

## Clinical and Translational Science Unit (CTSU) User Guide

Prior to establishing your studies budget or scheduling participants in the CTSU, we need to review your protocol needs so we can prepare the CTSU Fee Agreement and ensure we can meet your needs. This guide contains instructions about the how to set up a research protocol with the CTSU.

### 1. Request CTSU Services

- a. Inform your Research Institute (RI) representative that you need CTSU services for your study. If this is not completed prior to budget finalization CTSU cannot ensure that pricing will be within your budget but will still charge for all services provided.
- b. If the RI does not submit the request for services on your behalf, you can submit the request at the following link <http://www.kufrontiers.org/ctsu>
  - i. The form is located on the top, right side, of the page - the form must be completed, and study documents attached.
  - ii. The study does not have to be approved to complete the CTSU request for services; however, final approval must be received prior to seeing study participants.
  - iii. Including all documents required for study start up in this request will allow the CTSU to provide a more accurate quote. In particular, the most up to date protocol, lab manual, and pharmacy manual are needed for a thorough quote.
- c. Once CTSU receives the request for services information
  - i. A CTSU number will be assigned.
  - ii. A draft CTSU budget quote will be provided.

### 2. Schedule a study start-up meeting prior to seeing the first participant

- a. The study team schedules a **study startup meeting** with Elisabeth Pauley. Study start up needs to be scheduled a **minimum of 2 weeks** but **no more than 2 months prior** to seeing the first participant. Startup can be done either by email or in person depending on complexity of the protocol.
- b. To schedule the startup please view Elisabeth Pauley's outlook calendar for the time most convenient for you and send an appointment request.
- c. Items needed **1 week prior** to the study start up meeting:

<input type="checkbox"/> Speedtype for study billing	<input type="checkbox"/> HSC approval letter
<input type="checkbox"/> Most recent HSC approved protocol	<input type="checkbox"/> Current HSC approved consents
<input type="checkbox"/> MOP/MOO (if applicable)	<input type="checkbox"/> Lab manual/lab processing information
<input type="checkbox"/> Pharmacy manual (if applicable).	
- d. If follow up items are given to the study team please ensure follow up is provided to the CTSU within one working week after the study start up meeting.

\*CTSU will be happy to meet more often as needing during protocol planning but this does not substitute for the study startup.

### 3. What happens after the study startup meeting?

The completion of the startup meeting is our trigger to start the following processes.

- a. The CTSU will produce flowsheets for the CTSU specific tasks
  - i. If follow up items were given at start up, then we will start the flowsheets when CTSU has received follow up items.
  - ii. Flowsheets are sent to the study team for review and approval. If no response is received from the study team within one week or by the time the first participant is scheduled, then the flowsheets will be placed into circulation unless requested otherwise.
  - iii. It is critical when reviewing flowsheets, you ensure all order of procedures are correct and thoroughly review the document in entirety for accuracy and completion.
  - iv. **Flowsheet revisions?** Please email [epauley2@kumc.edu](mailto:epauley2@kumc.edu) and [Jsanchez3@kumc.edu](mailto:Jsanchez3@kumc.edu) with your request. Once revisions are 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.
- b. A “new study email” is sent to all CTSU staff. This email will include all pertinent study documents that must be reviewed by CTSU staff.

### 4. How to schedule a participant visit

CTSU Rainbow: email a calendar appointment via Outlook to [ctsurainbow@kumc.edu](mailto:ctsurainbow@kumc.edu)

CTSU Fairway: email a calendar appointment via Outlook to [ctsfairway@kumc.edu](mailto:ctsfairway@kumc.edu)

- a. On the subject line, include the CTSU# \_\_\_\_\_, which protocol visit it is for, and the subject's initials.
- b. For location. type CTSU Rainbow or CTSU Fairway, whichever is applicable
- c. Select the start time and end time that your participant will be in the CTSU.
- d. In the body of the appointment, include the full subjects’ name. It is also helpful if you include an anticipated schedule of the visit. If you need specific, rooms for your visit please include this in the body of the appointment.
- e. Your appointment request is NOT confirmed until you have received an email from the CTSU.
- f. For CTSU Fairway Exercise Physiology Services: add [CTSUExPhys@kumc.edu](mailto:CTSUExPhys@kumc.edu) to the appointment.
- g. For CTSU Rainbow Pulmonology Testing Services: [CTSUPulm@kumc.edu](mailto:CTSUPulm@kumc.edu)
- h. For URGENT requests or last-minute requests/changes, call ext. 8-0972 and ask for Elisabeth Pauley. If she is not available at the time, please speak with one of the nursing staff and they will assist with your scheduling needs.
  - i. Appointment times are firm. Any changes to the appointment time must be approved in advance by the CTSU prior to confirming the change with the participant. Please note CTSU reserves the right to request a reschedule if the participant arrives late for their visit or if the CTSU was not notified of the appointment.

### 5. Delegation of Duties and Training

- a. CTSU staff should *not* be listed on a delegation log, 1572, or as Clinical Trial Staff on research protocols. For study procedures that are not considered routine practice, CTSU administration may approve additional training for CTSU staff on a case by case basis. Please refer to CTSU policy for Delegation of Study Activities & Training for further information.
- b. CTSU administration can also approve addition of CTSU staff as Clinical Trial staff for sponsors who require it. In the event this is requested all CTSU staff must be added. This request can be made to [epauley2@kumc.edu](mailto:epauley2@kumc.edu).
  - i. Any study specific training will be billed at \$75.00 per hour per person with a minimum charge of one hour in a single setting. All training beyond that first hour will be billed in 15-minute increments. Any training must be completed by all CTSU staff.

6. Please note that any time a study team asks CTSU to go outside of regularly planned procedures in a protocol communication from sponsor must be provided to the CTSU to justify the deviation from the protocol.
7. Please ensure CTSU receives all study specific supplies and equipment at least one week prior to seeing the first participant.
  - a. CTSU does not provide any 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 does not inventory or monitor study supplies for adequate stock or expiration dates.
  - b. CTSU leadership must provide approval before study teams can store supplies or equipment in the CTSU.

#### **8. To schedule a tour of the CTSU**

- a. Please send an outlook appointment to both [epauley2@kumc.edu](mailto:epauley2@kumc.edu) and [alahner@kumc.edu](mailto:alahner@kumc.edu) and we will ensure coverage for your tour request.

#### **9. When your participants arrive in the CTSU:**

- a. Please instruct them to check in with the receptionist or CTSU staff. Study staff must ensure the CTSU is given the arrival time of the participant.
- b. If the subject is new to the CTSU, please ensure they fill out a 'CTSU Registration Form' which is located at the front nurse's station; return this form to CTSU staff before the subject leaves.
- c. Before study procedures start, ensure a signed copy of the most current consent is collected. Please ensure a copy is given to the CTSU staff as soon as possible. CTSU will need a copy of all consents collected from the participant.
- d. Upon completion of the visit, ensure the subject is signed out with the CTSU staff.

#### **10. Study visits with labs:**

- a. Ensure CTSU receives all lab materials (tubes, cryovials, labels, and requisitions) no later than **2 pm the working day prior** to your scheduled study visit. All requisitions, labels, etc. must be filled out appropriately.
  - i. Prior to dropping off lab kits, ensure the CTSU flowsheet, the protocol schedule of events, and the lab manual schedule for the day match the kit. If they do not match, email [mwright15@kumc.edu](mailto:mwright15@kumc.edu) and [epauley2@kumc.edu](mailto:epauley2@kumc.edu) prior to 2 p.m. drop off on the workday prior to the scheduled visit.
- b. If CTSU is hired to provide phlebotomy and KU lab is being used for resulting, all orders must be placed in advance in EPIC by the study team.
  - i. KU Lab will provide study teams with correct blood collection tubes specifically for KU labs. All other study materials must be provided by study team.
  - ii. If CTSU staff are hired to perform KU lab collection it is the responsibility of the study team to ensure delivery to KU labs.
  - iii. The study team must provide the labeled collection tubes to CTSU staff
    1. Label must have name and medical record number.
- c. If a central lab (non-KU lab) is being used, the study team is responsible for packing and shipping labs unless the CTSU has been hired to perform this service.
- d. CTSU only provides short-term sample storage on site. Any storage beyond 3 months will incur fees.

## 11. The Study Team MUST:

- a. Provide a complete signed order by the Investigator for subjects requiring medication administration.
- b. Provide CTSU with the most current HSC approved protocol, study documents, and signed ICF throughout the study.
- c. Ensure participant visits are scheduled and approved by the CTSU in advance. All CTSU delegated study procedures including lab processing and storage must occur between 7:30 a.m. and 4:30 p.m. All visits scheduled outside of CTSU hours requires leadership approval and must be submitted no less than two weeks in advance.
- d. Arrive at least 5 minutes early to the scheduled visit if you have a subject arriving in the CTSU. CTSU will call study teams as a courtesy to inform them of a participant's arrival however, the study team is responsible for ensuring their participant has arrived. As much as we would like to ensure administrative support for these tasks this is not always possible depending on census.
- e. Work with CTSU leadership prior to storing study supplies in the CTSU.