I. **Purpose:** This standard operation procedure (SOP) describes activities and identifies individuals responsible for documenting outpatient research subject care at the Clinical and Translational Research Center (CTRC).

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

III. **Applicability:** Accurate, timely documentation of outpatient care activities ensures that the CTRC meets JCAHO, NIH, and UNC Health Care documentation standards. It also assures that CTRC staff members provide coordinators and investigators (study staff) with needed source documentation of pertinent research activities.

IV. **Responsible Parties:** the CTRC Staff, the PI or sub-PI, and the Study Coordinator.

V. **Procedures:**

A. **Subject Arrival:**
   1. Upon arrival to the outpatient CTRC, the secretary will complete the “Outpatient Login Sheet” using the subject’s white hospital ID card.
   2. Prior to the subject’s admission to the outpatient CTRC, the PI or sub-PI will complete any needed “Physician Order Forms.” This is critical if a patient will be receiving any infusions or other high acuity study procedures.
      1. However, an RN may take a verbal order from the investigator to obtain orders. A study NP or PA may also complete the “Physician Order Form” in accordance with institutional standards of practice as well as accepted study procedures.
      2. However, only an MD (Attending or Fellow) may sign orders for chemotherapy or biotherapy.

B. **Specimens:**
   1. If specimens are needed, the study coordinator will complete the “Laboratory Request Form” and place it in the “Labs To Be Entered Tray”. This is to be done after the patient is checked in.
      1. The coordinator should assure that this form is signed by the PI, sub-PI, PA, or NP. However, a RN coordinator may take a verbal order and sign this form for a physician.
   2. The secretary will then enter needed labs into the computer system and print out the appropriate laboratory requisition slips. The secretary will place the “Laboratory Request Form” and the laboratory requisition slips in the “Completed Lab Slips Tray.”

C. **Documenting the Outpatient Care Procedures:**
   1. Once the secretary has stamped the “Outpatient Record Sheet” with the patient’s white hospital ID card and placed it the “Outpatients To Be Checked In Tray,” a member of the CTRC nursing staff will complete the appropriate parts of the “Outpatient Record Sheet” during the patient check-in process for all low acuity, non-infusion studies.
      1. This sheet will then be given to the patient, who will then give it to the coordinator. Or this sheet may be given directly to the coordinator by CTRC staff. With infusion studies or other applicable high acuity studies, the CTRC nursing staff may keep the “Outpatient Record Sheet” for further nursing documentation.
2. The study coordinator will provide the CTRC nurses with a study flow sheet if their study involves multiple PKs, infusions, or other applicable high acuity activities. The CTRC nurses will record all needed study activities on this flow sheet in an accurate, timely manner.

3. The CTRC nurses will complete all applicable parts of the “Chemotherapy Administration Note (MIM #816)” if their patient will receive this type of therapy.

4. If labs are to be drawn by the CTRC phlebotomist:
   1. The coordinator should review the “Laboratory Request Form” and ensure that the appropriate lab requisition forms have been printed by the secretary. The coordinator should then take this form as well as the requisition slips and place them in the tray on the door of the phlebotomist’s lab.
   2. The CTRC phlebotomist must complete the “Laboratory Log Sheet” to record all blood drawing activities.

D. **Upon Completion of Procedures:**
   1. CTRC nurses will place all applicable source documents into the “Worksheets Tray” located on the shelf in the outpatient nurses station.
   2. If any EKGs are performed by the CTRC nurses, a copy of this EKG will be placed in the “EKG Tray” located on the shelf in the outpatient nurses station.
   3. The study coordinator should then photocopy all needed source documents (e.g. patient care records, physician order forms, etc) and then place them in the “Medical Records Tray” located on the shelf in the outpatient nurses station.