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1. Overview

The purpose of this document is to describe the process for research sample management including transport, processing, storage, shipping, and review. When applicable, the sponsor-provided study protocol or laboratory manual will specify sample management procedures. If conducting an investigator-initiated study, the PI must thoroughly outline the sample management procedures, including sample collection, processing, storage, disposal, and shipping requirements.

This procedure applies to all investigators and research team members conducting research under the auspices of Drexel University.

2. Definitions

Category A Infectious Substance: an infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs (e.g., Ebola, Bacillus anthracis, Variola virus).

Category B Infectious Substance: An infectious substance not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs (e.g., Influenza virus, Hepatitis A, B, C viruses, SARS-CoV-2).

Time of Sample Collection: the actual clock time when the sample collection is completed.

3. Sample Collection

The approved study protocol or accompanying documents, e.g., laboratory manual, must be followed for sample collection procedures and parameters.

Individuals collecting samples must:

- Confirm positive participant identification prior to collecting any sample
- Wear gloves and other appropriate personal protective equipment (PPE) for all sample collection procedures
- Record the date, time of sample collection, and collector's initials
- Label samples immediately after collection

3.1 Sample Disposal

Notify the study sponsor for disposal of any remaining or leftover samples and dispose of samples as per protocol or Institutional policy. Document the disposal of the samples as required by sponsor or regulations.

4. Sample Processing

Sample processing, centrifugation and tube preparation must be completed as specified by the protocol, laboratory manual, or institutional policies. All processing steps must be documented in source records.

5. Sample Storage

Samples must be stored as specified by protocol, laboratory manual, or institutional policies. Samples must be stored under the protocol-specified temperature and environmental conditions. Temperature logs must be maintained when required. Storage access must be restricted to authorized personnel. The storage location and other requirements, e.g., back-up power systems, should be documented when required by sponsor or study procedures.

6. Sample Transport and Shipping

Universal precautions must be adhered to during preparation of samples. All samples should be labeled as biohazardous before transport and any remaining samples should be disposed of in an appropriate biohazard container. All tubes containing samples must be capped tightly and thoroughly checked.

Anyone packaging, handling, shipping or transporting biological materials must receive training in the general requirements of handling biological materials as well as function-specific training for the specific task(s) performed. The Drexel University Department of Environmental Health & Radiation Safety (EHRS) provides online training for shipping patient specimens. Laboratory personnel shipping Category A and/or B infectious substances must receive additional training. Training is required before performing any tasks associated with shipping biological materials. Most shipping companies provide shipping training for Category A and/or B infectious substances. The DOT provides free training at http://dothazmat.vividlms.com. Training documentation must be maintained for all personnel involved in the packing and shipment of any samples.

Participant specimens for which there is minimal likelihood that pathogens are present must be packaged in the following manner:

- Leak proof primary receptacle
- Leak proof secondary packaging
- Outer packaging of adequate strength for its capacity, mass, and intended use.
- Outer package with at least one surface having minimum dimensions of 100mm x 100mm.
- For liquids: Absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging.
- When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact.
- The outer container of the patient specimen shipment must include the following statement: “Exempt Human Specimen”

All individuals participating in sample shipment are required to take institutional EHRS training for biohazard shipping. A shipper includes someone who does any of the following:

- Marking and labelling packages
- Filling packages
- Accepting packages for shipment
- Supervising the shipping activities
- Preparing shipping documentation

- Loading trucks

Individuals participating in sample shipment must:

- Confirm shipping requirements per protocol.
- Use sponsor-provided packaging when available; otherwise order appropriate approved packaging for shipments.
- Create a shipping manifest for inclusion with samples.
- Package samples according to Drexel University standards, and/or protocol instructions.
- Ship as specified by protocol or institutional policies, using approved carriers and methods.
- Retain shipment documentation in study records.

See Drexel University Laboratory Safety Manual.

7. Documentation

The following must be documented where applicable:

- Collection date and time
- Processing details
- Storage conditions
- Shipping records and manifests
- Disposal documentation
- Deviations from protocol

8. Review of Diagnostic Laboratory Testing

Diagnostic research laboratory test results returned to the study team must be reviewed by the study PI or delegated co-investigator. The review should be documented by the investigator noting which results are clinically significant (CS) or not clinically significant (NCS) and include the investigator's signature. At a minimum, all abnormal lab values should have documented review by the investigator. Any clinically significant laboratory results should be documented as an adverse event, regardless of if the event is deemed related to the study.

If laboratory results indicate a medical need for follow-up outside of the research team, the participant should be referred to their primary care physician or other appropriate specialist for follow-up on the significant lab results.

9. Responsibilities

9.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, training, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

9.2 Principal Investigator

The PI retains overall responsibility for the study and following the protocol and institutional requirements for sample management and review as outlined in this guidance document, including performing or overseeing sample collection, ensuring correct labeling, processing, storage, shipping and disposal. The PI may document delegated responsibility for these procedures to appropriate qualified individuals under the oversight of the PI.

10. Resources

- ICH E6 R2 Guidance for Industry Good Clinical Practice
- ICH E6 R3 Guidance for Industry Good Clinical Practice
- Drexel University Laboratory Safety Manual
- U.S. DOT Transporting Infectious Substances Overview

11. Revision and Workgroup Members

11.1 Revision

Version 001/Effective Date 05/21/2026: Original Document – Sample Management Guidelines

11.2 Workgroup Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup Members:

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