

<b>Clinical and Translational Research Center TraCS Institute</b>	<b>Approved by:</b> Director of Nursing
<b>SOP Title:</b> CTRC Tours for Site Assessment and Monitoring Visits	<b>Revisions:</b>
<b>Effective Date:</b> 4/01/2026	<b>Page 1 of 4</b>

- I. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to define the process for coordinating and conducting tours of the Clinical and Translational Research Center (CTRC) for site assessment and clinical research monitoring visits, including, when applicable, the UNC Health 1 Memorial Observation Unit.
- II. **Scope:** This SOP applies to all requests for tours of the CTRC outpatient unit located in the Burnett-Womack building and the UNC Medical Center 1 Memorial Observation Unit in support of clinical research activities, including site assessment visits and monitoring visits.
- A clinical monitor is the person acting as an agent of a sponsor who oversees the progress of a clinical trial, and ensures that it is conducted, recorded, and reported in accordance with protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirements. The monitor may request a tour of the CTRC at any time during the study.
- A site assessment visit is conducted by a sponsor representative to evaluate whether the institution is capable of conducting a specific clinical trial. These visits may also be referred to as Site Selection Visits (SSV) or Pre-Study Qualification Visits (PSQV) and typically include a tour of the facility.
- III. **Responsible Parties:** The Director of Nursing and/or Charge Nurse are responsible for coordinating and facilitating tours of the CTRC for site assessment and monitoring visits.
- IV. **Procedures:**
- A. Requirements for Clinical Research Monitors**
1. Clinical research monitors are bound by the confidentiality agreement established between UNC at Chapel Hill and the study sponsor.
  2. Monitors must comply with unit-specific and UNC Health policies regarding infection prevention at the time of the tour (e.g., masking, immunization requirements).
- B. Requesting a Tour**
1. All tours must be scheduled in advance by emailing the Director of Nursing or the Charge Nurse.
  2. The tour request must include:
    - a. Date of the visit
    - b. Expected start time of the visit
    - c. Whether a CTRC representative is needed to provide a guided walkthrough
  3. When possible, tours should be scheduled Monday through Thursday afternoons or on Fridays when the unit is less busy to minimize disruption to patient care activities.
- C. Tour Guides**
1. Tours may be conducted by the Director of Nursing or the Charge Nurse.
  2. Study personnel familiar with the CTRC's outpatient unit and policies may provide a walkthrough without being escorted by CTRC staff when the tour is limited to the CTRC.
  3. Tours of the 1 Memorial Observation Unit require the presence of the Director of Nursing or the Charge Nurse.
- D. Tour of the Outpatient Unit by CTRC Staff:** If requested by the study team, the Director of Nursing or Charge Nurse will meet the study coordinator and monitor in the lobby of the

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Burnett-Womack building and escort them to the CTRC Waiting Room. The nurse will review the following unit information during the walking tour:

1. **Hours of Operation** – The monitor is informed that the CTRC outpatient unit is open Monday through Thursday from 7:30 am – 5 pm, and Friday from 7:30 am – 1 pm.
2. **Triage** – The monitor is shown Medical Engineering tags on an automated blood pressure machine and weight scale to illustrate that preventive maintenance is up to date.
3. **ECG** – The monitor is informed that ECGs can be performed by CTRC staff on either the machine provided by UNC Medical Center’s Cardiac Services (on loan) or on a sponsor-provided machine with training. Interpretations are available upon request through UNC Medical Center’s Cardiac Services.
4. **Specimen Processing and Storage Facility** – The monitor is shown five refrigerated centrifuges, a -80°C freezer, a -20°C freezer and a specimen refrigerator available for use by study teams. Dry ice and package pickup by FedEx or UPS are also described.
5. **Exam Room** – The monitor is shown a typical exam room setup, including exam table, otoscope, ophthalmoscope, and computer with Epic access. The monitor is informed that patient care areas are equipped with a nurse call system, wall oxygen and suction.
6. **Synchronized Clocks** – The monitor is informed that digital clocks are installed throughout patient care areas., with the signal transmitted from a tower atop a nearby building.
7. **Blood Collection** – The monitor is shown the two stations available for blood draws and is informed a phlebotomist is on staff.
8. **Nurse’s Station / Infusion Bay / Medication / Clean Utility Room** – The monitor is shown the centrally located nurse’s station that allows close monitoring of participants receiving study treatment. The monitor is informed a Pyxis is available for standard of care medications, and that adult and pediatric code carts are provided by UNC Medical Center on a rotation schedule. CTRC nurses check expiration dates daily and alert Central Distribution when replacements are needed. The monitor is informed that the infusion bay includes four infusion chairs. Medical supplies are stored in the Clean Utility Room adjacent to the nurse’s station.
9. **Extended Stay Rooms** – The monitor is shown a typical extended stay room setup and is informed that these rooms are used for longer visits, certain procedures, or when patient condition warrants.
10. **Small Coordinator Work Area** – The monitor is shown the area available for study coordinators and physicians.
11. **Back Hallway** – The monitor is escorted through the back hallway to view five additional exam rooms (three with stretchers) and a nourishment room for participant snacks and drinks. If exam room 8 is open, the monitor is shown this room, which is primarily used for pediatric visits. The monitor is also informed that the last exit door at the end of the hallway provides access to UNC Hospitals without going outside.
12. **Tube Station** – The monitor is shown the location of the tube station and informed that it is used to transport specimens to UNC Medical Center McLendon Labs as needed.

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13. **Procedural Care Suite** – The monitor is shown the Procedural Care Suite, which includes a small nurse’s station and three exam pods. The monitor is informed that the suite is reserved exclusively for food allergy research.
  14. **Large Coordinator Workroom** – The monitor is shown the area with workstations, a Xerox copier, and a fax machine.
  15. **Serial Processing Room** – The monitor is shown the room primarily used by CTRC-trained staff for Point of Care (POC) urine testing. The monitor is informed that an ice dispenser is available for specimen use and that the space may be used by study coordinators for sample processing. The room contains two centrifuges, one of which is equipped with a rotor designed to accommodate taller tubes.
  16. **Provider Workroom** – The monitor is shown the area that contains workstations and our Business Continuity Access (BCA) computer.
  17. **Director of Nursing Office** – The monitor is informed that any questions not addressed during the tour or in section F below can be directed to the Director of Nursing.
- E. Tour of 1 Memorial Observation Unit:** Permission to tour the Observation Unit must be obtained in advance by the 1 Memorial Nurse Manager. The study coordinator must contact the CTRC Director of Nursing to schedule the tour.
- F. Commonly Asked Questions During a Tour**
1. **How many patient spaces are available in the CTRC and 1 Memorial Observation Unit?**
    - a. The CTRC has 20 available patient spaces at any given time. These include 8 exam rooms, 1 consult room, 4 extended stay rooms with stretchers and an infusion chair, 4 infusion chairs, and a procedural care suite with 3 exam pods.
    - b. The 1 Memorial Observation Unit has up to 2 beds available for overnight research stays or post procedural recovery.
  2. **Are Code Teams and/or Rapid Response Teams available?**
    - a. The CTRC has coverage provided by UNC Medical Center Adult and Pediatric Code Teams and the Pediatric Rapid Response Team.
    - b. The 1 Memorial Observation Unit has coverage provided by UNC Medical Center Adult Code and Rapid Response Teams.
  3. **Are the specimen freezers and refrigerator monitored 24/7?**
    - a. Units in rooms 1019 and 1035 are monitored using equipment installed by Minus80Monitoring.
    - b. During CTRC operating hours, CTRC staff are alerted and respond to alarms in real time.
    - c. CTRC nursing staff are on call to respond if alarms are activated when the CTRC is closed.
  4. **Who performs preventive maintenance (PMs) and how often do they occur?**
    - a. Freezers and refrigerators – PMs are performed twice yearly, typically in June and December, by the UNC at Chapel Hill’s Facilities Department.

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- b. Centrifuges – PMs are performed twice yearly in March and September, by UNC Medical Center Biomedical Engineering Department.
- c. Other patient-related equipment (e.g., automated blood pressure machines, weight scales, ECG machine) – PMs are performed annually by UNC Medical Center Biomedical Engineering Department. Most patient-related equipment is serviced in September unless otherwise noted on the service tag.

**5. How do you obtain copies of temperature logs for the freezers and specimen refrigerator, and preventive maintenance logs for CTRC owned equipment such as automated blood pressure machines, weight scales, and centrifuges in Burnett-Womack?**

- a. Documents from Minus80Monitoring, UNC Medical Center Biomedical Engineering Department, and UNC at Chapel Hill Facilities Department are available to UNC study personnel on the CTRC SharePoint site at <https://adminliveunc.sharepoint.com/sites/CTRC2>.
- b. Documents are typically available on the website by the end of the month following the month in which the service was completed.

**6. Are the stadiometers and weight scales calibrated daily? How are the daily calibration logs obtained?**

- a. Stadiometers and weight scales located in the triage rooms are calibrated daily while the CTRC is open.
- b. The calibration logs are stored in the designated binder in the triage room. Study coordinators may review and make copies as needed.

**V. Related Documents:** N/A

**VI. References:** N/A

**VII. Attachments:** N/A