

Clinical and Translational Research Center NC TraCS Institute	Approved by: Director of Nursing
SOP Title: CTRC New User Orientation & Training Required for Use of the CTRC Facilities	Revisions: 2/24/2012, 3/29/2016, 7/20/2017, 6/9/2023
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- I. **Purpose:** The purpose of this SOP is to describe the orientation and training activities required of all members of the study team (study coordinators, research assistants, study lab personnel and other study personnel) who are new users of the Clinical and Translational Research Center (CTRC) for research participant visits.
- II. **Applicability:** The study team using the CTRC for study visits must be knowledgeable as to the requirements of their study protocol, CTRC procedures and the minimum required training for the University of North Carolina at Chapel Hill (UNC-CH). Adequate training must be completed to ensure that study coordinators and other study staff have the appropriate knowledge and skills necessary to provide quality care and generate accurate and reliable data. New users are defined as those who have not utilized the CTRC for research visits or for those who have not utilized the CTRC in the past 6 months.
- III. **Responsible Parties:** Study coordinators, research assistants, study lab personnel, Principal Investigators, UNC Internal Review Board, CTRC Director of Nursing, CTRC Staff, UNC Network for Research Professionals and the TraCS Regulatory Core.
- IV. **Procedures:** All new study coordinators and any study staff working with research subjects in the CTRC must complete the requirements and follow the procedures listed below. These requirements must be completed prior to utilizing the CTRC for research participant visits.
 - A. **Determination of Training Requirements:**
 1. The Principal Investigator and the employee's supervisor will determine what training is necessary depending on the study team member's role in the research study. The Principal Investigator is responsible for ensuring the minimum UNC-CH training requirements are met prior to utilizing the CTRC.
 2. The CTRC Director of Nursing (DON) will review the personnel list (specifically the study coordinator) on each protocol during the initial approval process to determine if he/she is a new user of the CTRC. The DON will include the following statement on the approval email notification to the Principal Investigator "It appears the study coordinator listed on this protocol is new to utilizing the CTRC. Please be aware that completion of the CTRC New User Orientation by the study coordinator is required prior to use of the CTRC facilities."
 - B. **Initial Training Requirements for New Users to the CTRC:**
 1. NC TraCS - CTRC New User Orientation
 - a. Attendance of one of the CTRC New User Orientation sessions is required prior to the utilization of the CTRC facilities.
 - b. The orientation includes a brief overview of NC TraCS, UNC Radiology and UNC Health Nutrition services as well as information specific to the utilization of the CTRC such as research participant scheduling, use of the lab processing facilities, phlebotomy ordering, key documents used and hours of operation. A walkthrough of the facility is given after the presentation is completed.
 - c. Training sessions will typically be offered on the first Monday and the third Tuesday of each month (excluding holidays) in the CTRC Conference Room (1045) located on the 1st floor of the Burnett-Womack building. Registration for the orientation is required and is done so by using the UNC Event Registration website found at <https://apps.research.unc.edu/events/> under the sponsor "NC TraCS."

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- d. The Principal Investigator and the licensed independent practitioner (physician, physician assistant, and nurse practitioner) are not required to attend the CTRC New User Orientation unless they are functioning as the “study coordinator” for the research visits.

2. UNC-CH Training Requirements

- a. UNC-CH training requirements are designated by the study team member’s Principal Investigator and supervisor based on their role in the research study and their job classification.
- b. The CTRC is a clinic environment and as such, study team personnel will be required to complete Environmental Health and Safety (EHS) training provided by the university. More information on the required training can be found at <http://ehs.unc.edu/training/requirements/>.
- c. In addition to other required university trainings, all UNC-CH investigators and research staff who are involved in the design, conduct, or reporting of clinical trials involving human subjects AND a drug, device, or biologic are expected to document completion of GCP training. The completion of the initial training is effective for 3 years. At the end of a 3-year period, a GCP refresher course will be required. The GCP training modules can be found at <http://www.citiprogram.org>.
- d. For more information on additional training requirements at UNC-CH, visit the IRB and Office of Human Research Ethics at <http://research.unc.edu/offices/human-research-ethics/> and the Office of Clinical Trials (OCT) at <http://research.unc.edu/offices/clinical-trials/>.

3. Epic Training

- a. The CTRC utilizes UNC Health’s electronic medical record system (Epic). Epic training will need to be completed prior to utilizing the CTRC.
- b. Epic training registration requires access to the UNC Health Care’s Learning Management System (LMS) using a Domain Account.
- c. Epic and CRMS tip sheets for “Research Training” and the “University Employee Epic Access Form” can be found on the Research Central site at <https://apps1.research.unc.edu/crms/researchcentral/>.
- d. For questions regarding which training track is appropriate for your job role or access issues, contact the ISD Help Desk at 984-974-4357.

4. Laboratory Training

- a. The Principal Investigator and department supervisor shall ensure study staff secures proper training regarding laboratory safety and usage. This training should include but not necessarily be limited to, personal protective equipment, usage of centrifuges and other laboratory equipment and laboratory dress codes. Lab training is required prior to study staff processing samples in the CTRC lab facilities.
- b. Please refer to the SOP on “Specimen Processing” for more information on laboratory training and lab etiquette.

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5. CTRC Etiquette Test

- a. Prior to gaining access to the Clinical Research Management System (CRMS) CTRC Scheduler and obtaining badge access to the facilities, the study team member will be required to review the “Etiquette Guidelines” and pass the “[Etiquette Test](#)” with a minimum score of 8 out of 11 questions. The “Etiquette Test” also includes affirmation that all training requirements have been completed.
- b. The Etiquette Test cannot be taken until study staff are listed as personnel on an IRB approved study.
- c. The Etiquette Test should not be taken until all training requirements including attendance to the CTRC New User Orientation have been completed as the test includes affirming that all university, CTRC and Epic training requirements have been completed. Affirmation that training requirements have been completed indicates to the DON that a request can be sent for the study staff to be added as a scheduling provider in Epic, gain badge access to CTRC space and access to the CTRC scheduler.
- d. The Etiquette Test must be completed even if there are no current plans to utilize the CTRC’s specimen processing and storage facilities.
- e. More information on the etiquette test and guidelines can be found at <https://tracs.unc.edu/index.php/services/ctrc/ctrc-orientation>.

C. Additional Training for Study Team Members

1. Study team members are encouraged to attend educational offerings hosted by NC TraCS. For a schedule of updated events please visit the “Events” section on the NC TraCS website at <https://tracs.unc.edu/index.php/calendar>.
2. Study coordinators or other members of the study team are encouraged to attend the “Orientation for New Clinical Research Personnel” series offered by NC TraCS. Visit UNC’s Network for Research Professionals (NRP) website at <http://nrp.tracs.unc.edu/> for more information.
3. As a refresher, study team members are required to attend another CTRC New User Orientation session if 6 months have passed since last utilizing the CTRC outpatient unit for a research visit.

D. Network for Research Professionals

1. All study team members are encouraged to join the Network for Research Professionals (NRP). The NRP is a peer group that is open to all research personnel on campus to help increase awareness and communication of best practices through a series of educational seminars, resources, mentoring and networking programs.
2. To learn more and to join the unc.crc listserv, visit their website at <http://nrp.tracs.unc.edu/>.

E. Documentation of Training

1. The DON or designated CTRC staff member will record attendance for the CTRC New User Orientation session in the UNC Event Registration system.

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2. The Principal Investigator, the study team member's supervisor and the study team member will maintain the training records for all required UNC-CH trainings. It is not necessary to provide copies of these records to the CTRC.
3. Completion of the CTRC's Etiquette Test is maintained in the CRMS CTRC Scheduler for the duration of the study.

V. **Related Documents:**

- A. SOP titled "Guidelines for Use of Specimen Storage Facilities in the CTRC"
- B. SOP titled "Guidelines for Specimen Processing and Use of Centrifuges at the CTRC"