I. **Purpose**: This Standard Operating Procedure (SOP) describes activities and identifies individuals responsible for assigning and utilizing the laboratory storage facilities in the Clinical 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 or Special Chemistry Lab) is for CTRC approved studies only. Study coordinators and/or 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 is responsible for requesting the use of freezer and/or equipment/supply storage space in the Specimen Processing & Storage Facility or Special Chemistry Lab. CTRC staff is responsible for arranging badge access for study staff and/or investigators to the labs and for making sure that 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 research coordinator.

V. **Procedures**:

A. **Storage Needs** – The nurse director or designee will meet with the study staff to discuss storage needs if needed. Freezer, cabinet and drawer space is limited and as such study staff should only store what is minimally needed for each visit. Every effort will be made to accommodate all needs of the study staff; however, study staff will be asked to remove supplies/samples in a timely manner if the study has been terminated or closed and space is needed for other study teams.

B. **Supplies** – The specimen storage facility attendant (CTRC phlebotomist) will assure that the required supplies needed for processing (e.g. pipettes, shields and biohazard waste receptacles) and labels for freezer storage boxes are available for study staff and investigators.

C. **The 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. Researchers that require hazardous chemicals as part of their study will need approval from UNC’s Department of Environment, Health and Safety prior to using them in the CTRC Investigators Lab. Please visit the EHS website at [http://ehs.unc.edu/](http://ehs.unc.edu/) for contact information.

D. **Completion of Requirements**: Badge access to the investigator lab will be granted and activated by the Nurse Director after all of the following requirements have been fulfilled.

1. All study staff utilizing the labs will be required to complete the online EHS training and CTRC Etiquette Post Test. Specimen Processing & Storage Facility information and required etiquette testing can be found via website:
   - [https://tracs.unc.edu/index.php/services/ctrc/ctrc-orientation](https://tracs.unc.edu/index.php/services/ctrc/ctrc-orientation)

2. Study staff that will be shipping specimens will also be required to complete the UNC-CH EHS shipping training that follows the IATA regulations prior to lab use. Please visit the EHS website for more information at:
   - [http://ehs.unc.edu/lab/shipping/](http://ehs.unc.edu/lab/shipping/)

E. **Responsibilities of Study Staff**: 


1. Inform the Nurse Director or designee of any chemicals stored in the investigator’s lab. A SDS (Safety Data Sheet) sheet must be supplied and 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.

2. The 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. Sample boxes must be large enough to completely enclose contents so that lid fits securely. Sample boxes need to include PIs name, date, study IRB number, contact name and number.

3. When placing specimens in a freezer, sign in on the log posted on the freezer and complete all required information. Once samples are removed, a line should be drawn through the entry.

F. Length of Storage:
   1. 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 their samples up to two months. Study staff is encouraged to find “long term” storage in advance prior to the end of their allowed two months.

   2. Study staff may store no more than one week worth of equipment/supplies in the drawers or cabinets of the investigator lab. Stored items are ultimately the responsibility of the PI and/or study staff and the CTRC is not responsible for missing items.

   3. Storage space will be on a first come, first serve basis. All equipment/supplies will be labeled including study number (IRB #) and a contact person’s name and number.

G. Freezer and Refrigerator Temperature Alarm Ranges: The freezers and specimen refrigerator temperature alarm ranges are listed below. CTRC Staff will be notified if the freezers are outside of this range. In the event the protocol requires samples to be maintained at temperature ranges other than what is listed, alternative freezer storage should be located.
   1. The -80 alarm ranges are set at -65°C to -90°C.
   2. The -20 alarm ranges are set at -10°C to -40°C.
   3. The Specimen Refrigerator alarm ranges are set at <2°C to >8°C.

H. Unauthorized Use: Any individuals found to be utilizing the investigator lab that are not authorized will be notified and asked to remove their samples immediately. Study staff is prohibited to give 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”