

CTSU Mission:

The Mission of The University of Kansas Clinical and Translational Science Unit (CTSU) is to support investigators and study teams and their need to successfully conduct clinical research.

Did You Know...?

KU Medical Center has three CTSU Locations:

- CTSU Fairway is located in a state-of-the-art facility in Fairway, Kansas.
- CTSU Rainbow is located on the main University of Kansas Medical Center campus in Kansas City, Kansas.
- CTSU Swope is located on Martin Luther King Jr. Boulevard in Kansas City, Missouri, designed to facilitate clinical research for investigators and their study teams in a location that serves the community and diverse populations.

Shelby Williams is the Clinical Director of the three KUMC CTSU locations. 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 is trained to support complex protocol procedures and collect & record research data.

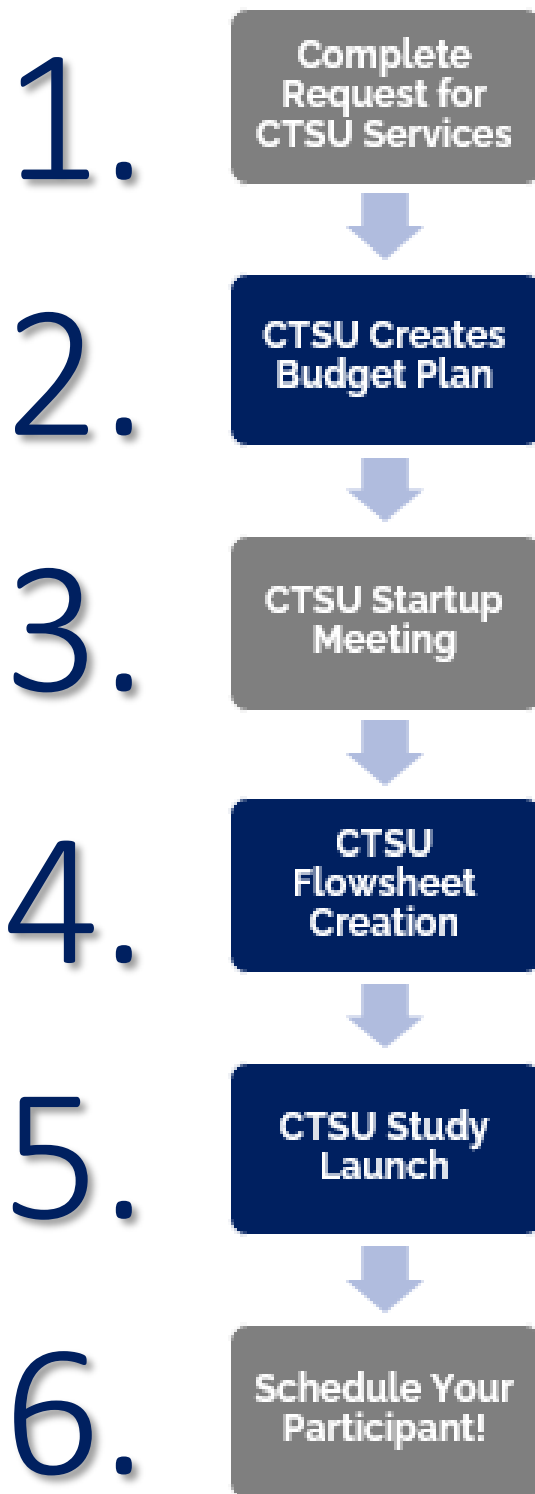
This CTSU user guide is intended to provide an overview of CTSU processes and guidelines. Thank you for choosing KUMC CTSU.

Reference Table

<u>Steps to Get New Study Started with CTSU</u>	<u>Pg. 3-6</u>
<u>CTSU Scheduling Process & Example</u>	<u>Pg. 7-8</u>
<u>CTSU Scheduling Guidelines & Contacts</u>	<u>Pg. 9</u>
<u>Study Team Responsibilities</u>	<u>Pg. 10</u>
<u>Visits with Labs</u>	<u>Pg. 10</u>
<u>CTSU Resources & Supplies</u>	<u>Pg. 11</u>
<u>CTSU Equipment Check out</u>	<u>Pg. 12</u>
<u>In & Out Times for Participant Visits/Lab Processing</u>	<u>Pg. 12</u>
<u>CTSU Lab Guidelines & Info</u>	<u>Pg. 13</u>
<u>CTSU Access, Tours, Documents, and Survey</u>	<u>Pg. 14</u>

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 CTSU.



Getting Started with the CTSU...

1. Request for CTSU Services – Study Team Completes and Submits the “Clinical Research Start Up Form”

The Clinical Research Start Up Form can be found in REDCap. Click the link below to complete your Clinical Research Start Up Form. <https://redcap.kumc.edu/surveys/?s=KFJYK87MAJ>

This is in combination with the Research Administration (RA) Redcap form. This informs the RI 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.

- The study does not have to be IRB approved to complete the CTSU request for services; however, final approval must be received prior to seeing study participants.
- 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 quote.

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. 0520R.
- 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 @ \$75.00/hour, per person, with a minimum charge of 1 hour in a single setting. After the initial hour billing will be in 15-minute increments.
 - An additional fee of \$75 per person will be assessed for each CTSU staff member listed on the Delegation log.
 - This request can be made to the CTSU Director Shelby Williams.
- 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.

3. CTSU Start Up – Study Team to Request Study Startup Meeting with the CTSU

Following Study Activation in MyAgreements, a startup meeting must take place before scheduling and/or seeing your first participant in the CTSU.

- Items 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)
 - Grant number / Cost Center (CC)
 - Lab manual / lab processing information (if applicable)
 - Pharmacy manual (if applicable)
 - MOP/MOO (if applicable)
- The study team sends a study startup meeting, via Outlook, to the **CTSU Director, Shelby Williams** at swilliams46@kumc.edu. Send the appointment for the date and time that best fits your schedule (also check Director availability by viewing the “scheduling assistant”).
- 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.

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.

4. Source Documents & Flowsheets - CTSU Will Create Flowsheets for Study Visits

Following your Study Startup Meeting, the 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 Director Shelby Williams, and Lead RN Danielle Hoage.
- 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.

5. 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. At this time, the CTSU will invoice for the study start-up/administration fee.

6. Schedule Participant Visits With CTSU

As stated above, after CTSU has launched your study, you can now schedule your participant visits. Refer to the step-by-step CTSU scheduling process and guidelines that follow.

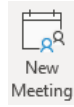


CTSU Scheduling Process:

CTSU User Guide

Schedule your participant via Outlook Calendar:

1. Select “New Meeting”



2. “Title” should include:

- CTSU Study #
- PI Last Name
- Study Visit #
- Participants initials

Example: Title #0520R Day 1 LRD

3. Send appointment to the following Outlook recipients:

Required

For CTSU Rainbow, send to ctsurainbow@kumc.edu

For CTSU Fairway, send to ctsufairway@kumc.edu

For CTSU Swope, send to ctsuswope@kumc.edu

- When scheduling for Pulmonary or CPET with John McLean at Rainbow, please send your appointment request after checking John’s availability on his personal calendar.
 - Send the appointment requests to the following:
 1. ctsurainbow@kumc.edu
Include the entire patient visit
 2. CTSUPulm@kumc.edu
ONLY include the time needed for the specific procedure
 3. John McLean at Jmclean@kumc.edu
ONLY include the time needed for the specific procedure
- When scheduling for Exercise Physiology Testing-specifically GXTs, please send your appointment request after checking Bill’s availability on his personal calendar.
 - Send the appointment requests to the following:
 1. ctsufairway@kumc.edu
Include the entire patient visit
 2. Bill Hendry at Bhendry@kumc.edu
ONLY include the time needed for the specific procedure

4. "Date & Start/End Time"

Start time	Fri 6/4/2021	8:00 AM ▼
End time	Fri 6/4/2021	10:450 AM ▼

(Use the calendar icon to select the date and select your start and end time).

5. "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)

Location	Delp G040 - negative pressure room
----------	------------------------------------

6. "Body of Meeting/Appointment Request" should include the following information:

- Participants full name
- Anticipated schedule of events needing CTSU support
- If necessary, a specific room can be requested.

Example: Need Hi/Low Bed, Need Consent Room, etc.

EXAMPLE

 Send	Title	#0520R Burns Day 1 LED		
	Required	CTSU Rainbow;		
	Optional			
	Start time	Fri 6/4/2021	8:00 AM ▼	<input type="checkbox"/> All day <input type="checkbox"/> Time zones
	End time	Fri 6/4/2021	10:450 AM ▼	Make Recurring
	Location	Delp G040 - negative pressure room		

Lazy E. Day

Agenda:

- 8:00- 8:30 - consent (study team)
- 8:30 – 8:45 - height / weight / vital signs (CTSU Rainbow staff)
- 8:45 – 9 – Brief Physical Exam (PI)
- 9 – 9:30 - questionnaires (study team)
- 9:30 – 9:45 blood collection (CTSU Rainbow)
- 9:45 – 10:00 – study drug admin. (CTSU Rainbow staff)
- 10 – 10:30 – post study drug monitoring (study staff)
- 10:30 – 10:45 – post study drug vitals (CTSU Rainbow staff)

✓ CTSU Scheduling Guidelines:

CTSU nurses, medical assistants, and PRN staff extend coverage across all three 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.

In the event that 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.

- Ensure that all participant visits are scheduled and approved by CTSU in advance. Your appointment is NOT confirmed until you have received an acceptance email back from CTSU in response for your appointment request.
- For appointments with less than 24 hours' notice or a change to an existing appointment you must advise CTSU by calling the numbers below. A cancellation fee of \$25 may be assessed for less than 24 hours' notice.
- 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.

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.

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.

For specialized exercise physiology testing that requires Bill Hendry (CTSU Fairway), please check Bill's Outlook calendar for availability prior to sending appointment request.

For specialized pulmonary testing that requires John McClean (CTSU Rainbow), please check John's Outlook calendar for availability prior to sending appointment request.

If a conference room is needed, please send meeting invite to the corresponding CTSU location via the outlook calendar(s) below.

✓ CTSU Scheduling Contacts:

CTSU Location	Scheduling Contacts	Outlook Email/Calendar	Phone #
Fairway	Kristy Anderson Autumn Beauchamp	ctsufairway@kumc.edu	913-588-7580 913-945-7579
Rainbow	Miranda Wright Danielle Hoage	ctsurainbow@kumc.edu	913-574-3007
Swope	Autumn Beauchamp	ctsuswope@kumc.edu	913-574-4594
Conference Room / Fairway		\\CRC Conf Rm Roeland Park CTSU Rm 3326 – cap	
Conference Room /Rainbow – Sudler		CTSURainbowConfRm@kumc.edu	

✓ Study Team Responsibilities Related to Participant Visits at CTSU

PRIOR TO YOUR APPOINTMENT...

- Ensure that all participant visits are scheduled and approved by CTSU in advance, prior to appointment.
- 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.

DURING YOUR APPOINTMENT...

- 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 to CTSU staff.

AFTER YOUR APPOINTMENT...

- Ensure check in/out times are documented on the sign in/out log. This includes lab processing times following completion of visit (if applicable). If the “in/out” times are not recorded, CTSU will invoice according to what they believe to be accurate based on the visit procedures.
- 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.*

✓ Study Visits with Labs:

- All study materials are purchased and provided by the study team.
- All lab kits should be delivered to the CTSU by 2 pm the working day prior to the scheduled appointment.
- All requisitions should be filled out prior to dropping off the lab kits.
- Ensure the CTSU flowsheet, protocol schedule of events, and the lab manual match the kit. If they don't match, please email the discrepancies to the proper team listed below before 2 pm the workday prior to the scheduled visit:
 - CTSU Rainbow: email ctsurainbow@kumc.edu and swilliams46@kumc.edu
 - CTSU Fairway: email ctsufairway@kumc.edu and swilliams46@kumc.edu
- 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.
- 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.

KU (TUKHS) Labs

- Lab orders must be placed in EPIC by the study team in advance of the study visit.
- The study team is responsible for delivery of the KU Labs to a KU lab location.

- KU Lab will provide study teams with correct blood collection tubes specifically for KU labs.
- The study team must provide the labeled collection tubes to CTSU staff.
- Label must have participants name and medical record number.

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.

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

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:

Medical Resources: Gloves, table paper, gowns, linens, cleaning supplies, vital sign machines, manual BP cuff, biohazard disposal bins, code cart and supplies, etc.

Laboratory Resources: Centrifuges, freezers, refrigerators, dry ice for shipping, etc.

Clinic Resources: Workstations, phlebotomy chairs, infusion beds, coffee/water/snacks for participants, etc.

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

Study-Specific Supplies

- CTSU does not provide study specific supplies. Upon request, CTSU can assist in ordering study supplies.
- All costs associated with ordering study supplies will be interdepartmental billed to the study at time of purchase.
- 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.

Other CTSU Supplies

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

Supply fee examples: lubricant, IV starting supplies, phlebotomy supplies, etc.

CTSU Equipment Check-Out

CTSU User Guide



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

CTSU Equipment Check-Out Log is located in the infusion room by the nurse's desk for checking out equipment.

Equipment and supply fees will NOT apply if CTSU is performing the procedures.

Equipment fee examples: ECG machine, Alaris pumps for infusions, 6MWT equipment, spirometer, veggie meter, EMG machine, Glucometer, Heated Hand box etc.

CTSU Equipment Sign In & Out Sheet

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



CTSU Resource Fee & In/Out Times on Daily Appointment Sheet

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.

Use the sign in/out sheet posted at the unit's established location to record the in/out times for your participants, as well as any additional times for lab processing, if applicable (pictured below). Please note that if CTSU staff is processing the labs, you do not need to note the LAB times on the sign in/out sheet.

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				

Lab Specimen Freezer Storage and logs:

- All samples will be maintained in cryovial boxes until shipment and will not be stored in individual shipping bags.
- Request a cryovial box from CTSU staff if you need one for your study.
- Use the labels in the lab intended for freezer use.

! 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.

- Be sure to use the freezer log for documenting frozen sample storage. Instructions are posted in the lab.

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.				
					<input type="checkbox"/> Blood <input type="checkbox"/> Urine <input type="checkbox"/> Other <small>(If Other, Specify Below: _____)</small>				PRIMARY SAMPLES OUT: Date _____Time _____Performed by: _____ 				

Important Reminder!

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.



✓ 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 Shelby Williams.

For Security Purposes: Managers, please inform Shelby Williams of any changes in staff (new hires and terminations), so she can update access accordingly in a timely manner.

✓ CTSU Tours & Access Requirements

New Study Team Staff Tours: Employees **MUST** have a guided tour of CTSU with Shelby Williams or designated CTSU staff member prior to receiving access to CTSU.

- **Fairway CTSU tour schedule**
 - Every Wednesday at 3:30PM starting June 7th, 2023.
 - Notify Stacie Rogers and Shelby Williams if you are wanting to schedule.
- **Rainbow CTSU tour schedule**
 - Every Tuesday at 2:00PM starting June 6th, 2023
 - Notify Nelda Mallett and Shelby Williams if you are wanting to schedule.

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 Shelby Williams.

Please include the following on your tour request:

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

✓ CTSU Documents: Temp Logs and Records for Sponsors

Visit Frontiers website at [Clinical Research Facilities \(frontiersctsi.org\)](https://frontiersctsi.org)

- Equipment Calibration Records and Logs
- CTSU User Guide
- Request CTSU Services
- Other Helpful Links & Info

✓ 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**