

Clinical and Translational Research Center NC TraCS Institute	Approved by: Director of Nursing
SOP Title and #: Guidelines for Scheduling Research Subject Visits	Revisions: 2/22/2012, 8/06/2016, 7/20/2017
Effective Date: 10/20/2009	Page 1 of 5

- I. **Purpose:** This Standard Operating Procedure (SOP) describes activities and identifies individuals responsible for the scheduling of outpatient study visits and inpatient admissions at the CTRC. This SOP assures room, resource and staff availability and facilitates fair access to CTRC resources.
- II. **Scope:** This SOP applies to study coordinators, investigators or any member of the study team (study staff) responsible for scheduling subject visits in the CTRC.
- III. **Applicability:** This SOP outlines procedures for investigators and research coordinators (study staff) who conduct studies in the CTRC that require outpatient rooms, overnight admissions or research on location services. Scheduling subject visits in advance using the designated online scheduling system and adhering to the scheduling guidelines is essential to assuring room, resource and staff availability and helps to assure a smooth study visit.
- IV. **Responsible Parties:** Study staff, CTRC staff and Director of Nursing who utilize the online scheduling system.
- V. **Procedure:**
 - A. **Protocol Approval to Schedule Visits in the Clinical Research Management System (CRMS) CTRC Scheduler:** Prior to being able to schedule visits in the CTRC CRMS Scheduler, the protocol must receive online approval by the Director of Nursing or designee. The approval process begins with the IRB online submission of the protocol with answering “yes” to the question “*Will subjects be studied in the CTRC or is the CTRC involved in any other way with the study?*” and subsequently completing the CTRC Addendum. If a contingency notice is given, the items detailed must be acknowledged or completed prior to receiving approval. Once the study receives approval by both the IRB and CTRC representative, the study will then be able to schedule visits using the online scheduling system.
 - B. **Study Staff Approval to Schedule Visits in the CRMS CTRC Scheduler:** Prior to scheduling visits in the CTRC, study staff are required to attend a CTRC New User Orientation session, complete the Etiquette Test with affirmation that all training has been completed and attend the required Epic training class (minimum of Research Administration) prior to scheduling subjects. Training on how to use the system is covered in the “Research Administration” class. Registration for the class is located in the Learning Management System (LMS). The study staff will then be given access to the online scheduling system by the Director of Nursing or designee.
 - C. **Hours of Operation:** Care is provided as indicated below. The CTRC is closed on all designated university holidays including the weekend leading up to or after a holiday that falls on a Monday or Friday. All designated holidays are indicated in the online scheduling system and are published on the university’s Human Resources website.
 1. Outpatient visits
 - a. CTRC Outpatient Unit located in the Burnett-Womack building
 - Monday – Thursday from 7:30 am – 5 pm; extended hours up to midnight are available with advance scheduling to accommodate visits that are longer than 8 hours
 - Friday from 7:30 am – 1 pm
 - b. Research on Location Services
 - Monday – Thursday from 7:30 am – 4:30 pm
 - Friday from 7:30 am – 1 pm

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Effective Date: 10/20/2009	Page 2 of 5

2. Admissions (Inpatient unit is located on 1 Anderson at UNC Hospitals)
 - a. Available 24/7 two weeks out of the month from Saturday at 8 am until closing on Friday at 12:30 pm. Friday admissions are not available.
 - b. Open weeks are designated by the CTRC Director of Nursing two months in advance on the inpatient Google calendar located in the “Helpful Information Links” on the home page of CRMS.
 - c. Open weeks generally begin on the 2nd and 4th Saturdays of the month with the exception of months that have holidays that fall during that period (i.e. Thanksgiving and Winter Break). The number of open days may be limited during these months.
 - d. The inpatient unit will close at any given time if there are no subjects scheduled by the deadline.
 - e. The inpatient unit will open at 8 am on any given day in which the unit was closed on the previous day.

D. Accessing the Online Scheduling System and Minimum Requirements needed prior to Scheduling Visits: The CTRC online scheduling system is ONYEN based and can be accessed via the web link <https://irbis.research.unc.edu/crms/>. The below items are required prior to scheduling visits.

- IRB and CTRC approved study
- Study is “active” in Epic (if applicable)
- Subjects have UNC Healthcare medical record number (can be obtained by calling 984-974-8150)
- Subjects have been accurately added to the study in CRMS with appropriate CRMS/Epic statuses
- Accurate billing account information is required to be entered in CRMS prior to scheduling visits as CTRC services are billed through InfoPorte using the provided study chart field string
- CTRC Schedule of Events and nursing profiles have been created in CRMS (to indicate services at each visit such as blood draw, infusions, peripheral intravenous access, frequent PK sampling, or other procedures requiring the assistance of a CTRC nurse)

E. Outpatient Scheduling Guidelines:

1. Scheduling guidelines and types of visits
 - a) Subject visits are considered outpatient if their visit is scheduled to be completed by 11:59 pm.
 - b) The CTRC utilizes a centralized scheduler email. All scheduling communication and special requests should be sent to ctrcheduler@med.unc.edu. Emails are generally checked at the beginning, midday, and the end of each business day. For any immediate needs, please call the CTRC Reception Desk at 919.966.1437.
 - c) Study staff is responsible for entering the subject’s appointment data into the CRMS CTRC online scheduling system prior to the start of the visit. The CTRC

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Effective Date: 10/20/2009	Page 3 of 5

staff will then enter the visit into Epic (room only visits are not entered into Epic).

- d) The online scheduling system closes at 4:00 pm for the next business day (weekends not included). For example, if a coordinator attempts to schedule a patient on Friday afternoon at 5 pm for the following Monday the online scheduling system will refuse the request.
 - e) The CTRC can accommodate same day outpatient visit requests if a room and adequate staffing is available. If a visit needs to be added after the system closes, the coordinator will need to call the clinic at 919.966.1437 during normal business hours and ask for the daily override code. The CTRC Staff will verify room and staffing availability prior to giving the override code. In the event the requested time is not available, CTRC Staff will give alternate times that the visit can take place.
 - f) Lower Acuity Visits – Visits lasting less than 2 hours that involve minimal nursing activities are automatically booked and do not require approval from CTRC Staff.
 - g) Higher Acuity Outpatient Visits – Visits involving complex nursing interventions or any visit lasting over 2 hours (i.e. serial PK's, study drug administration, procedures and observation by CTRC staff) require a **minimum of 48 hours** advanced notice to ensure staff availability and skill level for your study. To ensure room availability, it is recommended to request these visits **at least 2 weeks** ahead of the anticipated visit as rooms are limited. These types of visits will not automatically be scheduled in the scheduling system and must be approved by the Director or Charge Nurse before they will be placed on the official patient schedule for a given day. The coordinator will be notified in the event the visit cannot be accommodated at the time requested. Scheduling higher acuity requests with less than a 48 hours' notice should be made by calling 919.966.4744 and discussing the visit with the Charge Nurse. The CTRC will try to accommodate last minute scheduling requests, but scheduled subjects have priority and urgent requests are not guaranteed and are approved on an "as available" basis.
 - h) Extended Stay Visits – The CTRC Outpatient Unit can accommodate 8 – 12 hour PK/extended stay visits that need to remain on the unit past 5 pm Monday - Thursday. These visits must be requested in the online scheduling system at least 1 week prior to the requested date to ensure staffing availability.
 - i) Cancellations can be made using the online scheduling system for simple visits up until the day of the visit. If cancelling on the day of the visit, please notify the central scheduler by calling 919.966.1437 or by emailing ctrcscheduler@med.unc.edu as soon as possible for any unscheduled subjects.
2. Outpatient Visit Requirements
- a) Prior to outpatient check-in, the subject should receive instructions from the study staff on the location of the CTRC and the outpatient check-in desk. Directions can be found at <https://tracs.unc.edu/index.php/services/ctrc/ctrc-team>.
 - b) Study staff must ensure the contact name and number listed in the online scheduling system is correct prior to the subject arriving for their visit.

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Effective Date: 10/20/2009	Page 4 of 5

- c) The study staff must provide paper physician orders and nursing flow sheets for high acuity visits at least one day prior to the subject's visit.
- d) A member of the study team is required to process samples until at least 4 hours post dosing.

F. Inpatient Scheduling Guidelines and Visits:

1. Scheduling guidelines

- a) Subjects are considered inpatients if their planned visit extends beyond midnight on the day of the admission.
- b) Study staff is responsible for entering the subject schedule data into the online scheduling system. CTRC staff will then submit the bed request to the UNC Hospitals Admitting & Registration department to be entered into Epic.
- c) All inpatient visit requests require approval from the Director or Charge Nurse before being marked as "scheduled" in the official online scheduling system. The study staff will be notified by email in the event an admission cannot be accommodated and alternate dates will be given.
- d) Study staff is required to schedule inpatient admissions approximately 2 weeks in advance by Mondays at 3 pm to ensure room and resource availability.
- e) The inpatient unit has 4 rooms available for subjects ages 18 and above (ages 16 – 17 can be admitted if subject can be treated as an adult in an emergent situation). All inpatient rooms are private and one family member is allowed to stay with the subject overnight unless otherwise indicated in the study protocol.
- f) Room availability and open weekends can be viewed in the inpatient Google calendar found under "Helpful Information Links" on the homepage of CRMS.
- g) Cancellations that occur after the 2 week admission deadline must be made as soon as possible by calling the Charge Nurse at 919.966.4744 during normal outpatient business hours or by paging the Administrative Pager at 919.216.6991 when the outpatient unit is closed. Cancellations made before the 2 week deadline can be submitted by email to ctrcscheduler@med.unc.edu.

2. Admissions Requirements

- a) Prior to the admission, the subject should receive instructions or a tour from the study staff on the location of 1 Anderson and the appropriate Admitting & Registration desk at UNC Hospitals (or the Emergency Department if arriving afterhours). It is recommended that study staff meet the subject on arrival to the hospital for the first admission and escort them to the designated areas.
- b) Study staff must ensure the contact name and number listed in the online scheduling system is correct prior to the subject arriving for their visit.
- c) The study staff must provide paper physician orders and nursing flow sheets for the admission at least one day prior to the subject's arrival.
- d) Study staff must also enter admission orders in Epic as required by UNC Hospitals. These include at a minimum orders for the admission, medications, labs, diet and discharge orders.

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Effective Date: 10/20/2009	Page 5 of 5

e) A member of the study team is required to process samples until at least 4 hours post dosing.

VI. Related Documents and Additional Information:

- A. SOP titled "Outpatient Check-in, Triage & Check-out."
- B. SOP titled "Adverse Weather Policy."
- C. Quick reference tip sheet titled "Using the CTRC Scheduler" located at [Research Central](#).
- D. Quick reference tip sheet titled "CRMS Records & Participants" located at [Research Central](#).
- E. Quick reference tip sheet titled "Interface Troubleshooting Guide" located at [Research Central](#).