

Clinical and Translational Research Center TraCS Institute	Approved by: Director of Nursing
SOP Title and #: Guidelines for the Documentation of Outpatient Care Activities	Revisions: 02/18/2015, 2/15/2017, 09/22/2019
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- I. **Purpose:** This standard operation procedure (SOP) describes activities and identifies individuals responsible for documenting the care of outpatient research subject 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 and needed information for billing of study visits.
- IV. **Responsible Parties:** All CTRC and study staff (Principal Investigator, study coordinator, research assistant, study physician, physician’s assistant or nurse practitioner).
- V. **Procedures:**
 - A. **Document Standards for Study Specific Forms (e.g. orders and flow sheets) and UNC Hospital Approved Paper Documents:** Only dark ink (black or dark blue) will be used for study documentation, black ink is strongly preferred and must be used by all CTRC staff members per CTRC management. Whiteout, pencils and colored pens are prohibited.
 - B. **Subject Arrival:**
 1. Upon arrival to the outpatient CTRC, the Administrative Support Associate or nursing staff (front desk staff) covering the reception desk will record the subject’s arrival time in CRMS and will complete the Epic check-in process (“Room Only” visits do not have a corresponding visit in Epic).
 2. In addition to the computer check-in, CTRC staff will use the daily paper log to record times in the event they are unable to check-in the subject in CRMS at the time of the subject’s arrival. The arrival time must be recorded in CRMS as soon as staff is able to do so.
 3. The front desk staff will print a subject wristband for subjects receiving study medications that are to be administered by CTRC nursing staff.
 - C. **Documenting Triage Vital Signs:**
 1. Vital signs that are obtained in Triage will be documented in Epic and not on study specific documents. Measurements will be documented in either the “Visit Navigator” or in the “Flowsheets” section depending on the complexity of the vital signs requested. The “Flowsheets” section allows for greater documentation detail such as BP location, method used and patient position.
 2. Prior to escorting the subject to the triage room, Triage staff will review the comment section of the daily CTRC scheduler to ensure study specific vital signs instructions are followed.
 3. In addition to collecting vital signs, triage staff are required to update travel, allergy and reason for visit information in Epic with each new subject visit.
 4. Study subjects admitted for medication administration or requiring any other nursing procedures (visits requiring a nursing flow sheet) will have a pain score assessment, weight and height (if applicable) measured and documented in Epic by the Triage staff before being escorted to their assigned room or infusion chair. Remaining arrival vital signs will be obtained in the room or infusion chair by the assigned nursing staff prior to treatment as indicated on the provided flow sheet.

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D. Epic and Paper Orders:

1. Signed orders are required prior to procedures being carried out by CTRC staff. Pended orders are not considered signed orders and cannot be carried out until signed by an appropriate provider.
2. The study coordinator will drop off signed paper orders for higher acuity visits to the outpatient nurse's desk at least 24 hours but no more than 7 days prior to the scheduled visit.
3. Most procedures for lower intensity visits such as hospital labs sent to McLendon, a phlebotomy research draw, pregnancy testing and ECG's are ordered in Epic. Study specific orders which are not available in EPIC may be ordered using the approved paper physician order form located at <https://tracs.unc.edu/index.php/services/ctrc/ctrc-operations/nursing-services>. All paper order forms will require the subject's current visit epic label in each of the three order sections. Additionally, study specific nursing orders not otherwise available in Epic should be entered in Epic using the "Misc nursing order (specify) or NUR608" order.
4. After reviewing the Epic orders, the CTRC nurse will release signed Epic orders with the required documentation (see Epic tip sheets).
5. After reviewing the paper order form and comparing it with the provided flow sheet, the CTRC nurse will sign off on the orders by recording the date, time and signature.
6. Any discrepancies between paper orders, Epic orders and flowsheets will be addressed with the study team prior to proceeding with any study related procedures.

E. Flow sheets:

1. The study coordinator will drop off flow sheets for higher acuity visits to the outpatient nurse's desk at least 24 hours prior but no more than 7 days prior to the scheduled visit.
2. The CTRC nurse will record activities on the study provided flow sheet in an accurate and timely manner.
3. Double charting should be kept to a minimum. Frequent procedures (such as serial blood draws or vital signs) will be recorded on the flow sheet and not in Epic. However, in recognizing documents may take at least a week to be uploaded into the electronic medical record, the initial and discharge vital signs (if requested per protocol) will be recorded in the Epic chart. Vital signs that are assessed outside of the times requested on the flow sheet will be recorded in Epic (i.e. repeated vital signs, adverse events). The nurse will document "see flow sheet" or "see Epic" to direct where the information was recorded.
4. Documentation on the approved flow sheet will be completed as described below.
 - a) The subject's Epic label displaying the correct CSN number of the current visit will be affixed to the top right corner of each page of the flow sheet
 - b) The date will be recorded in the "Date" column. If the visit occurs over multiple days (i.e. a 24 hour PK visit), then each new day will be recorded in the appropriate row.
 - c) Once time "0" has been established, the CTRC nurse will record the target time for the remaining activities in the "Target Time" column.

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- d) The actual time of the procedure or activity will be recorded in the “Actual Time/Initial” column and will include the nurse or study staff’s initials.
- e) Blood pressure, heart rate, respiratory rate, temperature and other vital signs will be recorded in the appropriate columns as indicated on the study specific flow sheet.
- f) Additional documentation will be recorded in the “Procedure” column as indicated on the study specific flow sheet.
- g) The CTRC nurse carrying out a procedure will document their initials and signature at the bottom of every page of the flow sheet in which a procedure was completed and as indicated on the study specific flow sheet.

F. Nursing Notes, Medication Administration Record (MAR) and Flowsheets in Epic:

- 1. In addition to completing the study flow sheet, the CTRC nurse will write a minimum of one nursing note in Epic. This note will include a summary of the visit from arrival to discharge.
- 2. Any adverse events will be recorded in Epic. Documentation will include the study staff notified and any action or resolution to the event.
- 3. Any study drug administration will be documented on the MAR in Epic.
- 4. Placement and discontinuation of a Peripheral Intravenous Line (PIV) will be documented in Epic under the flowsheet section “IV assessment”. The verification of a patent PIV via checking for a brisk blood return prior to and after study drug administration must be documented in the nurses notes or on the “IV assessment” flowsheet.

G. Documenting Phlebotomy draws:

- 1. Each kit lab tube is required to have the proper identification (either current Epic label or subject specific identifiers) written on the tube(s). The tubes should then be placed in a plastic biohazard bag. A label with the subject’s name, date of birth and medical record number must be placed on the outside of the bag. The phlebotomist or nurse will record, time, initials and total volume on the label on the outside of the bag.
- 2. Once blood samples are drawn, the CTRC phlebotomist or nurse will record the date and times the sample(s) was drawn in Epic.
- 3. The CTRC phlebotomist will also complete the daily “Clinical Research Blood Drawing Log” to record all blood drawing activities that includes the time, date, initials, number and type of tube, and amount of blood drawn. This log will be kept for two (2) years from the date of service and then placed in the Shred-It Bin.

H. Error Correcting:

- 1. On paper documents, corrections must be corrected by the individual who made the incorrect entry. A single line must be drawn through the error or incorrect entry, making certain the original entry is still legible. Enter the correction above or near the original entry. The individual making the correction must date and initial the revision. If there is any question as to why the entry is being corrected, explain the reason (e.g., “wrong subject record”). If further explanation is needed, write “see Epic note” and continue documentation in the subject’s medical record.
- 2. Refer to the online tip sheet for correcting errors in Epic.

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I. Subject Discharge Time:

1. Discharge times are to be recorded in CRMS and EPIC by CTRC staff. Times should accurately reflect the time of discharge to ensure proper billing.
2. For low acuity visits, the study coordinator will record the discharge time on the provided "Sign-out Sheet" located at the reception desk and the Coordinator Workroom. The CTRC front desk staff will then record the discharge time in CRMS and in Epic.
3. For high acuity visits, the CTRC nurse assigned to the visit will record the discharge time in CRMS and in Epic.

J. Upon Completion of Procedures:

1. If any ECGs are performed by the CTRC nurses using hospital provided equipment, a copy of the ECG will be given to the study staff and a copy placed in the "ECG" tray (yellow folder, middle tray) located at the outpatient nurses' desk. The second copy will be retained for 3 months and then placed in the Shred-It bin. Only ECG's that have been requested to be interpreted by UNC Cardiology will have a copy placed in the subject's medical record in Epic.
2. If paper orders and flow sheets were used, the CTRC nurse will place the subject's chart in the "Coordinator" tray (red folder, bottom tray) at the outpatient nurses' desk for the study staff to copy within 7 days from the date of service. If the study staff has not made copies by this time period, the chart will be sent to UNC Hospitals' Health Information Management (HIM) Department. It is then the study staff's responsibility to locate forms in Epic after they have been scanned into the subject's chart and make necessary copies.
3. Once the study staff has copied the subject's paper chart, the study staff will place the chart or any other documents such as consent forms, in the "Medical Records" tray (blue folder, top tray) located at the outpatient nurses' station. UNC Hospitals' HIM Department will pick up the records at least once a week and scan them into the subject's medical record in Epic.

VI. Additional Information:

- A. SOP titled "Outpatient Check-in, Triage and Check-out"
- B. SOP titled "High Intensity Visit Requirements"
- C. SOP titled "Triage Process"
- D. SOP titled "Phlebotomy"
- E. SOP titled "Pediatric Phlebotomy"