

Clinical Translational Research Center TraCS Institute	Approved by: Director of Nursing and Director of Administration
SOP Title and #: Guidelines for Determining Levels of Care	Revisions: 2/22/12 & 05/26/2010
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- I. **Purpose:** This standard operating procedure (SOP) describes the criteria to be used for determining the level of care of an outpatient research subject visit to 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:** All administrative and clinical personnel who determine the level of care of an outpatient research subject visit to the CTRC for billing or scheduling purposes.
- V. **Procedures:** In order to determine the level of care of an outpatient research subject visit applicable administrative and clinical staff will assign research subject visits to one of four levels of care using the following criteria:
 - A. **Level 1: Basic Clinical Services - \$75.** Choose any four of the following:
 1. Any visits lasting up to 2 hours
 2. Phlebotomy by CTRC staff (hospital and/or study labs) that may include simple processing or single blood draw for patients \geq 2 years old by CTRC staff
 3. Simple vital signs (adults or pediatrics) which includes height, weight, and O2 saturation by CTRC staff
 4. Orthostatic vital signs (lying, sitting, and standing) by CTRC staff
 5. Simple ECG's by CTRC staff
 6. Simple oral medication administration (one agent of "approved use", e.g. Tylenol) by CTRC staff
 7. Questionnaires given to subjects for self completion by CTRC staff
 8. Specimens (e.g. blood, urine, stool) collected offsite and requisitioned by CTRC to be sent to McLendon Lab by CTRC staff (please note that generation of lab slips only are no charge)
 9. Discontinuing intravenous access by CTRC staff
 10. Urine Point of Care pregnancy testing by CTRC staff
 11. Whole blood Point of Care glucose testing by CTRC staff
 - B. **Level 2: Minimal Care - \$142.** Choose any level 1 care and up to three of the following:
 1. Any visits lasting longer than 2 hours but less than 4 hours
 2. Pediatric blood draws by CTRC staff (up to 3) for patients less than 2 years old by CTRC staff
 3. 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
 4. Patients requiring isolation precautions
 5. Simple pharmacokinetic (PK sampling of up to 3 blood draws) sampling by CTRC staff
 6. Nasal, Oropharyngeal, or Throat swab collection by CTRC staff
 7. Medication administration given - subcutaneous, intramuscular, intradermal or intravenous; single agent, non-study medication (e.g. Depo-Provera, PPD) by CTRC staff
 8. Oral administration of a single investigational study medication by CTRC staff without PK sampling or observation time required
 9. Medication given by physician/study coordinator and observation and/or vital signs are performed by CTRC staff for up to 4 hours post dose

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10. Subcutaneous, intramuscular, or intradermal injection of study medication by CTRC staff with less than 2 hours observation by CTRC staff
11. Initiating and discontinuing intravenous access by CTRC staff
12. Accessing and/or deaccessing portacath or other central line that includes line flushed per UNC policy by CTRC staff
13. Central line dressing change with required line flushed per UNC policy
14. Oral glucose tolerance test with up to 3 blood draws by CTRC staff (INCLUDES amount of time patient is required to be on the CTRC for study procedures)
15. Wound dressing change and/or wound care by CTRC staff
16. Invasive procedures at bedside (e.g. lumbar puncture, pelvic exam, etc) performed at bedside that require assistance from CTRC staff (e.g. passing of instruments, holding patient, etc)
17. Questionnaires given to subjects by CTRC staff that require CTRC staff to be present and assist patient with completion
18. Patient teaching by CTRC staff
19. Timed cardiac walks by CTRC staff
20. Cognitive testing activities by CTRC staff
21. Timed meals monitored by CTRC staff

- C. **Level 3: Moderate Care - \$260.** Visits generally lasting more than 4 hours but less than 6 hours and may include any Level 1 care, more than three Level 2 care, and/or up to one of the following:
1. Medication given by physician/study coordinator and observation and/or vital signs performed by CTRC staff for more than 4 hours but less than 6 hours post dose
 2. Visits lasting up to 6 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
 3. Subcutaneous, intramuscular, or intradermal injection of study medication by CTRC staff with more than 2 hours observation by CTRC staff
 4. Visits lasting up to 6 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
 5. Visits lasting up to 6 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
 6. 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
 7. Visits lasting up to 6 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

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- 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.)
8. Administration of one blood product (e.g. one unit of blood)
 9. 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
 10. Oral glucose tolerance test with more than 3 blood draws (INCLUDES amount of time patient is required to be on the CTRC unit for study procedures)
 11. Visits lasting up to 6 hours and requiring multiple timed investigational ECG's at several time points throughout study visit by CTRC staff
- D. **Level 4: Complex Care - \$342.** Visits lasting more than 6 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:
1. Any visit that requires patient to remain on the unit for more than 6 hours but less than 8.5 hours
 2. Any protocol requiring assistance of two licensed nurses at any time point for any length of time
 3. Infusions involving MORE THAN ONE of the following: chemotherapies, immunotherapies, investigational drugs, fluid boluses, blood products, electrolyte solutions, antibiotics, or other IV medication
 4. 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
 5. 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)
 6. 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.)
 7. Pediatric patients < 16 years old requiring intravenous agent administration with or without simple PK sampling
 8. Visits lasting greater than 6 hours and requiring multiple timed investigational ECG's at several time points throughout study visit by CTRC staff
 9. Procedures requiring conscious sedation
 10. 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.)

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- E. **Visits greater than 8.5 hours:** Visits lasting more than 8.5 hours will be charged a Level 4 fee plus \$64.00 per hour for every hour thereafter.