I. **Purpose**: This Standard Operating Procedure (SOP) describes activities and identifies individuals responsible for the handling and processing of specimens and using the CTRC provided centrifuges.

II. **Scope**: This SOP applies to CTRC staff, study coordinators, investigators, and any member of the study team (study staff) responsible for processing study samples in the Specimen Processing & Storage Facility, Serial Processing or Special Chemistry Lab (CTRC Facilities) areas of the CTRC.

III. **Applicability**: Study staff using any of the centrifuges located in the CTRC outpatient or inpatient units.

IV. **Responsible Parties**: Study and CTRC staff who are utilizing the CTRC centrifuges for sample processing.

V. **Procedures**:

A. **Training**:

1. Prior to gaining badge access to the CTRC Facilities, study team personnel will be required to complete university EHS Training, visit Occupational Health for an immunization review, review the Etiquette Guidelines and complete the Etiquette Test which includes affirming that all university and Epic training requirements have been completed. Further information on the Specimen Processing & Storage Facility and the required etiquette testing can be found at [https://tracs.unc.edu/index.php/services/ctrc/ctrc-orientation](https://tracs.unc.edu/index.php/services/ctrc/ctrc-orientation).

2. The Etiquette Test is required to be completed even if there are no current plans to utilize the Specimen Processing & Storage Facilities, Serial Processing or the Special Chemistry Lab.

3. Additional training may be necessary depending on role of the study team member and may include training such as EHS Shipping Training (IATA - [http://ehs.unc.edu/lab/shipping/](http://ehs.unc.edu/lab/shipping/)). Study team members are advised to check with their Principal Investigator or direct supervisor for more information regarding their training needs.

4. All coordinators and research assistants new to the CTRC are required to attend a CTRC New User Orientation prior to utilizing the CTRC Facilities including the lab and processing areas.

5. Study staff will be trained on how to use the tube station (located in room 0120) by CTRC staff on an as needed basis. Study staff is required to seek out assistance from a CTRC staff member prior to using the tube station for the first time.

B. **Responsibilities of Study Staff while Processing**:

1. Study staff is required to have basic knowledge of processing samples which includes the proper use of the centrifuge and freezer/refrigerator. It is expected that study staff will be trained by the Principal Investigator or designee on how to properly use the lab equipment.

2. Study staff is required to review the Eppendorf manual prior to utilizing the equipment. The manual is located in the outpatient Specimen Processing & Storage Facility.

3. Study staff is required to ensure that the centrifuge is properly balanced; the correct size tube holders are used, specimen tubes are placed in an upright position and that caps are tight.

4. Prior to starting the centrifuge, study staff is required to check the centrifuge chamber to ensure that there are no loose items such as caps.
5. Gloves must be used at all times when processing or transferring specimens. Processing of samples must occur behind a face shield.

6. No open-toed shoes and no food/beverages are allowed in the processing labs.

7. All specimen tubes and aliquot tubes must be labeled. Aliquot tubes must be labeled according to Specimen Storage SOP prior to being placed in the freezer.

8. Aliquot tubes or kits should not be set up on the bench hours prior to use and left unattended.

9. Study staff is required to remain with the sample(s) until processing is completed. In the event you must leave centrifugation or any lab process unattended; leave a note with your contact information. Study staff should determine when the spin will end and plan to return at that time. If CTRC or other study staff is not able to determine who “owns” the samples, the samples will be removed from the centrifuge and placed at room temperature next to the centrifuge.

10. Any type of spill and subsequent clean-up will be the responsibility of the lab user. Refer to Environmental, Health and Safety for guidelines and requirements.

11. Mechanical problems with the centrifuge or other CTRC owned equipment should be reported to the Charge Nurse (outpatient CTRC facilities) or Inpatient Nurse (Special Chemistry Lab).

C. Urine or other Biological Samples – for study “kits” and McLendon Lab testing (this does not include tests ordered in Epic requiring blood samples and collected by CTRC Staff that are sent to McLendon Labs for testing):

1. The following information applies to the outpatient unit.
   a. Study staff is responsible for collecting and processing simple urine samples. This includes either sending to McLendon Labs or processing as part of a study “kit.”
      i. The subject should be given a labeled specimen container and plastic bag prior to collecting a sample. The label must be placed horizontally on the specimen cup.
      ii. Instruct the subject to place the collected sample inside the plastic bag and seal it before placing it in the wall cabinet
      iii. Verify the sample removed is for your subject by reviewing the subject information on the label
      iv. If at all possible, remove the sample from the wall cabinet as soon as it is collected
      v. Any sample remaining in the cabinets at the close of the business day will be discarded
   b. Serial timed urine collections for high acuity visits (such as level 3 or 4) will be collected by CTRC Staff and processed as ordered and as detailed on the study provided flow sheet.
c. All other biological samples including stool, sputum, cervical vaginal fluid and semen samples will be collected, processed and sent to McLendon Lab (if applicable) by the study staff.

d. When requesting a point of care (POC) urine pregnancy or a urinalysis dipstick test in the outpatient unit, the study staff must indicate the request on the dry erase board in the Nurse’s Suite. Study staff will indicate whether or not the remainder of the sample should be saved for study purposes or disposed of upon completion of testing. The specimen container is required to have an Epic label with the current CSN number as well as the date, time and initial of the collector. The label must be placed horizontally on the specimen cup so that the barcode can be read by the scanner. The sample should then be placed in the designated location in the Serial Processing room. An order in Epic must be signed before the test will be performed. Refer to the SOP on “Urine Pregnancy” and “Urine Dipstick” testing for more information.

2. On the inpatient unit, urine for an ordered POC urine pregnancy or dipstick test will be collected by nursing staff. Study staff will indicate whether or not the remainder of the sample should be saved for study purposes or disposed of upon completion of testing on the flow sheet. The nursing staff collecting the specimen should ensure the container has the required Epic label with the current CSN number as well as the date, time and initial of the collector. Refer to the SOP on “Urine Pregnancy” and “Urine Dipstick” testing for more information.

D. Serial Processing Room (1039): In the event the Specimen Processing & Storage Facility is occupied, study team members may use this area to process samples. The study team member should request access to use this space from the daily Charge Nurse as indicated on the dry erase board.

E. Point of Care (POC) Processing Lab Room N1035 (Inpatient Processing):
1. This area will be utilized for CTRC approved inpatient studies for the processing of inpatient samples only.
2. Lab jackets are required when utilizing this space.

F. Requesting CTRC Staff to Process Samples (simple processing only):
1. Study staff is required to process samples (inpatient or outpatient) until at least 4 hours post dosing.
2. The study staff will provide detailed written instructions for simple specimen processing performed by CTRC staff. The written instructions will be detailed on the study specific flow sheet. Instructions should include the below information.
   • Tube type(s), amount of specimen to be obtained and the time of collection
   • For PK studies, clearly labeled tubes corresponding to those called for on the study flow sheet and/or orders should be provided for the indicated times for inpatient and outpatient studies
   • Tube order to be drawn, if any (outside of the standard tube draw set by McLendon Labs)
   • Whether tube is to be kept at room temperature, on ice, on wet ice or flash frozen
• Time window for processing, if any
• Whether specimen should ‘sit’ or be processed as soon as sample is obtained
• If specimen is to be placed in the centrifuge as part of processing, the speed, temperature and length of spin must be provided for the specimen(s)
• Instructions as to whether or not hemolyzed specimens need to be re-drawn should be provided. If no instructions are provided, the hemolyzed specimen will be aliquoted and stored.
• The unit to be used for storage (-80, -20 or specimen refrigerator), shelf and container where the specimen is to be stored must be provided and the container in the freezer must be clearly labeled with the study number.
• The amounts of specimen per aliquot tube
• If processing instructions and study staff are not available for guidance, specimens will be processed at a standard 3000 rpms at 4 degrees centigrade for 10 minutes

VI. **Additional Information:**

A. SOP titled “Guidelines for Use of Specimen Storage Facilities in the CTRC”
B. SOP titled “Guidelines for Urine Pregnancy Testing in the CTRC”
C. SOP titled “Guidelines for Urine Dipstick Testing in the CTRC”