



Clinical & Translational Science Unit

This CTSU user guide is intended to provide an overview of CTSU processes and guidelines.

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Contact List: Clinical & Translational Science Unit



CTSU Clinical Director: Shelby Williams is the Clinical Director of the KUMC CTSU locations.

CTSU provides essential services and support for Investigators conducting Clinical Research. CTSU staff include experienced research nurses & medical assistants, specialized staff in exercise physiology & pulmonology, and administrative support. Additionally, each KUMC CTSU is overseen by a Medical Director. CTSU staff are trained to support complex protocol procedures and collect & record research data.

CTSU Staff Contacts (CTSU PRN staff are not listed)

Clinical Director	Shelby Williams	swilliams46@kumc.edu Fairway Extension: 80980 Rainbow Extension: 43018
Administrative Business Officer	Stacie Rogers	srogers12@kumc.edu Fairway Extension: 80046
Clinical Research Nurse	Brooke Manning	bmanning4@kumc.edu
Clinical Research Nurse	Erin McHenry	emchenry2@kumc.edu
Clinical Research Nurse	Yvonne Sanchez	ysanchez2@kumc.edu
Clinical Research Medical Assistant	Kenesha Harris	kharris18@kumc.edu
Clinical Research Medical Assistant & Admin/Primary Scheduler (Fairway)	Autumn Beauchamp	abeauchamp@kumc.edu
Clinical Research Medical Assistant & Admin/Primary Scheduler (Rainbow)	Miranda Wright	mwright15@kumc.edu
Office Coordinator (Rainbow)	Nelda Mallett	nmallett@kumc.edu Rainbow Extension: 43007
Clinical Research Assistant (Wichita)	Allie Karns	akarns@kumc.edu
Clinical Research Assistant (Wichita)	Ashley Ast	aast2@kumc.edu
Marketing & Recruiting Coordinator	Hannah Hancock	hhancock@kumc.edu
Exercise Physiologist (Fairway)	Bill Hendry	bhendry@kumc.edu
Respiratory Therapist (Rainbow)	John McLean	jmclean@kumc.edu

Other: Website, Booking Conference Rooms, and New Study Team CTSU Tours

CTSU Website	https://frontiersctsi.org/clinical-research-facilities
Conference room Fairway – 3 rd floor CTSU	CRCConfRmRoelandParkCTSURm3326-cap10@kumc.edu
Conference room Rainbow- Sudler	CTSURainbowConfRm@kumc.edu
CTSU Fairway 4350 Shawnee Mission Pkwy, Fairway, KS 66205	New study team staff tours every Wednesday at 3:30PM Notify Stacie Rogers and Shelby Williams if you want to schedule tour Send to Outlook scheduling calendar ctsufairway@kumc.edu
CTSU Rainbow 3901 Rainbow Blvd, Kansas City, KS 66103	New study team staff tours every Tuesday at 2:00PM Notify Nelda Mallett and Shelby Williams if you want to schedule tour Send to Outlook scheduling calendar ctsurainbow@kumc.edu

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Steps to Getting Your Study Started with the CTSU

CTSU offers a variety of resources and services to assist your clinical research study to get up and running. Follow these steps to get your study started with the CTSU.

Step 1: Study Team Completes and Submits the “Clinical Research Start Up form” Click the link below to complete your Clinical Research Start Up Form. [Clinical Research Start Up Form](#)

The Clinical Research Start Up Form can be found in REDCap. This is in combination with the Research Administration (RA) Redcap form and informs the RA that you will need CTSU services. This will help with budget finalization as the CTSU fees can be included within your study budget for negotiations. If possible, all documents required for study start up (most up to date protocol, lab manual, and pharmacy manual) should be included in this request. This will allow the CTSU to provide a more accurate estimate for your CTSU Budget Plan.

Step 2: CTSU Setup – CTSU Will Assign Study # & Draft Budget Plan

Once CTSU receives the request for services, the following items will be completed within 2 weeks of request:

- A CTSU Study number will be assigned, e.g. 6123R-F-D
 - CTSU Study # Identifiers: R=Rainbow F=Fairway S=Swope W=Wichita (Primary location is first letter following study #, followed by backup location if applicable)
 - Study Category: A=Non-Industry D=Industry
- A draft CTSU budget plan will be provided to the requestor for study team approval.
- As stated in Step 1, please include all pertinent study documents when completing the Clinical Research Start Up Form so CTSU can provide you with the best estimate for CTSU services and resources.

Delegation of Duties and Training: CTSU Staff should NOT be listed on a delegation log, 1572, or as Clinical Trial Staff on research protocols. CTSU administration may approve additional training for CTSU staff for study procedures that are not considered routine practice. This will be decided on a case- by-case basis. CTSU administration may approve CTSU staff to be listed on the delegation log if required by the sponsor.

If listed on the Delegation Log, the following pertains to all staff.

- Training will be billed per current rates.
- This request can be made to the CTSU Clinical Director.
- Any time the study team asks CTSU to go outside of regularly planned protocol procedures, communication from sponsor must be provided to CTSU to justify the deviation from the protocol.

Step 3: Study Team Requests a Study Startup Meeting with the CTSU

While the CTSU may be present at the Research Administration (RA) Start-up Meeting, **CTSU requires a separate start-up meeting following RA study activation, to discuss necessary details required for launch. Start-up administrative fees are due following RA activation. All studies MUST be launched prior to scheduling your participants.**

Study team requests a CTSU start-up meeting by sending an email to the CTSU Clinical Director. **Please be sure to include the PI name, and CTSU study # or IRB in the request.** The CTSU Director will schedule the appointment for the start-up meeting. Study startup needs to be scheduled a minimum of 2 weeks but no more than 2 months prior to seeing the first participant.

Startup meeting can be done by video, or in person. These items are needed prior to the study startup meeting:

- IRB approval(s)
- Protocol: Most recent & approved version
- Informed Consent Form(s) ICF: Most recent & approved version(s)

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- Grant number / Cost Center (CC)
- Lab manual / lab processing information (if applicable)
- Pharmacy manual (if applicable)
- MOP/MOO (if applicable)
- IB - Investigator Brochure (if applicable)

CTSU will be happy to meet more often as needed during protocol planning. Please note, these meetings are not a substitute for the study startup.

CTSU Will Create Flowsheets for Study Visits: CTSU will create source documents / flowsheets for the CTSU specific tasks once all required information is received from the study team. Once completed, these are sent to the study team for review and approval. **It is critical that the study team thoroughly review these to ensure the order of procedures are accurate per protocol and is inclusive of all required tasks.**

NOTE: The study will **not** be launched in the CTSU until the study team has approved all flowsheets (with the exception of “resource only” flowsheets).

If there are flowsheet revisions:

- Please email your request to the CTSU Clinical Director.
- Once completed, the revised version will be sent to the study team for approval.
- Turnaround time for revisions should not exceed 1 week unless otherwise arranged with the study team.

Step 4: Study Will be Launched by the CTSU

CTSU will send out a Study Launch email to CTSU staff and the study team. This email serves as confirmation to the CTSU staff and study teams that the study is active, and participant visit requests can be made and accepted. **All studies MUST be launched prior to scheduling your participants.**

CTSU Appointment Requests

CTSU nurses, medical assistants, and PRN staff extend coverage across all KU-Med CTSU locations. The increased flexibility within our CTSU staffing resource pool allows us to ensure staff coverage as we aim to accommodate all visit requests.

Once you have sent your CTSU visit request, CTSU will review your request to ensure that all necessary resources are available to accommodate your visit. If CTSU is unable to support the requested date and time of your request due to resources, we will reach out to you and work with you to find a solution.

Your appointment is NOT confirmed until you have received an acceptance notification in response to your appointment request. **Prior to your visit, ensure that your visit has been accepted by CTSU.**

For appointments with less than 24 hours’ notice or a change to an existing appointment you must advise CTSU by calling the appropriate CTSU contact via Microsoft Teams or phone. Changes to the appointment time or order of events must be approved. **This should be PRIOR to confirming the change with the participant.**

If the participant arrives late for the visit or if CTSU was not notified of the appointment, CTSU will do their best to accommodate, but reserves the right to request the appointment be rescheduled.

A cancellation fee of \$25 may be assessed for less than 24 hours’ notice.

CTSU Scheduling Process- Outlook Calendars

- **Select “New Meeting”** Send your appointment request to schedule your participant via Outlook Calendar to the appropriate CTSU location.

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- **“Date & Start/End Time”** (Use the calendar icon to select the date and select your start and end time).
- **“Location”** If your appointment requires reserving a specific room or bookable space, click the “Location” field and select the room. (This mainly applies to CTSU Rainbow. Some examples include: CTSU Rainbow Sudler, CTSU Rainbow Delp, or a specific conference room.)

***Pulmonary testing and CPETs have additional scheduling requirements.**

If your appointment is ONLY using CTSU Equipment (NO CTSU space, resources, or staff), please send appointment request for equipment only. Normal equipment fees will apply.

Scheduling with the CTSU	
CTSU Fairway 4350 Shawnee Mission Pkwy Fairway, KS 66205	Send ALL visits at Fairway to: ctsufairway@kumc.edu Include the entire visit: Any time blocks and resources necessary that you are requesting to reserve for your appointment at the CTSU. *If any portion of visit includes exercise testing or CPET by Bill Hendry: 1. Please send your appointment request after checking availability on his personal outlook calendar 2. Send the entire visit to ctsufairway@kumc.edu as stated above, and 3. Send only the exercise testing portion of the visit to bhendry@kumc.edu, including only the time needed for specific procedure on this calendar
CTSU Rainbow 3901 Rainbow Blvd Kansas City, KS 66103	Send ALL visits at Rainbow to: ctsurainbow@kumc.edu Include the entire visit: Any time blocks and resources necessary that you are requesting to reserve for your appointment at the CTSU. *If any portion of your visit includes pulmonary testing or CPET by John McLean: 1. Please send your appointment request after checking availability on his personal outlook calendar 2. Send the entire visit to ctsurainbow@kumc.edu as stated above, and 3. Send only the pulmonary or exercise testing portion of the visit to jmclean@kumc.edu and to ctsupulm@kumc.edu, including only the time needed for specific procedure on these calendars
CTSU Swope 4001 Dr. Martin Luther King Jr. Blvd Kansas City, MO 64130	Send ALL visits at Swope to: ctsuswope@kumc.edu Include the entire visit: Any time blocks and resources necessary that you are requesting to reserve for your appointment at the CTSU
CTSU Wichita 1010 N Kansas St Wichita, KS 67214	Send ALL visits at Wichita to: ctsuwichita@kumc.edu Include the entire visit: Any time blocks and resources necessary that you are requesting to reserve for your appointment at the CTSU

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Scheduling with the CTSU – What details to include in your appointment request

Appointment Title: CTSU Study # / PI last name / Protocol # or short name / Visit Title and Flowsheet / Participant Initials

Body of the Appointment:

- **Participant's Full Name**
- **MRN**
- **DOB**
- **Age**
- **Study ID**
- **Study Coordinator**
- **Visit Title and Flowsheet**– *Why do we need this?* CTSU uses the visit title to identify and print the correct corresponding flowsheet for the visit
- **Visit Agenda** - *Why do we need this?* CTSU uses the information on the visit agenda to ensure the proper resources and CTSU staff are available to support your visit
- **Additional information if applicable**- Examples: Service animal will accompany participant, hard stick, faint with blood draws, high/low table etc.
- **Summary of changes if previously accepted visit** - *Why do we need this?* To ensure the proper resources at your visit, indicate if there are changes to CTSU resources, staff, or procedures; or “no CTSU changes”.

Visit Agenda:

Time	Procedure	Staff	Room Needed - (phleb. bay, clinic room, consent room, inf bay, cog, high low bed)

Average time durations per task for your reference:	
ECG	10 minutes
Triplicate ECG	20 minutes
Vital Signs	10 minutes
Triplicate/Ortho Vital Signs	20 minutes
Height and Weight	5 minutes
Urine Collection	5 minutes
IV Placement	10 minutes
Blood Collection	5-10 minutes depending on # of tubes
Lab Processing	1 hour for basic (up to 10 tubes) 2 hours complex (over 10 tubes)

Please be specific with the times and procedures needing CTSU support and allow adequate time for procedures on your timetable. Include the order of procedures, and rooms or resources needed.

For blood collection- Please also indicate if lab processing if performed by CTSU

For IP Admin- please specify route: infusion, injection, etc. Please also include the post observation time, if applicable.

Reminder: It is very important to send a separate appointment with specific times of specialized exercise physiology and pulmonary testing to their personal Outlook calendars so others can view availability for scheduling these procedures.

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Study Team Responsibilities: Related to Participant Study Visits at CTSU

Prior to your Visit

- Ensure that all participant visits are scheduled and approved by CTSU in advance, prior to appointment.
- Please be prepared to verify current protocol, ICF, and lab manual versions to CTSU staff at your visit.

IF YOUR APPOINTMENT INCLUDES LABS:

- **Lab kits AND corresponding lab requisition forms should be filled out, labeled, and delivered to the CTSU by 2 pm on the working day prior to the scheduled visit.**
- **Lab kits should match the CTSU flowsheets, lab manual, and protocol schedule of events.** If they don't match, please email the discrepancies to the proper CTSU location's outlook inbox and the CTSU Clinical Director listed below before 2 pm the workday prior to the scheduled visit. Refer to page 1 for CTSU contacts.
- **For all KU (TUKHS) labs:** KU lab will provide study teams with correct blood collection tubes specifically for KU labs. Study team **MUST** provide a lab requisition **PRIOR** to lab collection. CTSU **WILL NOT** collect labs without a requisition. Lab orders must be placed in EPIC by study coordinator and collection tube labels must match patient identifiers in EPIC (Full name, MRN, etc.)

During your Visit

- Study Coordinators need to arrive at least 5 minutes early to receive their scheduled participant in the CTSU lobby or waiting area. The study team is responsible for ensuring their participant has arrived.
- When you greet your participant in the lobby, be sure to document the IN time on the sign in/out log. Use the sign in/out sheet posted at the unit's established location to record the in/out times for your participants. If the "in/out" times are not recorded, CTSU will invoice according to what they believe to be accurate based on the visit procedures.

Staff	Room	Subject	Start Time	End Time	Description	In	Out	LAB In	LAB Out
	INF	CTSU Study # Protocol Short Title or Acronym Participant Study ID and Initials Visit or Week #	8:00:00 AM	10:30:00 AM	Initials	Participant Time IN for Visit	Participant Time OUT for Visit	IN time for lab processing by study team if outside participant visit times	OUT time for lab processing by study team if outside participant visit times
	10	CTSU #5311 IgPro20_xxxx 1234567 Week 2 SDR	8:00:00 AM	10:30:00 AM	SDR				

- Provide a signed copy of the most current ICF to the CTSU staff.
- Ensure a completed and signed order by the Investigator is provided to CTSU staff if your visit requires medication not specified in the protocol.
- Complete a CTSU Registration form for all new participants and give it to CTSU staff.

After your Visit

- When your visit is completed, be sure to document the OUT time on the sign in/out log, as well as any additional times for lab processing following completion of visit (if applicable- record times in columns "Lab in/Lab out").
- Study teams are responsible for cleaning the exam rooms once the visit is complete. Cleaning supplies, exam table paper and pillow covers are provided by the CTSU and are in each exam room. (CTSU staff is responsible for cleaning the phlebotomy bays, infusion room, and exercise physiology areas.)

CTSU Specimen Storage and logs

Sample Storage: CTSU provides short-term sample storage on site free of charge for less than 3 months. Sample storage longer than 3 months will be charged a storage fee.

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! All samples should be placed in a specimen freezer box labeled as followed.

All labels **MUST** include:

- CTSU Study #
- Box #
- PI



Place label on lower side of BOX

Please place the label low enough so lid does not cover label when lid is on the box.

CTSU # 1234 Box 1
Rogers

Only use labels intended for freezer use. CTSU provides freezer labels, ask team member if you need assistance.



Required: All samples going IN and OUT of the freezer must be logged. Follow any departmental or PI shelving assignments posted on the freezers, if applicable.

Each freezer has a log posted on the door. Instructions are posted in the lab. See log snip below. .

LOCATION: [CTSU Location; Freezer Name and Identifier] _____

Instructions: It is required to complete the applicable log fields every time biospecimen samples are stored or removed from the freezer.

Samples must be individually labeled and stored in a freezer box that has been labeled with the study name and CTSU number and Box number.

CTSU # and PI	Subject # and Initials	Visit #	Shelf	Box #	Stored in Freezer: IN				Removed from Freezer: OUT				Comments
					Qty and Sample Type	Date	Time	Performed by:	Check box to indicate sample type and quantity removed.				
					☐ Blood ☐ Urine ☐ Other (If Other, Specify Below: _____				PRIMARY SAMPLES OUT: Date _____ Time _____ Performed by _____ ☐ Blood ☐ Urine ☐ Other _____				
								BACK-UP SAMPLES OUT: ☐ N/A Date _____ Time _____ Performed by _____ ☐ Blood ☐ Urine ☐ Other _____					

IMPORTANT: CLOSE THE FREEZER DOOR IMMEDIATELY after opening it when storing or removing your samples.

DO NOT leave the freezer doors open for longer than 5 seconds, as this can compromise the integrity of the samples.

Shipping Labs

Study Team is primarily responsible for packing and shipping labs to the study's central lab. CTSU can be hired to perform the task if the study team requests.

KU (TUKHS) Labs- The study team is responsible for delivery of the KU Labs to a KU lab location. CTSU Fairway TUKHS courier comes to the CRC building to pick up KU labs four times per day. **Labs must be downstairs by 4:00pm for the last courier pick up of the day. If labs are not sent down by 4:00pm they will be picked up at the next Courier pick up time the following day.**

Please be sure to follow any shipping-specific policies regarding color-coding stickers to identify the shipping department.

Sharps Container Etiquette

- **Sharps only!** Do not place ordinary trash, gauze, gloves, alcohol pads, wrappers, urine cups, or other non-sharps in the container. Discard urine in toilet and throw away collection container in the restroom trash.
- Activate the safety device and dispose of the sharp immediately after use.
- Never recap, bend, break, or remove contaminated needles.
- Never reach into or force items into a sharps container.

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- Do not fill past the marked fill line.
- Notify designated unit staff when a container needs replacement.

CTSU Resource Fee includes the following resources, equipment, and supplies:

The CTSU Resource fee is charged for a minimum of 1 hour followed by 15-minute increments. The resource fee is charged for the entire time your participant is at the CTSU for a visit, as well as any additional time the study team uses the CTSU lab for processing.

CTSU Resource fee includes medical supplies, office supplies, clinical & laboratory workstations, and equipment.

Examples of CTSU resources include the following, but are not limited to:

Clinical/Medical: Gloves, otoscope/ophthalmoscopes table paper, gowns, linens, cleaning supplies, vital sign machines, manual BP cuff, biohazard disposal bins, code cart & supplies, oxygen, workstations, phlebotomy chairs, infusion beds, procedure beds, coffee/water/juice/crackers for participants, etc.

Laboratory: Centrifuges, freezers, refrigerators, dry ice for shipping, incubators, micropipettes, vortex, etc.

Office: Computers, monitors, printers, copy/fax/scan machine, copy paper, label maker, etc.

CTSU Equipment Check-Out

Equipment fees will apply for all equipment not covered in the CTSU resource fee when study teams are conducting the procedures.

The CTSU Equipment Check-Out Log in the infusion room near the nurse's desk for checking out equipment.

Examples: ECG machine, Alaris pumps for infusions, 6MWT equipment, spirometer, veggie meter, EMG machine, Glucometer, etc.

CTSU Equipment Sign In & Out Sheet

Date	Time	CTSU Study #	PI	Equipment	Name	Date & Time Returned

CTSU Guided Tours

New Study Team Members: Employees MUST have a guided tour of CTSU with the CTSU Clinical Director or designated CTSU staff member prior to requesting and receiving access to CTSU

When booking tours of CTSU space, please send the tour as a meeting in Outlook to the scheduling CTSU calendar for that location AND to the CTSU Clinical Director. In the Title, please include the first and last name of the new hire. Refer to the contact list on pg. 1 for routine scheduled tour times and contact information for CTSU Fairway and CTSU Rainbow.

Sponsor/Other Tours:

CTSU is happy to accommodate tours of our space. **For access & security purposes, we MUST be aware of all tours.**

When booking tours of CTSU space, please send the tour as a meeting in Outlook to the scheduling CTSU calendar for that location AND to the CTSU Clinical Director. Please include the following in your tour request:

- Name of the group and/or individuals in the tour
- Reason for tour (Sponsor, etc.).
- Please indicate if you need CTSU staff to guide the tour. Sponsor tours may be given by the study team.

Study-Specific Supplies

- CTSU does not provide study specific supplies (example: vaccines).

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- Upon request, CTSU can assist in ordering study supplies. All costs associated with ordering study supplies will be interdepartmentally billed to the study at time of purchase and include a 3% CTSU service fee. CTSU will not inventory or monitor study supplies for adequate stock or expiration dates.
- CTSU leadership must provide approval before study teams can store supplies or equipment in the CTSU.
- **Per University and Hospital Policy: Study Teams not located in the CRC (Fairway CTSU) will need to address their packages to be delivered to their assigned physical locations rather than the CTSU.**

CTSU Access & Security

Per the KUMC Badge Office, badge access is NOT granted for convenience purposes and is ONLY granted when deemed necessary and must be documented as such.

- Badge access is not needed in CTSU areas during daytime hours between 0730 – 1630.
- After Hours Access to all CTSU points does require additional specified badge access to be granted by the CTSU Clinical Director.
- For Security Purposes: Managers, please inform the CTSU Clinical Director of any changes in staff (new hires and terminations), so access can be updated accordingly in a timely manner.

CTSU Satisfaction Surveys

We actively use feedback to provide you with the best possible service and experience with CTSU. We encourage feedback from study teams, participants, and visitors. Complete the short survey in our unit, or online. Visit the URL below or scan the QR Code.

<https://redcap.kumc.edu/surveys/> Enter Code: J379LCPXK



Frontiers membership is required for all Principal Investigators utilizing the CTSU

Frontiers Clinical and Translational Science Institute members at all our partner institutions have access to the following resources:

- Support for Clinical and Translational Science
- Training for Researchers and Research Staff
- Funding Opportunities

Membership is free, Join Today! To complete the Frontiers membership form [CLICK HERE](#), scan the QR code, or visit www.frontiersctsi.org/become-a-member

