I. **Purpose**: This standard operating procedure (SOP) describes the criteria to be used for determining the level of care billing rate of an outpatient research subject visit in the Clinical and Translational Research Center (CTRC).

II. **Scope**: This SOP covers all outpatient research subject visits to the CTRC.

III. **Applicability**: This SOP applies to all CTRC staff who will determine the acuity levels of research subject visits.

IV. **Responsible Parties**: CTRC nurses, nursing assistants and administrative staff as well as the study team members who determine the level of care of an outpatient research subject visit in the CTRC for scheduling or billing purposes.

V. **Policy**: The level of care is determined by the number and type of services provided by the CTRC nursing and medical support staff as well as the equipment and supplies utilized. The level of care can also be determined using the Level of Care Worksheet. Protocol categorization and level of care each play a unique and integral role in determining fees. It is important to understand both areas in order to prepare accurate budgets for a research study. CTRC rates are subject to change and studies will be charged the current rates.

VI. **Procedures:** In order to determine the level of care of an outpatient research subject visit, study team members and CTRC staff will assign a level of care using the criteria listed below.

A. Levels of Care:

1. **Level 1: Basic Clinical Services** – Choose up to four of the following for visits up to 2.5 hours.
    - Any visits lasting up to 2.5 hours
    - Simple phlebotomy (one or two non-timed samples) by CTRC staff
    - Simple vital signs (adults or pediatrics) which includes height, weight, and O2 saturation by CTRC staff
    - Orthostatic vital signs (lying, sitting, and standing) by CTRC staff
    - ECG by CTRC staff
    - Oral medication administration of one agent of approved use (e.g., Tylenol) by CTRC staff
    - Questionnaires given to subjects for self completion by CTRC staff
    - Specimens (e.g., blood, urine, stool) collected offsite and requisitioned by CTRC to be sent to McLendon Lab by CTRC staff
    - Discontinuing intravenous access by CTRC staff
    - Urine point of care pregnancy or urine dipstick testing by CTRC staff
    - Whole blood point of care glucose testing by CTRC staff
2. **Level 2: Minimal Care –** Choose any level 1 care and up to three of the following for visits lasting 2.5 hours up to 4.5 hours.
    - Any visits lasting longer than 2.5 hours but less than 4.5 hours
    - Complex vital signs (e.g. BP measured 3 times manually five minutes apart & BP measured 3 times by automatic device five minutes apart) by CTRC staff
    - Simple pharmacokinetic (PK) sampling (sampling of up to 3 blood draws) by CTRC staff
    - Nasal, Oropharyngeal, or Throat swab collection by CTRC staff

- Medication administration given – subcutaneous, intramuscular, intradermal, or intravenous; single agent, non-study medication (e.g., Depo-Provera, PPD) by CTRC staff
- Oral administration of a single investigational study medication by CTRC staff without PK sampling or observation time required
- Medication given by physician/study coordinator and observation and/or vital signs are performed by CTRC staff for up to 4 hours post dose
- Subcutaneous, intramuscular, or intradermal injection of study medication by CTRC staff with less than 2 hours observation by CTRC staff
- Initiating and/or discontinuing intravenous access by CTRC staff
- Accessing and/or deaccessing portacath or other central line (including line maintenance as outlined in the UNC hospital policy) that by CTRC staff
- Central line dressing change (with required line maintenance per UNC policy
- Oral glucose tolerance test with up to 3 blood draws by CTRC staff (INCLUDES amount of time subject is required to be on the CTRC for study procedures)
- Wound dressing changes and/or wound care by CTRC staff
- Invasive procedures (e.g., lumbar puncture, pelvic exam, etc) performed at bedside that require assistance from CTRC staff (e.g., passing of instruments, holding subject, etc.)
- Questionnaires given to subjects by CTRC staff that require CTRC staff to be present and assist subject with completion
- Subject teaching by CTRC staff
- Timed cardiac walks by CTRC staff
- Cognitive testing activities by CTRC staff
- Timed meals monitored by CTRC staff

3. **Level 3:** Moderate Care – Visits generally lasting more than 4.5 hours but less than 6.5 hours and may include any Level 1 care, more than three Level 2 care, and/or up to one of the following.

    - Any visit lasting longer than 4.5 hours but less than 6.5 hours OR one of the Level 3 items below (cannot be selected in combination with any other Level 3 item)
    - Visits lasting up to 6.5 hours and requiring data collection (e.g., vital signs, pulse oximetry, questionnaires, ECG, etc.) and/or specimen collection (e.g., PK sampling, sputum collection, urine collection, swab collection, etc.) at several time points throughout the visit
    - Subcutaneous, intramuscular, or intradermal injection of study medication by CTRC staff with more than 2 hours observation by CTRC staff
    - Visits lasting up to 6.5 hours without study medication given by CTRC staff and requiring data collection (e.g., vital signs, pulse oximetry, questionnaires, ECG, etc.) and/or specimen collection (e.g., PK sampling, sputum collection, urine collection, swab collection, etc.) at several time points throughout the visit

- Visits lasting up to 6.5 hours and requiring administration of a single agent (oral, intravenous, subcutaneous, intradermal, or intramuscular) study medication such as investigational drugs, chemotherapy, or immunotherapy with specimen collections no more frequently that every 30 minutes (e.g. PK sampling, sputum collection, urine collection, swab collection, etc.) and may include data collection (e.g. vital signs, pulse oximetry, questionnaires, etc.) at several time points throughout the visit
- Visits requiring nursing interventions or monitoring such as frequent dose adjustment of study drug (e.g., titration of chemotherapy) up to 1 hour and/or frequent vital signs (e.g., every 5 minutes up to 1 hour) after study drug administration
- Visits lasting up to 6.5 hours and requiring administration of more than one study medication in any combination (oral, subcutaneous, intradermal, or intramuscular) such as investigational drugs, chemotherapy, or immunotherapy with specimen collections no more frequently that every 30 minutes (e.g., PK sampling, sputum collection, urine collection, swab collection, etc.) and may include data collection (e.g., vital signs, pulse oximetry, ECG, questionnaires, etc.)
- Procedures (e.g., liver biopsy, bronchoscopy, lumbar puncture) that requires recovery or observation to be done by CTRC staff and that may include specimen collection and/or vital signs
- Oral glucose tolerance test with more than 3 blood draws (INCLUDES amount of time subject is required to be on the CTRC unit for study procedures)
- Medication given by physician/study coordinator and observation and/or vital signs performed by CTRC staff for more than 4.5 hours, but less than 6.5 hours post dose

4. **Level 4: Complex Care –** Visits lasting more than 6.5 hours but less than 8.5 hours, includes at least two Level 3 care, or includes one or more of the following and may include any combination of Level 1 or Level 2 care.

    - Any visit that requires subject to remain on the unit for more than 6.5 hours but less than 8.5 hours
    - Any protocol requiring assistance of two licensed nurses at any time point for any length of time
    - Infusions involving MORE THAN ONE of the following: chemotherapies, immunotherapies, investigational drugs, fluid boluses, blood products, electrolyte solutions, antibiotics, or other IV medication
    - Visits requiring intravenous administration of a single agent such as investigational drugs, chemotherapy, or immunotherapy with specimen collections more frequently that every 30 minutes (e.g., PK sampling, sputum collection, urine collection, swab collection, etc.) and may include data collection (e.g., vital signs, pulse oximetry, questionnaires, etc.) at several time points throughout the visit

- Visits requiring nursing interventions or monitoring such as frequent dose adjustment of study drug (e.g., titrating chemotherapy) over at least 1 hour and/or frequent vital signs (e.g., every 5 minutes over at least 1 hour)
- Visits requiring administration of more than one study medication in any combination (oral, subcutaneous, intradermal, intravenous, or intramuscular) such as investigational drugs, chemotherapy, or immunotherapy with specimen collections more frequently that every 30 minutes (e.g., PK sampling, sputum collection, urine collection, swab collection, etc.) and may include data collection (e.g., vital signs, pulse oximetry, ECG, questionnaires, etc.)
- Pediatric subjects < 16 years old requiring intravenous agent administration with or without simple PK sampling
- Visits lasting greater than 6.5 hours and requiring multiple timed investigational ECGs at several time points throughout study visit by CTRC staff
- Any visit requiring emergency interventions such as with a hypersensitivity reaction (e.g., use of bedside emergency kit, call to Rapid Response Team or a Code Blue) or requiring admission to UNC Hospitals or any visit that requires a nurse-to-patient ratio 1:1 for more than 30 minutes (such as hypoglycemic reaction, fainting episode, etc.)

B. **Visits Greater than 8.5 hours:** Visits lasting more than 8.5 hours will be charged a Level 4 fee plus current extended hours rate for every hour thereafter.

C. **Research on Location and Mobile Visits:**

1. Visits utilizing research on location (ROL) and mobile services will be categorized as a Level 0 and billed at an hourly rate in 30-minute increments. The rate will be detailed in the study's Memorandum of Understanding (MOU) prior to study initiation.
2. The total time for the visit will include the CTRC staff's pre-visit preparation (e.g., gathering needed supplies and travel time to subject location), actual subject care and post visit procedures (e.g., travel time back to CTRC and completion of documentation).

D. **Guidelines and Other Helpful Information:**

1. The level of care assigned to each visit when the budgeting process occurs may not always be the level of care that is invoiced once the visit has been completed. Actual billed levels of care will be reassigned by CTRC staff in the event visit lengths and procedures are different from the original assigned level of care.
2. Review each intervention prior to assigning the level of care as some are not based on the length of the visit but type of service (e.g., intravenous administration of one study drug is considered a Level 3 care even though the visit may not last for 4 hours).
3. When assigning the initial level of care, begin with the most complex nursing service requested and determine which level of care it should be. Then check the remainder of the services that apply to the visit.

VII. Additional Information and Resources

A. More information can be found on the CTRC website under the category "Fee Determination" at https://tracs.unc.edu/index.php/services/ctrc/ctrc-operations/fees.

B. SOP titled "Inpatient Care Fees"