STANDARD OPERATING PROCEDURE FOR
SPECIMEN HANDLING

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1. INTRODUCTION & PURPOSE

The proper management of human biological samples for laboratory testing and analysis is essential to assure the quality and integrity of data collected in clinical trials, as well as to protect the safety of all those who handle the samples.

2. SCOPE

This standard operating procedure (SOP) describes the procedures related to biological sample management, including the collection, processing, storage and handling.

3. APPLICABLE REGULATIONS AND GUIDELINES

Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials
FDA Code of Federal Regulations, Title 21
International Conference on Harmonisation; Good Clinical Practice: Consolidated Guidelines
Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans
University of Western Ontario Biosafety Guidelines and Procedures Manual

4. REFERENCES TO OTHER APPLICABLE SOPs

All SOPs are cross-referenced to this SOP.
The SOPs for the Phlebotomy Room are applicable to this SOP

5. ATTACHMENTS

There are no attachments to this SOP.

6. RESPONSIBILITY

This SOP applies to all clinical personnel involved in collecting, processing, storing or handling biological specimens.

7. DEFINITIONS

The following definitions apply to this SOP:
Source Documents: Original documents, data and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, subject’s diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Universal Body Substance Precautions (BSP): A system that consistently interrupts the transmission of infections thus ensuring increased protection for both patients and health care providers.

8. PROCESS OVERVIEW

A. Biological sample management
B. Collecting biological samples
C. Processing and storing biological samples
D. Preparing samples for shipment

9. PROCEDURES

A. Biological Sample Management

1. Obtain all of the sample management details from the sponsor or central laboratory if not described in the protocol, including:
   a. Laboratory contact information (for central laboratories)
   b. Requirements for specimen collection, labelling, processing and storage
   c. Supplies
   d. Packaging and shipping specifications
2. The sponsor should provide detailed instructions for sample management prior to study activation. All supplies should be available prior to study activation.
3. Equipment such as centrifuges, storage refrigerators/freezers and thermometers should be calibrated and checked on a regular maintenance schedule. Service/maintenance logs should be available and updated as equipment is checked.

B. Collecting biological samples

1. Ensure that proper informed consent has been obtained from the study participants prior to specimen collection.
2. Obtain and prepare the necessary equipment and supplies for sample collection, paying close attention to collection tube colour and type.
3. Add the appropriate labels to the collection containers.
4. Prepare any required laboratory requisitions.
5. Using universal body substance precautions (BSP), collect samples according to the protocol instructions. Ensure that the appropriate specimens identified in the study protocol are collected.
6. For time-sensitive samples, ensure that the clocks used to record the drug administration time and sample collection times are synchronized.
7. Record the date and collection time in the participant’s source documents and on the laboratory requisition as required. Ensure that a copy of the completed laboratory requisition is maintained with the participants source documents.
8. Prepare samples for immediate processing as instructed in the protocol.

C. Processing and Storing Biological Samples

1. For those samples not sent immediately to the laboratory for analysis, prepare the necessary equipment and supplies for sample processing.
2. Ensure that the appropriate specimen handling area is used as indicated.
3. Label all storage containers.
4. Process the samples according to the protocol instructions.
5. For centrifuged samples, harvest the required specimen and transfer to the appropriate storage container.
6. Dispose of any unused specimens, or specimen waste, using proper disposal methods.
   a. Refer to the Phlebotomy Room SOPs and the UWO Biosafety Guidelines for information regarding proper disposal methods.
7. Record any additional information not already pre-printed on the label.
8. Store the sample in a dedicated area under the required storage conditions and temperatures.
9. Refrigerator and freezer temperatures should be monitored using calibrated devices and recorded on a regular basis to ensure the temperatures remain within the ranges allowed in the protocol.
10. It is recommended that uninterrupted power supplies be available for refrigerators and freezers used for storage of biological samples.

D. Preparing Samples for Shipment

1. Confirm the appropriate method of transportation of samples from the site to the laboratory with the sponsor.
2. Determine if any special forms, permits or custom processes are required for shipment of samples.
   a. Refer to the Phlebotomy Room SOPs for information on customs requirements for sending biological samples out of the country.
3. Determine the proper timing for sample shipments and the anticipated turnaround time for results, if applicable.
   a. Ensure that the lab will be open to receive samples on the anticipated delivery date to prevent spoilage.
4. Review the sample packaging requirements and package the sample(s) as indicated in the protocol or central laboratory manual. The sponsor should supply a checklist with specific packaging and transportation instruction, which should include the following information:
   a. How the samples should be packaged for transport
   b. How the samples should be contained
   c. How the samples should be labelled
   d. Instructions for transportation of the samples
   e. Instructions for storage conditions of the samples including temperature and stability requirements
   f. Shipping documents and how to complete correct information
   g. Proper labelling of the samples (e.g. type of class)
   h. Proper safety mark for the samples
   i. Number of samples that can be shipped at one time
   j. Contact numbers and names of personnel to be notified of transport

5. If dry ice is needed, review the proper technique for handling dry ice.
6. Complete the appropriate documentation
7. Maintain the required storage temperature while waiting for pickup.
8. Retain a copy of the shipping receipt (or courier waybill) and commercial invoice and file in the investigator study files with copies to the sponsor as required.