

Clinical Trial Plan for Patients Requiring Hospital Level Services at UTHSC-Memphis

Background:

There are many opportunities to conduct clinical research at the Memphis campus of UTHSC. There are multiple affiliated clinical trial offices each of which controls at least one physical clinical trial space. Some of these offices employ full time coordinators while some lease coordinators or use individual investigator coordinators. Some of these offices exclusively contract through UTHSC; others allow for contracting through MLH or other sponsors with operational funds passing through to UTHSC. Some of the offices are college or department specific, others support researchers across campuses and departments. The creation of these offices occurred organically over the course of many years to meet various needs of different researchers. Because of the overlapping nature of these offices, the CTGB was created in 2016 to create a federated model by which best practices could be determined, resources could be shared, and leadership in clinical research identified.

The current members of the UTHSC CTGB representing offices in Memphis include:

Clinical Trials Unit (CTU): The Clinical Trials Unit provides various research related services to providers participating or interested in clinical research. The CTU has specialized staff to support various and unique roles in the research setting allowing providers to streamline research trials independent of their clinic staff. Its research personnel have experience in various drug and device trials including phase I, phase II, phase III, phase IV, observational, post market, sponsor-investigator initiated, investigator initiated, and government sponsored trials. The CTU has office locations on both the UTHSC and Methodist University Hospital campuses with the ability to provide research support in outlying hospitals and physician offices. Csaba Kovesdy, MD, FASN, is the CTU Medical Director, and a member of the CTGB.

Clinical Research Center (CRC): The CRC is geared to supporting federally funded studies. This office is located on the 8th floor of Methodist University Hospital and is therefore well situated to support inpatient clinical trial needs. The CRC is staffed on weekdays from 7:00am-4:00pm by dedicated research coordinators and nurses and can support inpatient studies on a per diem basis. The CRC has approximately 6,750 sq. ft. of space and is primarily an outpatient facility. It has nine examination rooms, a three-bed patient bay, an exercise physiology room, a medical records room, a bio-nutrition teaching lab, a dual energy x-ray absorptiometry (DXA) procedure room, a processing laboratory, storage rooms in addition to six offices for the staff members. The CRC also houses an environmental chamber (cold room) that is used as a psychological/physical stressor to produce systemic vasoconstriction. Sam Dagogo-Jack, MD, BM, MSc, FRAP, is the director of the CRC, and a member of the CTGB.

Office of Preventive Medicine Clinical Research: Preventive Medicine (Prev Med) has conducted clinical research projects at the 66 N. Pauline building location and in a clinic at 756 Ridgeland Boulevard in East Memphis for nearly 30 years. Prev Med trials typically support the faculty of

Preventive Medicine in conducting clinical trials and epidemiologic studies funded by the NIH, pharmaceutically sponsored trials, and studies funded by foundations. Prev Med also provides space and support for investigators who are not members of the department. The Medical Director Chair of the Prev Med Clin Research group is Karen Johnson, MD, MPH, who serves on the CTGB.

Children's Foundation Research Institute (CFRI): The CFRI conducts clinical research in support of investigators in the Department of Pediatrics. Located in Le Bonheur Research Building, the Department of Pediatrics supports both inpatient and outpatient studies within the various departments and divisions within Le Bonheur. There is dedicated outpatient space on the 7th floor of the Research Building as well as capability to conduct research within the various Le Bonheur pediatric clinics. The CFRI can support both federally funded and pharma-funded research as well as certain investigator-initiated studies. CFRI carefully regulates by scientific and operational review which studies will be conducted within the Department of Pediatrics and studies must be approved by CFRI leadership before the trial may be conducted. The Scientific Director is Dennis Black, MD, a member of the CTGB.

Nephrology Clinical Outcomes and Clinical Trials Program (COCTP): Located in the UTHSC Pauline building, the COCTP supports clinical trials conducted in the division of nephrology. Generally, this unit supports pharmaceutical trials that do not require inpatient support. The COCTP has patient rooms, clinical study coordinators, and some regulatory and data support. Trial choice and support decisions are governed by the medical director of the unit. The director is Dr. Csaba Kovessy, a member of the CTGB.

Dental Clinical Research Center: The College of Dentistry has historically conducted clinical trials within their dedicated clinical research center. It contains patient treatment areas as well as specialized research equipment for dental studies. The research coordinator is Colette Stewart, RDH. The medical director is Franklin Garcia-Godoy, DMD, a member of the CTGB.

University Clinical Health Research Unit: UCH is a UTHSC affiliated practice group that has recently begun to conduct their own clinical research. They can support research conducted by certain UCH employed clinicians. They currently do not employ dedicated nurse coordinators but are in the process of building their resources. They do not currently have dedicated clinical research space but rather support studies in the outpatient or inpatient setting for their physicians. The research infrastructure at UCH is managed by Courtney Love, CAO and Vice President of Organizational Effectiveness. Dr. Penny Asbell conducts research through UCH and represents UCH on the CTGB.

Non-Memphis campuses: Several clinical trial offices associated with other UTHSC campuses are also represented on the CTGB. A short description of each follows. Of note, this policy document applies only to Memphis-based studies with hospital needs. Each of the below locations may develop their own policy to support inpatient-type studies.

Ascension St. Thomas Research Institute (ASTRI), Nashville: Ascension St. Thomas Health is the health system associated with UTHSC-Nashville and operates several hospitals and clinics in Nashville. ASTRI provides a robust clinical research infrastructure to support pharmaceutical and device clinical trials, translational research and comparative effectiveness research that addresses clinical questions in a wide array of diseases, interventions, and populations. Residents and faculty have access to dedicated staff to assist in the assessment of research projects, statistical design, protocol development, clinical research coordinators and support staff to manage data and publication creation and review. The director of ASTRI is Geoffrey Smallwood, MD, a member of the CTGB.

University Medical Center, Knoxville: UTHSC in Knoxville performs clinical research out of two distinct research offices - the Office of Clinical Trials (OCT) within the University of Tennessee Medical Center, and a small clinical trials group within the UT Graduate School of Medicine (UTGSM). There is also a for-profit CRO (volunteer research group) that runs trials at UTMC. Of the two faculty driven research groups, the OCT is larger and more closely collaborates within the hospital system. OCT has full research staffing capabilities including budgeting, contracting, regulatory, invoicing, research laboratory capabilities, and research nurse coordinators. The executive director of the OCT is Kim Mason, PharmD, while the medical director of the UTGSM's group is Paul Hauptman, MD, dean of UTGSM, a member of the CTGB.

Erlanger Health System, Chattanooga: Erlanger Health System is the health system affiliated with UTHSC-Chattanooga. The Erlanger Institute for Clinical Research (EICR) supports clinical trials for investigators affiliated with the Erlanger Health System. EICR provides contracting, budgeting, research nursing, regulatory support, and research nurse coordination. The clinical research program at EICR is overseen by Giuseppe Pizzorno, PhD, Chief Research Officer for Erlanger and Associate Dean of Research at UTHSC-Chattanooga. Dr. Pizzorno are members of the CTGB.

Other colleges and departments have representation on the CTGB for visibility and development purposes despite not having a dedicated clinical research program. These include the College of Medicine, represented by Sr. Associate Dean for Research, Andy Griffith, MD, ADR and the College of Nursing, represented by Associate Dean for Research, Ansley Stanfill, PhD, RN.

Roles of Clinical Trial Offices

As evidenced from the above, the various offices have overlapping functions and offerings. Investigators are encouraged to reach out to the CTGB leadership to determine which office is best able to handle their clinical trial needs. A few general guidelines for Memphis studies are as follows:

1. Faculty within a department or division that has a clinical trials office (e.g., Pediatrics, Nephrology, Preventive Medicine) should approach their department/division's office first. If their departmental trials office is unable to meet their trial needs, opportunities exist within both

- the CTU and CRC to provide support.
2. Trials that require dedicated research space at the Methodist University Hospital campus should be performed by either CTU or CRC, as these offices both have locations at MUH.
 3. Investigators that do not have their own personal or departmental dedicated research nurses can usually access research nurse support for their trials through CTU or CRC.
 4. Most clinical trial offices on campus, especially those providing research nursing support, require a portion of the trial budget dedicated to them to compensate for their role in conducting the study. In pharmaceutical studies, the payment to the dedicated office is pre-determined based on a line-item of the budget. In federally funded studies, percent effort may be allocated to office study staff to compensate for their time supporting the study.
 5. All trials are subject to review by the respective covering office to ensure scientific validity, operational feasibility, and financial sustainability.

Inpatient Clinical Trial Needs

Trials that require inpatient services fall into 3 categories with 3 subcategories, each of which requires a different coverage plan.

Type 1: Hospital studies. These studies need to be performed fully in the inpatient setting (either at bedside or procedure-side). These include intra-operative studies, ICU-based studies, and certain transplant studies. These studies require a great deal of coordination between the clinical nursing/physician team and the research team. Generally, the research team must have inpatient privileges at the hospital and the clinical team and research team must proactively divide responsibilities with full knowledge of each other's roles.

Type 1a. 24-hour hospital study. This type of fully inpatient study requires research services in a 24-hour staffing setting. Research nurses need to be available to conduct study procedures (e.g., administration of study drug, pharmacokinetic lab draws) at any hour. An example of this may be an ICU study requiring blood draws every 4 hours.

Type 1b: Work hour hospital study. This type of fully inpatient study requires hospitalization with 24-hour clinical care required but only requires research team staffing during working hours on weekdays. Any IP can be scheduled for during the workday and research specific laboratory draws can be completed during the workday. Research specific 24-hour procedures are limited to what would otherwise be standard of care and can be performed by a clinical nurse. An example of this could be a surgical study requiring intraoperative implantation of a research device.

Type 2: Inpatient studies. This type of trial needs to be conducted with patients hospitalized for other reasons (inpatients) but does NOT require being performed on the hospital wards themselves or in an operating room. Inpatients may be transported for all study procedures to an on-campus location (either within or without the area covered by rapid response).

Type 2a. 24-hour study inpatient study. This type of trial requires research services in a 24-hour staffing setting. Patient transport services may bring the patient to a research unit within the hospital at any hour for study procedures. An example might be pharmacokinetic studies for a patient hospitalized for uncomplicated deep-venous thrombosis.

Type 2b. Work hour inpatient study. This trial requires study procedures for patients who are hospitalized for other reasons but only require study procedures during daytime hours, for which patients may be transported to the research unit for all study procedures. A possible of example of such a study would be once daily research dosing studies for patients hospitalized with CHF.

Type 3: Admission Studies: This type of trial is similar to Type 2a, but the patients are hospitalized specifically to undergo study procedures requiring 24-hour observation or testing. Some of these studies require full admission to the hospital with research lab draws. Others are similar to outpatient studies but have extensive procedures requiring staffing and patient participation outside of working hours.

Type 3a: Hospital admission studies: These studies require the patient to be registered as a patient in a specific inpatient unit to undergo research procedures. The patient can be transported to a research unit for these procedures. An example of this type of study would be a Phase 1 dosing study requiring 24-hour inpatient follow-up.

Type 3b: Research Unit Admission Studies: These studies do not require hospital admission, but require procedures to be done outside of normal working hours, with the patient able to come or go without checking out of the hospital. Examples of this type are sleep studies or outpatient studies requiring laboratory draws at odd hours.

Clinical Trial Coverage Plan for Hospital Studies (Type 1)

These trials are the most challenging for which to provide research coverage. A clear plan must be in place to segregate research activities from clinical activities. Clinical support staff (nurses, techs, etc.) must be made clear that they are not to undertake study procedures. Research nurses must have privileges at the participating hospital. Contracting generally must be done by the hospital itself. Based on these requirements, researchers with an interest in conducting hospital trials should approach the CTU for trial support. CTU nurses have privileges at both Methodist and Regional One hospitals and are equipped to support trials outside of dedicated research units. The CTU can also facilitate contracting for trials by the hospitals themselves.

For type 1a trials, the CTU will allocate a dedicated coordinator for support of the trial during business hours, and will develop an on-call system of nurse coordinators that will be available to perform research processes at any given time, and the call schedule will be made available once a patient begins screening for the trial in question.

For type 1b trials, the CTU will assign a dedicated research nurse to support the trial during business hours.

Access to the call pool is not necessary, however if research procedures unexpectedly go over into nights or weekends, the call pool from CTU nurses will be activated.

Clinical Trial Coverage for Inpatient Studies (Type 2)

These studies may be performed in research units even for inpatients. As such, resident research nurses in the dedicated hospital-affiliated research units may serve as the study nurses for these studies if patient transport is available to these units. At the current time, the only clinical trial office that is within patient transport range for inpatients is the CRC at Methodist University Hospital. For these studies, the CRC will be utilized as space. Research support for these trials will be either CRC nurses or CTU nurses, depending on investigator preference. Regardless, the CRC will be made available to dedicated nurses after-hours if necessary. These trials may not require contracting by the hospital itself but may be contracted either through the hospital or through UTHSC.

For Type 2a studies, either the CRC or CTU will provide a dedicated study coordinator with access to CRC and develop an on-call system by which research nurses may access the CRC and call for patient transport as necessary for nights and weekend study procedures. The call schedule will activate when a patient begins screening for the study.

Clinical Trial Coverage for Admission Studies (Type 3)

These studies are in-effect similar to outpatient studies except that they require the patient to be present beyond a simple work-day period. Generally, these trials can be supported by research units.

For Type 3a trials, patients will be admitted to MUH but will be transported to the CRC for the duration of their study period. During daytime hours, the patients will be monitored by either CRC or CTU research nurses, and any IP or lab draws will be performed in the CRC. The call-pool will be activated to ensure observation of the patient during the entire study period. The patient will be discharged once the required study period has ended. Of note, all rates for hospitalization for research purposes only will be pre-negotiated with MUH prior to finalization of a study budget with the study sponsor and/or investigator. The negotiated hospitalization rate may not change during the study except by official modification of the budget with the study sponsor. All efforts will be made to obtain necessary discounts for this rate to reflect the needs of the study and investigator.

For Type 3b studies, admission to the hospital is not necessary. As such, patients will come directly to either the CRC or to another office for the required study period. Generally, patients may be able to come and go as they please during this period if the study allows. For the purposes of these studies, a call pool will be utilized to ensure coverage beyond work hours. Clinical trial units that can support this research include CRC and CTU.

Summary

Given the broad availability of clinical trial offices affiliated with UTHSC, it can be confusing to determine whether any individual study is feasible. Given the needs of studies that have a hospital-like component, it is necessary to ensure a policy by which interested researchers can be assured that their studies will be supported. Under the federated model of the CTGB, studies requiring services beyond outpatient business hours in Memphis should be governed through conversation with CTU and/or CRC as per the above plan and the specific needs of the study.