Human Biological Specimen Collection, Handling, and Shipping

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-CO-570.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure establishes the VCU/VCUHealth standards and procedures for the collection, receipt, storage, or use of human biological specimen(s), and materials originating from participants enrolled in a clinical research study conducted at a VCU/VCU Health facility, affiliate, or participating site.

2. REQUIREMENTS

During the course of a research study, biological specimen(s) and materials may be collected or received for diagnostic, therapeutic, experimental, or storage purposes. Collection, receipt, storage, and/or use of biological specimen(s) must adhere to all applicable federal, state, VCU, and VCU Health policies and regulations. To adequately ensure accurate data and specimen integrity, human biological specimens and materials must be collected, processed, stored, and shipped (as necessary) according to the IRB-approved protocol.

VCU and VCU Health staff receiving or preparing shipments of human biological specimens and materials must obtain training and be certified in the transport of infectious substance specimens according to VCU Occupational Health and Safety policies and applicable portions of 49 CFR 172 Subpart H. Transportation couriers and shipping vendors must comply with relevant transportation and appropriate labeling, marking, and packing regulations for human biological specimen(s) and materials.

All research involving the collection, receipt, storage, or use of human biological specimen(s) and material(s) must be reviewed and approved by an Institutional Review Board (IRB) and any other applicable oversight committees prior to the initiation of any research activity.

3. DEFINITIONS

Human Biological Specimen- Any material of human origin, which may include, but is not limited to: blood, tissue, organs, urine, saliva, or any other cells or fluids.

Human Research Repository- An organized collection of retrievable human biological specimen(s)/ material(s) that is intentionally stored and maintained for use as a prospective instrument in the conduct of clinical research.

Residual/Remnant Human Biological Specimen- A residual or remnant specimen is excess tissue, blood, fluid, or medical waste collected during a standard of care procedure that is not required for diagnostic or treatment purposes.

4. PROCESS

Prior to initiating research-specific specimen collection, handling, and/or shipping, the investigator(s) and research staff should be familiar with and comply with VCU/VCU Health policies:

- VCU Employee and Facility Use Guidelines for Clinical Research
- VCU Health Policy – Specimen Collection, Labeling and Handling
- VCU Health Policy – Tissue Tracking, Storage and Documentation

All research activities involving the collection, receipt, storage, or use of biological specimen(s), and materials must adhere to the following procedures:

A. The following training is required for those processing/handling research specimens in a VCU Health space:

- * Bloodborne Pathogen Exposure and Infection Control Plan (Workday module)
- Cryogenics Safety (Workday module)
- Review VCU Health System Department of Pathology Safety Manual (via VCU Health Policy Manager)
- * Complete BioRaft Dangerous Goods Shipping
- * CITI training (Basic/Refresher Human Subjects Protection for Biomedical Research + Good Clinical Practice for Clinical Investigations of Drugs and Devices)

Note: An asterisk (*) indicates training that overlaps with VCU's suggested training.

B. Biological Sample Collection and Handling

- Methods for collecting and handling of specimens must comply with all federal, state, VCU, and VCU Health policies and procedures.

- All delegated study personnel involved in the collection and/or handling of specimens must observe the appropriate precautions based on VCU Occupational Health and Safety guidelines and VCU/VCU Health policies for the handling of bodily fluids and the collection of the appropriate biological specimen(s) identified in the research study protocol.

- Collection of all human biological specimens and materials is performed according to the approved IRB (as applicable) research study protocol while observing appropriate precautions and training.

- Written informed consent and authorization of Protected Health Information (PHI) must be obtained from the research participant before collection of a biological specimen for research purposes.

- All delegated study personnel collections and labeling of human biological specimen(s) and material(s) should be in accordance with study procedure (e.g, Manual of procedures (MOP), lab manual, etc.).

- The date and time of the collection of any retained biological specimen(s), and material(s), as well as any relevant information pertaining to the participant's status at the time of the collection(s) should be promptly documented and retained in the participant-related research records or a biological specimen log. This documentation will collectively comprise the biological specimen accountability record for the study.

- The specimen(s) and material(s) will be processed according to the requirements defined in the clinical research study protocol and any study-specific laboratory order processes (e.g., centrifuge speed, duration, temperature requirements). All laboratory order process(es), information, and procedures should be established between the research team and the laboratory prior to initiation of the study. If the specimens(s) will be transported to the VCUH clinical laboratory, it is essential that the specimen(s) are transported in a timely manner to ensure the laboratory has sufficient time to process the samples within the time specifications indicated by the study protocol.

C. Storage, Shipping, and Receiving of Human Biological Specimen(s) and Material(s)

- Methods and processes for storing, shipping, and receiving of human biological specimen(s) and material(s) must comply with all federal, state, and VCU/VCU Health policies.

- All human biological specimen(s) and materials are to be stored in a secure location with limited access and comply with the clinical research study protocol requirements and sponsor-provided instructions. Access to physical locations used to store identifiable human biological specimen(s) must be recorded and tracked. (e.g., through electronic card swipe, or a sign-in/sign-out procedure)

- Storage of biological specimen(s) will occur at a VCU/VCU Health facility or IRB and sponsor-approved participating site. Exceptions to this requirement must be approved by the IRB.

- The IRB must review any plan to transfer stored human biological specimens and material(s) to an outside collaborator(s) for research.

    - Specimens and materials must be coded prior to transfer. Any exception to this procedure must be approved by the IRB.

    - Any form of biological specimen(s) or material(s) transferred/shipped to outside collaborator(s) must be accompanied by a detailed manifest, inventory, and/or requisition, a copy of which should be filed in the clinical study regulatory binder.

    - A Material Transfer Agreement (MTA) between VCU and outside collaborator(s) must be in place prior to the transfer of stored biological specimen(s), or material(s) to an outside collaborator(s) for research.

- Only designated research personnel trained in the handling of human biological specimens per VCU/VCU Health policies and all applicable regulatory requirements may receive human biological specimen(s), and material(s).

- Upon receipt of biological specimen(s), and material(s), the PI or their designee must conduct an inventory of the shipment to ensure that the information on the packing slips matches what has been sent to the site (as well as the expected shipment amounts). If any discrepancies are identified, the PI or their designee should immediately notify the sender. Documentation of the inventory should be filed in the regulatory binder.

- If the sender includes a form in the shipment to acknowledge receipt, obtain the appropriate signature, and submit the form back to the sender. A copy of the receipt should be filed in the regulatory binder.

- After the inventory has been reviewed and acknowledgement of receipt has been made, the biological specimen(s) and material(s) should be properly labeled and then delivered to the appropriate laboratory department for secure storage.

D. Close-out

- Human biological specimen(s), and material(s) accountability records must be maintained according to VCU/ VCU Health Standard Operating Procedures CR-CO-555: Record Retention.

- At study close out, all remaining biological specimen(s) and materials must be retained or destroyed in accordance with the IRB approved research study and federal regulations. For biological specimen(s) and material(s) to be returned to a sponsor, adherence and compliance to the instructions provided by the sponsor and IRB must be met. Documentation of the storage, destruction, or return of the biological specimen(s) should be filed in the study master file or investigator site file.

5. REFERENCES

A. US Code of Federal Regulations

- 21 CFR Part 312: Investigational New Drug Application
  - 312.62 – Investigator Recordkeeping and Record Retention
- 49 CFR Part 172: Transportation – Hazardous Materials Table
  - Subpart H – Training

B. Good Clinical Practice

- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)

C. VCU Health Policies

- Specimen Collection, Labeling and Handling
- Tissue Tracking, Storage and Documentation

D. VCU HRPP Policies and Guidance; HRPP Toolkit

- HRP-103 Investigator Manual
- HRP-502 Template Consent Document
- HRP-503a Template SBS Protocol
- HRP-503 Template Protocol
- HRP-503 Template Site Supplement

F. VCU

- VCU Occupational Health and Safety trainings
- VCU Employee and Facility Use Guidelines for Clinical Research
- VCU Division of Sponsored Programs - Pre-Proposal; Confidentiality (non-disclosure), material transfer and data use agreements
- VCU/ VCU Health Standard Operating Procedures
  - CR-CO-555: Record Retention

Review/Revision History CR-CO-570		
Version No.	**Effective Date**	**Description**
CR-CO-570.3	08/04/2025	● Clarified roles, labeling, and documentation for specimen accountability ● Updated procedures for storage, shipping, and transfer, including MTA and IRB requirements ● Updated training requirements to include VCU Occupational Health and Safety and 49 CFR 172 Subpart H ● Updated guidance on coded specimen transfer and IRB oversight ● Aligned with ICH E6(R3) ● Aligned with HRPP Toolkit ● Updated references ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-570.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-570.1	06-01-2018	● Original