Clinical and Translational Research Center **TraCS Institute**	**Approved by:** Director of Nursing
SOP Title and #: Guidelines for Specimen Processing and Use of Centrifuges	**Revisions:** 8/23/2015, 7/26/2016, 7/20/2017, 10/20/2023
Effective Date: 10/1/2009	**Page 1 of 4**

I. **Purpose**: This Standard Operating Procedure (SOP) describes activities and identifies individuals responsible for the handling and processing of specimens and the use of 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, storing, and shipping study samples in the Specimen Processing & Storage Facility (1035) or Serial Processing (1039) areas of the CTRC.

III. **Applicability**: Study and CTRC staff using any centrifuges or lab spaces located in the CTRC outpatient unit.

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

V. **Procedures:**

A. Training:

1. Prior to gaining badge access to the CTRC Facilities, study staff will be required to complete university EHS Training, visit Occupational Health for an immunization review, review the Etiquette Guidelines and complete the CTRC 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.
2. The Etiquette Test is required to be completed even if there are no current plans to utilize the Specimen Processing & Storage Facility or Serial Processing room.
3. Additional training may be necessary depending on the role of study staff and may include training such as Dry Ice Shipping and Shipping Hazardous Materials (https://ehs.unc.edu/training/self-study/?area=laboratory-safety). Study staff are advised to check with their Principal Investigator or direct supervisor for more information regarding their training needs.
4. All study 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 in how to use the tube station (0120) by CTRC staff on an as needed basis. Study staff are required to seek assistance from a CTRC staff member prior to using the tube station for the first time.
6. Study staff are required to have a basic knowledge of processing samples which includes the proper use of a centrifuge, freezer, and refrigerator. It is expected that study staff will be trained by the Principal Investigator or designee on how to properly use the lab equipment.

B. Responsibilities of Study Staff while Processing:

1. Study staff are required to review the Eppendorf manual prior to utilizing the equipment. The manual is located in the cabinet closest to the sink in the Specimen Processing & Storage Facility.
2. Study staff are 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.

3. Prior to starting the centrifuge, study staff are required to check the centrifuge chamber to ensure that there are no loose items such as caps.
4. Gloves must always be worn when processing or transferring specimens. Processing of samples must occur behind a bench top shield.
5. Disposable sleeve covers are provided in the labs and are recommended when processing samples.
6. No open-toed shoes, food or 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 workbench hours prior to intended use and left unattended.
9. Study staff are 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 are 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.

C. McLendon Labs and Blood Specimens

1. Laboratory tests ordered in Epic that require blood specimens to be drawn and collected by CTRC staff are sent directly to McLendon Labs by CTRC staff for resulting in the electronic health record.
2. Blood collection tubes for any laboratory tests ordered in Epic are provided by the CTRC.

D. Urine or Biological Samples other than Blood

1. Study staff are responsible for collecting and processing simple urine samples for non-nursing visits (those not requiring a RN). This includes either sending to McLendon Labs or processing as part of a study "kit."
    a) The subject should be given a labeled specimen container and plastic bag prior to collecting a sample. The label must be placed vertically on the specimen cup.
    b) Instruct the subject to place the collected sample inside the plastic bag and seal bag before placing the sample in the wall cabinet.
    c) Verify the sample removed is for your subject by reviewing the subject information on the label.
    d) If possible, remove the sample from the wall cabinet as soon as it is collected.
    e) Any sample remaining in the cabinets at the close of the business day will be discarded.

2. Serial timed urine collections for nursing visits (those requiring a RN) will be collected by CTRC Staff and processed as ordered and as detailed on the study provided flow sheet.
3. All other biological samples including stool, sputum, cervical vaginal fluid, and semen will be collected, processed and where applicable, will be sent to McLendon Labs by the study staff.
4. 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 (1037).
    a. Study staff will indicate whether the remainder of the sample should be saved for study purposes or disposed of upon completion of testing.
    b. The specimen container is required to have an Epic label with the current visit's CSN number as well as the date, time and initial of the collector.
    c. The label must be placed vertically on the specimen cup so that the barcode can be read by the scanner.
    d. The sample should then be placed in the designated location in the Serial Processing room.
    e. An order in Epic must be signed before the test is performed. Refer to the SOP on "Urine Pregnancy" and "Urine Dipstick" testing for more information.

E. Serial Processing Room (1039):

1. In the event the Specimen Processing & Storage Facility is occupied, study team members may use this area to process samples or when processing taller tubes that cannot be processed using the swing bucket rotors in the Specimen Processing & Storage Facility.
2. Study staff should request access to use this space from the daily Charge Nurse as indicated on the dry erase board.

F. Requesting CTRC Staff to Process Samples for Nursing Visits:

1. Study staff are required to process samples for all non-nursing visits.
2. For nursing visits, study staff are required to process samples for at least 6 hours post dosing.
3. CTRC staff can be requested to perform simple processing of samples only. Complex sample processing must be completed by study staff.
4. Study staff will provide detailed written instructions for specimen processing performed that will be performed by CTRC staff. The written instructions will be listed 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 serial blood draw studies, clearly labeled tubes corresponding to those called for on the study flow sheet and/or orders should be provided for the indicated times
    - 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 bath or flash frozen
- Time window for processing the sample (if applicable)
- If specimen should be allowed to clot or be processed as soon as sample is obtained
- If specimen requires centrifugation, the speed, temperature, and length of spin must be provided for the specimen(s)
- Instructions as to whether hemolyzed specimens need to be re-drawn should be provided. If instructions are not provided, the hemolyzed specimen will be aliquoted and stored.
- The volume of specimen per aliquot tube
- Unit or area to be used for storage (-80 freezer, -20 freezer, specimen refrigerator, at room temperature)
- The shelf, rack and/or container where the specimen is to be stored
- The storage container must be clearly labeled with the study number and contact information
- 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”