Collection of Specimens for Clinical Research	CR-305
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

X	Principal Investigator	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates		Financial Analyst/Contract Management Accountants
X	Data Specialist		Central Research Office Personnel

This standard operating procedure (SOP) describes the necessary steps for fulfilling the regulatory and clinical requirements involved in specimen collection and handling. The proper collection and processing of specimens obtained from study participants are part of the data collected in a clinical trial. The specimens provide important information about the drug's interaction within the participant along with the participants biologic and clinical response. To ensure accurate data, specimens must be collected at specified time points indicated in the study protocol, processed, possibly stored, and shipped appropriately. Research and ancillary staff must be properly trained and certified to adhere to good laboratory practices when collecting, processing, and shipping of specimens.

This SOP may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. All research conducted at Penn State College of Medicine and Penn State Health that involves the collection and processing of specimens obtained from study participants must be submitted, reviewed, and approved in accordance with Penn State Policy: ***Use of Regulated and Biohazardous Materials in Research and Instruction (PR-11)***.
    a. SOPs are required as part of this process. The College of Medicine Clinical Trials Office (CTO) will maintain a curated collection of SOPs that can be used by study teams to as part of their submission to the Institution Biosafety Committee (IBC). If adopted by the PI and study team, they:
        i. are responsible for training on the applicable SOPs;
        ii. must adhere to the applicable SOPs;
        iii. may not modify the SOPs; and
        iv. must create SOPs for work not covered by the curated SOPs.
    b. The SOPs curated for use by the study team do not require review and approval of the Associate Dean of Clinical Research or Associate Dean of Research. These SOPs can be administratively approved by the CTO Director after review by clinical members of the IBC.
    c. The SOPs curated for use by the study team may be shared with Sponsors and/or CROs upon request.

2. Training and Certification
    a. Prior to collecting specimen from research participants, the following training must be completed:
        i. CITI Annual Biosafety Training
        ii. CITI OSHA Bloodborne Pathogens Training
        iii. Biological Materials Shipping and Dry Ice Training (IATA) if shipping own samples.
    b. Training must be renewed prior to expiration indicated on the training certificate.

3. Collecting the specimens
    a. Observing appropriate precautions based upon OSHA guidelines, infection control manual, and/or the institutional procedure manual for the handling of bodily fluids, collect the appropriate specimens identified in the study protocol.
    b. In the participant's source documentation, note the date and time of the collection as well as any relevant information pertaining to the participant's status at the time of the procedure, or place a copy of the collection form (if applicable) in the source
    c. Confirm participants name and date of birth
    d. Label the tubes or other containers with participant identifiers, date, time, and any other information required.

4. Processing the specimens
    a. Process the specimen according to the specifics defined in the protocol and/or central lab manual.
    b. Label the study-specific test tubes or other transport containers with the participant's ID number identifiers, date, time, and any other information required to prepare for storage or shipment.
    c. Complete the laboratory requisition slip. Include one copy with the specimens when shipped, retain one copy and file it with the other study-related participant records.

5. Preparing the specimens for shipping to the testing laboratory
    a. Label the study-specific transport containers per the lab manual.

    b. Prepare and package the specimens according to the shipping instructions specified in the protocol and/or central laboratory procedure manual.
    c. Complete a specimen shipping log
    d. Retain a copy of the shipping receipt and file with the other study-related participant records.

6. Central and Core Facilities and Service
    a. If utilizing the CSPC, specimens will be processed and shipped per CSPC procedures and SOPs. CSPC will use the central lab manual for guidance on shipping.
    b. If utilizing a Penn State Health (PSH) facility's clinical lab, specimens will be processed per the PSH facility's procedures and SOPs.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Bloodborne pathogens (29 CFR 910.1030)

International Conference on Harmonization Good Clinical Practice E6(R2)

Penn State Policy: Use of Regulated and Biohazardous Materials in Research and Instruction (PR-11)

Clinical Research Specimen Core website https://research.med.psu.edu/core-facilities/clinical-research-biospecimen-core/

CR-305a - Biosafety Clinical Research Specimen SOP – for use by PIs and study team for Local Labs being processed by a Penn State Health clinical lab.

CR-305b - Biosafety Clinical Research Specimen SOP – for use by PIs and study team for Central Labs being processed by the Clinical Specimen Processing Core.

APPROVALS

Approved:	Kevin Gardner, Jr., MS, BSN, RN, CCRC Director, College of Medicine Clinical Trials Office Adam McDowell, BA, JD, CRA Director, Office of Research Affairs, Contracts Thomas Brydebell Director, Office of Research Affairs, Grants Ray Scheetz MS, RBP (ABSA) Director, Research Quality Assurance, Biosafety & Lab Safety Compliance Institutional Biosafety Officer Elizabeth Galgocy, MEd, RN, CIP Director, Research Quality Assurance, Human Research Trials
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CONTENT REVIEWERS AND CONTRIBUTORS

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Institutional Biosafety Officer

HISTORY OF REVIEWS AND REVISIONS

July 2024	
Scope and Purpose	Entities removed as all research at Penn State Health facilities are required to follow the policies and SOPs of College of Medicine Updated "Financial Analyst/**Contract Management Accountants**", but unselected this category it is not relevant to this group. Added "Regulatory Specialists" and "Central Research Office Personnel." Notation made that this SOP may be shared with Sponsors and/or CROs upon request.
Policy and Procedure Statements	Subsection "Collecting, filing and storing study-related documents and records" renamed to "General standards." Subsection "Electronic" renamed to include "maintenance of files." Subsection "Sponsor/CRO-provided electronic Trial Management File (eTMF)" added.
Approvals	"Authorized" and "Approved" switched to align with CR-101. Added College of Medicine Institutional Biosafety Officer as an approver.
History of Reviews and Revisions	Section added.