

Clinical and Translational Science Unit Delegation of Study Activities Training Requirements

Purpose:

To provide the Principal Investigator, Clinical Trial Staff, and Clinical and Translational Science Unit (CTSU) staff guidelines and procedures for appropriately documenting delegation of study tasks and applicable training.

Responsible Personnel:

Clinical and Translational Science Unit (CTSU) Staff, Clinical Trial Staff and Principal Investigators involved in activities performed within the CTSU.

Background:

The CTSU is a department for hire within the University of Kansas Medical Center. Any Principal Investigator under the University of Kansas or other institution with which there is reciprocity can seek ancillary research services from the CTSU to support an approved research protocol. CTSU staff provide ancillary services and do not make a direct and significant contribution to the clinical data therefore are not 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.

All clinical research conducted at the CTSU must be compliant with federal and local laws and regulations. The PI is responsible for ensuring the clinical trial is conducted according to these requirements. The PI may delegate some of these responsibilities to qualified authorized individuals, but retains overall responsibility for conduct of the clinical trial.

Regulation and Guideline Reference(s):

[ICH Harmonised Tripartite Guideline: Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice, E6 \(R2\) Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs](#)

Definitions:

Clinical Trial Staff: Individuals identified by the Investigator, who are responsible for study coordination, data collection and data management. The central focus of Clinical Trial Staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical Trial Staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

Clinical and Translational Science Unit (CTSU) Staff: Provide ancillary research services for approved research protocols. CTSU staff do not make a direct and significant contribution to the clinical data. CTSU staff may provide administrative, nursing, laboratory, exercise and other services to investigators.

Procedure:

1. 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.
2. Prior to CTSU service utilization, the protocol must be approved by University of Kansas Medical Center IRB/HSC or by an external IRB with relevant reciprocity.
3. The following study start-up activities and training are performed by the PI, Clinical Trial Staff and CTSU staff:
 - a. CTSU leadership or designee reviews the approved protocol and any study related documents relevant to any procedures being performed at the CTSU, as provided by the PI or Clinical Trial Staff.
 - b. A study-specific flowsheet outlining protocol requirements for each visit is developed by the CTSU staff in conjunction with the Clinical Trial Staff. The flowsheet and relevant study-specific information is reviewed with CTSU staff.
 - c. All necessary documentation and clinician orders for each visit are provided to the CTSU staff by the Clinical Trial Staff.
 - d. Documentation of training for CTSU staff is maintained within the CTSU. Study specific flowsheets, clinician orders, protocols, and supporting documents are stored in a central location available to all CTSU staff for later reference.
 - e. In accordance with KUMC process, CTSU staff complete Human Subjects Training through the CITI program, and other applicable training required by KUMC.
4. Protocol amendments and/or study documents must be provided to the CTSU staff by the Clinical Trial Staff as soon as they are obtained. It is the responsibility of the Clinical Trial Staff to ensure necessary changes to CTSU flowsheets have been made prior to the relevant subject visit.

Approved By:

Jeffrey Burns, MD
Andra Lahner, BS, BSN, RN, CRCC
Elisabeth Pauley, BS, BSN, RN, CCRP

Original Approval Date:

February 21, 2019

Original Effective Date:

March 4, 2019