds certification in rehabilitation nursing as well. She enjoys reading, watching and playing sports, and is currently expanding her culinary skills, particularly in baking. With both degrees, she had hoped that one day she could combine both in research nursing and is very excited to have the opportunity to do so.



Cynde Sturm, MS, RN, received her Bachelor of Science in Nursing and Master of Science in Nursing Education from Texas Woman's University in the Texas Medical Center. She started working in the CRU in August 2018. Her background is in critical and emergency care, as well as educating in various settings, from clinical to university nursing programs. She chose to work in clinical research because it enables her to work directly with patients, as well as utilize her education background. She loves working in the CRU and being a part of cutting-edge research!

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

1. The person in charge of a clinical trial or a scientific research grant is called a _____ .
2. Qualified individuals who are not MDs can participate in clinical trials either as principal investigators or sub-investigators provided that an MD or DO (or DDS depending upon the study) is either a sub-investigator or is listed in the IND as an individual who will be responsible for drug administration and evaluation of patient safety.
3. The principle investigator signs the form 1572, but the sub investigator does not.
4. The PI may delegate study tasks to site staff, provided that they are qualified to perform that task.
5. Every individual delegated by the PI to perform any study-related duties should sign the _____ log.
6. What FDA document must all investigators sign prior to participating in a drug clinical trial?

Answers: 1. Principal Investigator, 2. True, 3. True, 4. True, 5. Delegation of Authority (DOA) Log, 6. Form 1572

CERTIFICATIONS FOR CLINICAL RESEARCH PROFESSIONALS

If you are seeking to advance your career and become certified as a Clinical Research Professional, then you may wish to consider [ACRP](#) (Association of Clinical Research Professionals) for CCRC certification or [SOCRA](#) (Society of Clinical Research Associates) for CCRP certification. Both ACRP and SOCRA have similar missions, which is to ensure quality clinical research, promote global protection of research participants, and offer clinical research professionals educational opportunities and resources. If you need to choose between SOCRA and ACRP certification, consider your job title, roles, and budget. Overall, ACRP maybe more expensive, but certification as a CCRC through ACRP is specific to the role of the clinical trial coordinator, whereas certification as a CCRP through SOCRA covers a wide spectrum of clinical research roles.



CCRP Certification: For those interested in becoming a Certified Clinical research Professional, the next exam in Houston is at the Methodist Hospital on 8/3/2019 and application deadline is on 6/22/2019. For more information click [here](#).



CCRC Certification: The next exam dates for certification as a clinical Research Coordinator (CRC) are September and October 2019. For more information click [here](#).

Both ACRP and SOCRA have global annual conferences to offer educational opportunities, contact hours, and networking opportunities. [2019 Annual SOCRA Conference](#): September 27, 28, 29, 2019 in San Antonio, Texas. [ACRP 2019](#): April 12-15 in Nashville, Tennessee.

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: 5/7/19, 5/30/19, 6/18/19, 7/10/19, 8/1/19, 8/27/19

Time: 1:30am – 4:00pm (except 5/30/19 is 9:30am – Noon)

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: May 22, 2019

Topic: "Best Practices for a Successful IRB Application" by Stephanie M. Francisco, BA and Laura K. Lincoln, BS

Time: 11:30 am – 1:00 pm

Location: MSB B.645

Registration is not required.

TMC – SoCRA METS

Objective: The TMC Clinical Research Professional Training and Education Committee and SoCRA Houston Galveston are pleased to announce the Monthly Education Training Series (METS), which is designed to serve as a monthly training and educational event for clinical research professionals from TMC member institutions.

Date: May 1, 2019

Topic: "Informed Consent: Where We Were – Where We Are – And Where We May be Going" by Daniela Westerhold, CCRP, Director of Protocol and Regulatory Affairs, Texas Children's Hospital Cancer and Hematology Centers

Time: 3:30 pm – 4:30 pm

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