

Clinical and Translational Research Center TraCS Institute	Approved by: Medical Director and Director of Nursing
SOP Title and #: Guidelines for Use of Specimen Processing & Storage Facilities in the CTRC	Revisions: 9/1/2010, 9/30/2013, 8/15/2015, 10/20/2023
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- I. **Purpose:** This Standard Operating Procedure (SOP) describes the requirements and procedures needed for the use of the specimen processing & storage facilities located within the Clinical and Translational Research Center (CTRC).
- II. **Scope:** This SOP applies to procedures for requesting, assigning, and utilizing storage space for study samples and supplies in the CTRC.
- III. **Applicability:** The use of the designated CTRC specimen storage space (Specimen Processing & Storage Facility) is for CTRC approved studies only. Study coordinators and/or Principal Investigators (study staff) who are utilizing the CTRC Lab for their studies and would like to store specimens, samples, equipment and/or supplies may do so by selecting the appropriate box in the CTRC Addendum when submitting the protocol to IRB.
- IV. **Responsible Parties:** Study staff are responsible for requesting the use of freezer and/or equipment/supply storage space in the Specimen Processing & Storage Facility. CTRC staff are responsible for arranging badge access for study staff and/or Principal Investigators to the labs and for making sure the freezers are monitored and maintained. However, the integrity of the specimens cannot be assured; all specimens stored at the CTRC are ultimately the responsibility of the PI and/or study staff.
- V. **Procedures:**
 - A. **Specimen Storage Needs:** Freezer and refrigerator space is limited, and samples should be stored on a short-term basis. Every effort will be made to accommodate all specimen storage needs of each study. Study staff will be asked to remove samples in a timely manner if the study has been terminated or closed, samples have been stored longer than two months and space is needed for other study teams. Refer to section “Length of Storage” for additional information.
 - B. **Non-specimen Storage Needs:** The Nurse Director or designee will meet with the study staff to discuss non-specimen storage needs and assign space to store supplies if available. Cabinet, drawer, locker, and shelf space are limited and as such, study staff should only store what is minimally needed. Every effort will be made to accommodate all the needs of the study staff. However, study staff will be asked to remove supplies in a timely manner if the study has been terminated or closed and space is needed for other study teams. Refer to section “Length of Storage” for additional information.
 - C. **Lab Processing Supplies:** The specimen storage facility attendant (CTRC phlebotomist) will ensure the required supplies needed for processing (e.g., pipettes, benchtop shields and biohazard waste receptacles) and are available for study staff.
 - D. **CTRC Specimen Processing & Storage Facility** – is a clinical lab used for processing clinical specimens and is not equipped for hazardous chemical use. Examples of hazardous chemicals include concentrated acids and bases, flammable solvents, carcinogens or highly toxic materials and any chemical that should be used inside a chemical fume hood. Study staff that require hazardous chemicals as part of their study will need approval from UNC-CH’s Department of Environment, Health, and Safety (EHS) prior to using them in the CTRC and if approved, provide a copy of the Safety Data Sheet (SDS). Please visit the EHS website at <http://ehs.unc.edu/> for contact information.
 - E. **Completion of Requirements:** Badge access to the Specimen Processing & Storage Facility will be granted and activated by the Nurse Director after the following requirements have been fulfilled.
 1. All study staff utilizing the labs will be required to complete online UNC-CH EHS training required for their role and complete the CTRC Etiquette Post Test once all requirements

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have been completed. Training requirements for gaining access to the Specimen Processing & Storage Facility as well as how to access the required Etiquette test can be found via the CTRC website at <https://tracs.unc.edu/index.php/services/ctrc/ctrc-orientation>.

- 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.

F. Responsibilities of Study Staff:

- Study staff are required to inform the Nurse Director or designee of any chemicals that will be stored in the Specimen Processing & Storage Facility. In addition to the SDS, the storage container must be labeled including opening date and expiration date as outlined by EHS. Any chemicals placed in containers other than in their original form must be properly labeled with the contents of container.
- Study staff will be required to provide freezer storage boxes and aliquot tubes. All specimens must be placed in a freezer storage box and be properly labeled. Labels for freezer storage boxes are provided by CTRC staff if needed. Sample boxes must be large enough to completely enclose contents, so the lid fits securely. Sample boxes need to include PIs name, study IRB number, coordinator contact name and phone number.
- When placing specimens in the -80 freezer, study staff are required to use the paper log posted on the freezer door and complete all required information. Once samples are removed, a line should be drawn through the entry to indicate the samples have been removed.

G. Length of Storage:

- All -80°C and -20°C freezers and the Specimen Refrigerator located in the labs are for “short term” storage only. Study staff may store samples for up to two months. Study staff are encouraged to find long-term storage or ship samples prior to the end of their allowed two months.
- Study staff may store no more than one week worth of equipment/supplies in the drawers or cabinets of the lab. Stored items are ultimately the responsibility of the PI and/or study staff and the CTRC is not responsible for missing items.
- Storage space will be on a first come, first served basis. All equipment/supplies will be labeled including UNC IRB number and a contact person’s name and phone number.

H. Freezer and Refrigerator Temperature Alarm Ranges: The specimen refrigerator and freezer alarm ranges are listed below. CTRC Staff will be notified if the freezers or the refrigerator are outside of this range and will determine whether specimens will need to be relocated to a backup unit or if the unit needs to be locked to allow the unit to return to normal operating temperatures. In the event the protocol requires samples to be maintained at temperature ranges other than what is listed, alternative freezer storage should be located.

- The -80 alarm ranges are set to alarm at >-65°C (warmer) and <-90°C (colder).
- The -20 alarm ranges are set to alarm at >-10°C (warmer) to <-40°C (colder).
- The Specimen Refrigerator alarm ranges are set at <2°C (colder) to >8°C (warmer).

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- I. **Unauthorized Use:** Any individuals found to be utilizing the labs that are not authorized will be notified and asked to remove their samples immediately. Study staff are prohibited from giving out their access badge to an unauthorized user.
- VI. **Related Documents:**
- A. SOP titled "Guidelines for Specimen Processing and Use of Centrifuges at the CTRC"