I. **Purpose**: This SOP describes the guideline for the outpatient check-in, triage & check-out process at the CTRC.

II. **Scope**: This SOP applies to all outpatients at the CTRC.

III. **Applicability**: This SOP will facilitate an efficient and participant-friendly outpatient check-in, triage, and check-out process, and assure the safety of all research participants.

IV. **Responsible Parties**: All members of the study team, Principal Investigator and CTRC employees.

V. **Procedures**:

A. **Check-In Process**

1. Outpatient visits must be entered into the Clinical Research Management System (CRMS) CTRC Scheduler prior to the start of a participant's visit. A UNC Health medical record number is needed to submit a visit request in CRMS. The participant or study coordinator may obtain a new medical record number by calling UNC Medical Center at 984-974-8150 or by going to one of the Admitting and Registration Desks (i.e., Women's or Cancer Hospital) prior to scheduling a visit in the CTRC.
2. In the event of an unanticipated visit, the study coordinator will need to obtain an override code by calling 919-966-1437 or by asking for the code from the CTRC front desk or nursing staff depending on the type of the visit. The study coordinator will then enter the visit into the CTRC Scheduler prior to the participant being checked in.
3. The study coordinator should ensure that the participant receives instructions on the location of the outpatient CTRC and the check-in desk. Directions can be found at https://tracs.unc.edu/index.php/services/ctrc/ctrc-directions.
4. The participant's arrival time will be recorded in the CTRC Scheduler by the CTRC staff member checking in the participant. The CTRC front desk staff checking in the participant will verify the information (participant name, medical record number and date of birth) in Epic matches the information that is listed in the CTRC Scheduler and will notify the study coordinator of any issues. The participant will then be marked as arrived in Epic (except for room only visits).
5. Once the participant is checked-in for both CRMS and Epic (if applicable), the front desk staff will print out participant labels and place them in the tray at the front desk. This will signify to the CTRC triage staff that vital signs are ready to be performed (if applicable).
6. If the study coordinator needs labels prior to vital signs being obtained, only half of the sheet should be taken, and the other half should be left in the tray.
7. The CTRC front desk staff will contact the study coordinator listed for the visit in the CTRC Scheduler using the telephone or pager number provided. When possible, two contact numbers should be listed so that the front desk staff are able to reach the coordinator when the participant arrives. When the study coordinator arrives to the CTRC, they will self-assign the participant to a room by indicating this on the dry erase room assignment board. An extended stay room or infusion chair will be assigned by CTRC nursing staff for visits that are considered high intensity (i.e., infusions or other study drug administration, serial blood draws, monitoring).

B. **Triage Process**

1. Prior to CTRC staff performing any procedures the participant must be consented for a specific IRB-approved research protocol. This includes but is not limited to obtaining vital signs, height, weight, and collection of urine on arrival at CTRC.
2. Once consent has been obtained, vital signs, height and weight for participants will be obtained as instructed in the comment section of the CTRC Scheduler as detailed by the study coordinator and recorded in Epic. If comments are not entered by the coordinator in either the "Profile" or "Visit" notes section of the CTRC scheduler (appears as "not specified" in the CTRC staff view), CTRC staff will obtain temperature, heart rate, blood pressure, respiratory rate, weight, and height (as detailed in B.4.).
3. The minimum information recorded in the participant's chart in Epic will include the measurements listed below unless otherwise requested in the visit comment section of the CTRC Scheduler. Any measurement needed in addition to the measurements listed below must be specifically requested by the study coordinator in the visit note section such as pulse oximetry, recording rest period, manual readings, or orthostatic blood pressures.
    a) Blood pressure – with location (i.e., right arm, left arm) noted
    b) Heart rate
    c) Respiratory rate
    d) Temperature (in Celsius) – oral temperatures will be obtained for adult participants, and oral or temporal (if permitted per protocol) temperatures will be obtained on pediatric participants.
    e) Weight (in kilograms)
    f) Height (in centimeters) – will only be obtained on adult participants on the first visit (i.e., consent) of the study unless requested by the study coordinator in the CTRC Scheduler visit comment section. Height will be obtained at every visit for pediatric participants (<18 years old) unless otherwise requested by the study coordinator in the CTRC Scheduler visit comment section.
4. Study participants who can do so will be instructed to be in a seated position with feet flat on the floor prior to vital sign (BP, HR, RR) measurements being obtained unless otherwise instructed by the study coordinator.
5. Study participants will be asked to remove shoes and bulky clothing or assistive gear (if appropriate/able) prior to height and weight being obtained. If a participant refuses or is unable, a comment will be written in Epic. In the event the participant is receiving a study medication or is having other weight/height-based procedures, the study physician or PI will be notified if the participant refuses or is unable to remove their shoes, bulky clothing, or assistive gear.
6. Exceptions to CTRC triage staff obtaining participant's arrival vital signs, height and/or weight will either be indicated by the study coordinator in the visit profile

notes or by the indicator listed in the nurse procedure column in the CTRC staff view of the CTRC Scheduler. Exceptions include,

a) Blood draw only visits – vital signs, height and weight are not measured

b) Room use only visits – vital signs, height and weight are not measured

c) POC urine testing (pregnancy, dipstick) only visits – vital signs, height and weight are not measured

d) If the protocol specific guidelines require study team to perform vital signs, height and/or weight using specific equipment or procedures

e) Written comments in the visit profile of the CTRC Scheduler states vital signs, height and/or weight are not to be obtained on arrival (i.e., participant must be consented)

f) Any visit using an approved CTRC flow sheet that requires a registered nurse (RN) to assist with procedures such as study drug administration, serial blood draws via a peripheral venous catheter (PIV), monitoring post study drug administration or any other type of procedure requiring a RN, only weight and height (if applicable) will be measured by triage staff. For these visits, vital signs will be obtained by the RN assigned to the visit once the participant is roomed.

7. In the event vital sign measurements are outside of the normal range, the measurement will be repeated by CTRC staff after the participant has remained seated for 5 minutes. Abnormal vital signs will be reported to the study coordinator associated with the protocol visit who will then report the findings to the protocol's Principal Investigator or designated physician, nurse practitioner or physician assistant. It is ultimately the Investigator's responsibility to review the data and determine the next course of action, based upon the participant's history and study protocol.

8. After the CTRC staff records the vital sign information in the participant's chart in Epic, the participant will be given the printed Epic visit labels and instructed to return to the waiting room. This will signify to the coordinator that vitals have been obtained. If the coordinator or provider bypasses this step and escorts the participant to a room prior to vitals being obtained, it becomes the responsibility of the coordinator/provider to notify the triage staff that the participant is ready for arrival vital signs. The participant should then be escorted back to the waiting room and vital signs will be obtained in order of request.

9. To assure the safety of all research participants, vital signs will be obtained on any participant that reports to the CTRC with new symptoms or complaints of shortness of breath, chest pain, radiating pain, severe nausea or any other complaints that are not mentioned above and that is judged to be serious or life threatening regardless of the exceptions. It is recognized that these urgent procedures may occur prior to obtaining consent for a specific IRB-approved research study, since that discussion may not have occurred prior to the participant arriving at the CTRC.

C. **Check-Out Process**

1. The study coordinator is responsible for ensuring that the requested vital signs, height, and weight have been obtained and are documented in Epic prior to the participant leaving the unit.
2. The study coordinator is responsible for recording the participant's departure time on the "sign-out" log or verbally notifying front desk staff of the participant's departure time. The sign-out log is located on top of the Shred-It bin in the reception area. The participant's departure time will be recorded by a CTRC staff member in the CTRC Scheduler as well as Epic (if applicable) Epic. If the study coordinator does not record the departure time on the sign-out log or does not notify front desk staff, the CTRC staff will email or call the coordinator to determine the participant's departure time. If there is no response to the request in a reasonable amount of time, the CTRC staff will enter the daily closing time of the unit as the check-out time. It is the responsibility of the study coordinator to ensure check-out times are correct by viewing the "CTRC Billing Report" located in the "Research Participants" tab in CRMS.
3. The study coordinator is responsible for wiping down surfaces and pulling new exam table paper once the table is dry at the completion of each visit. Super Sani-Cloths are in each room for this purpose and gloves must be worn when using the wipes. The study coordinator is required to notify the Charge Nurse if they are unable to complete this task prior to exiting the room. Once notified, the Charge Nurse is then responsible for ensuring the room has been cleaned.
4. Once the room is cleaned, the study coordinator is responsible for erasing the room information off the dry erase board at the completion of their visit.
5. CTRC staff will record the departure times for high intensity visits in which an RN has been assigned to care for the participant. These visits include serial PK's, study drug administration and extended observation visits.

VI. **Related Documents**:

A. Quick Reference – Viewing CTRC Billing Report