

GENERAL INFORMATION

APPLICABILITY SOP:

This SOP applies to biospecimens collected from research participants and being processed by Clinical Specimen Processing Core (CSPC) Room C6529 by CSPC Staff. This SOP may NOT be used for any other purposes.

CLINICAL SOPs CURRENTLY USED:

CSPC's SOP and policies

Clinical Research Locations (CR-107) – Penn State College of Medicine – Clinical Research

Collection of Specimens for Clinical Research Name (CR-305) – Penn State College of Medicine – Clinical Research

RESEARCH BIOSPECIMEN PROCEDURES

SAMPLE COLLECTION AND PROCUREMENT

COLLECTION/PROCUREMENT

Specimen Handling Person(s): Study team members listed in CATS Safety, Penn State Health clinicians and phlebotomists.

Location(s) where samples will be collected: Inpatient and outpatient clinical spaces. approved research spaces

Collection/Procurement Procedure:

Samples will be collected from participants. Archival tissue samples will be procured from Pathology per study protocol.

Samples will be taken from participants at outpatient clinics, phlebotomy draw locations, inpatient locations, infusion rooms, procedural area and/or clinical spaces. A study staff member will collect the specimen from the corresponding collection location when needed and deliver the sample to the CSPC for further processing.

TRANSPORT

RESEARCH SAMPLE PACKAGING FOR TRANSPORT

Specimen Handling Person(s): Study team members listed in CATS Safety

Packaging:

CR-305b: Biosafety Clinical Research Specimen SOP for Central Labs - CSPC

Samples will be placed in a specimen biohazard bag and transported in a secondary container. Samples will be accompanied by our local requisition form as well as the central lab's requisition form.

RESEARCH SAMPLE TRANSPORT

Specimen Handling Person(s): Study team members listed in CATS Safety and CSPC staff.

Transport Method:

Samples will be placed in a specimen biohazard bag and transported in a secondary shatterproof container (e.g., a tube inside a Tupperware container or Ziploc bag). No gloves will be worn in the hallway. Gloves are not worn in public areas during transport. Specimens will be transported via service/freight elevator and/or stairwell. Specimens will not be transported in patient elevators.

USE AND STORAGE OF MATERIALS: Research Laboratory Information

STORAGE OF MATERIALS:

Laboratory Room Number / Freezer Location(s): CSPC, Room C6529

PI Name(s) for space(s): CSPC's medical director listed in CATS Safety

Specimen Handling Person(s): CSPC staff

Freezer Monitoring: Samples will be monitored as per the CSPC's policies and SOPs.

Storage Duration: Duration of storage is short term and specimens will be shipped within the sponsor's specifications outlined in the lab manual approximately 24 hours from collection.

MANIPULATION OF MATERIALS:

Laboratory Room Number(s): CSPC, Room C6529

PI Name(s) for space(s): CSPC's medical director listed in CATS Safety

Specimen Handling Person(s): CSPC staff

Description of manipulation (include equipment and safety precautions [including PPE]):

Samples will be manipulated as per testing requirements, and in accordance with CSPC's policies and SOPs.

Samples will undergo centrifugation and aliquoted as per testing requirements. CSPC staff will wear appropriate PPE as per their lab SOP when manipulating the samples.

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RESEARCH MATERIAL SPILL AND EXPOSURE INFORMATION

Specimen Handling Person(s): CSPC staff

Accidental Spill and Exposure Procedure:

Spills and Exposures Occurring in CSPC

CSPC staff will follow their lab SOPs for spills and exposures.

Spills and Exposures Occurring Prior to Biospecimen Reaching CSPC

- Cover spill with a paper towel and saturate with germicidal cleaner.
- Allow solution to soak into the contaminated material.
- Work from the outside edges of the spill inward when applying the bleach solution.
- Only mechanical means, such as a brush and dustpan, tongs or forceps are allowed to be used to pick up glass, needles or other sharp objects that may puncture the skin.
- Wipe up bleached material with paper towels or blue absorbent pads.
- Decontaminate with the bleach solution all reusable tools or protective equipment used in the clean-up.
- Anything that cannot be effectively cleaned must be disposed of as waste.
- After the contamination area has been cleaned, use fresh water to remove bleach residue from all surfaces.
- Place bleached material, gloves and other disposable materials into a double bagged red biohazard trash container located in the lab.
- If you believe you were exposed to biohazard material that has not been decontaminated with bleach solution, follow these recommended steps:
 - Skin exposure – Vigorously wash affected skin with plenty of soap and water while removing contaminated clothing and shoes.
 - Eye exposure – wash eyes for at least 15 minutes with copious amounts of water, listing the upper and lower eyelids occasionally.
 - Seek follow-up medical attention by contacting your supervisor, employee health and the biosafety officer.

SHIPMENT OF MATERIALS

Will materials be transferred between institutions/locations: ☒ Yes

☐ No (*subsection complete*)

Specimen Handling Person(s): CSPC staff

Shipment Method: All shipping supplies will be provided by the central lab and shipped using a courier contracted by the study's sponsor.

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Shipping materials are provided by the sponsor for this study. The samples will be placed within a dry ice shipment container for delivery. Shipment materials will include serum, plasma, whole blood, and archival tissue.

MATERIALS AND WASTE DISPOSAL

Specimen Handling Person(s): CSPC staff

Describe disposal of materials after study has completed:

Materials will be disposed of in accordance with CSPC SOPs.

ADDITIONAL INFORMATION

Any other information that was not covered above:

No samples or portions of samples will be manipulated or stored outside of CSPC or by CSPC.

Revision History

Date Revised	Changes Made
July 2024	New