

**GENERAL INFORMATION****APPLICABILITY SOP:**

This SOP applies to biospecimens collected from research participants and processed by a Penn State Health (PSH) facility's clinical lab, or a reference lab contracted by a PSH facility. Results will be entered into the electronic medical record. This SOP may NOT be used for any other purposes.

**CLINICAL SOPs CURRENTLY USED:**

PSH facility's clinical lab 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 at outpatient clinics, phlebotomy draw locations, inpatient locations, infusion rooms, procedural area and/or clinical spaces. Samples undergoing local evaluation will be immediately taken/sent to the PSH facility's clinical lab for processing and resulting. Samples undergoing evaluation by a contracted reference labs will be immediately taken/sent to the PSH facility's clinical lab for processing and shipping to reference lab for evaluation. Biopsy tissue will be obtained by the individual performing the procedure.

**TRANSPORT****RESEARCH SAMPLE PACKAGING FOR TRANSPORT**

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

Packaging:

## **CR-305a: Biosafety Clinical Research Specimen SOP for Local Labs**

Samples will be placed in a specimen biohazard bag and transported in a secondary container. Samples will be accompanied by a local requisition form.

### **RESEARCH SAMPLE TRANSPORT**

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

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 or pneumatic tube system.

### **USE AND STORAGE OF MATERIALS: Research Laboratory Information**

*List all locations where unfixed human materials will be stored, manipulated, etc.:*

#### **STORAGE OF MATERIALS:**

Laboratory Room Number / Freezer Location(s): PSH facility's clinical lab

PI Name(s) for space(s): PSH facility's clinical lab's medical director

Specimen Handling Person(s): PSH facility's clinical lab staff

Freezer Monitoring:

Samples will be monitored as per the PSH facility's clinical lab's policies and SOPs.

Storage Duration:

Not applicable as specimens are used for diagnostic purposes and disposed of as per PSH facility's clinical lab policy.

#### **MANIPULATION OF MATERIALS:**

Laboratory Room Number(s): PSH facility's clinical lab

PI Name(s) for space(s): PSH facility's clinical lab's medical director

Specimen Handling Person(s): PSH facility's clinical lab staff

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

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

### **RESEARCH MATERIAL SPILL AND EXPOSURE INFORMATION**

Specimen Handling Person(s): PSH facility's clinical lab staff

Accidental Spill and Exposure Procedure:

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### Spills and Exposures Occurring in the Clinical Lab

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

### Spills and Exposures Occurring Prior to Biospecimen Reaching the Clinical Lab

- 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): PSH facility's clinical lab staff

Shipment Method:

If samples are undergoing evaluation by a contracted reference lab, samples will be shipped by PSH facility's clinical lab staff as per the contract with the reference lab.

## MATERIALS AND WASTE DISPOSAL

Specimen Handling Person(s): PSH facility's clinical lab staff

Describe disposal of materials after study has completed:

Materials will be disposed of in accordance with PSH facility's clinical lab SOPs.

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### ADDITIONAL INFORMATION

Any other information that was not covered above:

No samples or portions of samples will be manipulated or stored outside a PSH facility's clinical lab.

### **Revision History**

<b>Date Revised</b>	<b>Changes Made</b>
July 2024	New