





## 1. Purpose

The objective of this operating procedure is to describe the management of biological samples used in the context of a clinical trial.

## 2. Responsibilities

**CERU:** CERU is responsible for providing participating research sites with adequate training to fulfill protocol related responsibilities and ICH GCP requirements.

**Research Site:** The research site is responsible for participating in protocol specific training and executing tasks related to biological samples in compliance with the study protocol, local requirements and ICH GCP.

## 3. Definitions

3.1 Biological Sample: Refers to blood and its components, cells, tissues and organs.

3.2 Management of Biological Samples: Refers to all activities related to the collection, storage, analysis and destruction of biological samples.

## 4. Procedures

4.1 CERU should manage biological samples used in the context of a clinical trial.

4.2 Using the study protocol, CERU, or a delegated laboratory, should generate study specific laboratory procedures outlining all activities related with the collection, storage, analysis and destruction of biological samples. Procedures should include, but are not limited to:

- 4.2.1 Responsibilities (research site, methods centre and delegated laboratory)
- 4.2.2 Biological sample collection schedule
- 4.2.3 Biosafety
- 4.2.4 Collection supplies and equipment
- 4.2.5 Collection techniques
- 4.2.6 Labeling, packaging, storage and shipment
- 4.2.7 Processing and analysis
- 4.2.8 Equipment maintenance and calibration
- 4.2.9 Documentation

4.3 The Informed Consent Form should outline the collection of all biological samples required for the study, including any risks or discomforts associated with the procedures. Refer to SOP 204: Development and Administration of Informed Consent.



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4.4 CERU, or a delegated laboratory, is responsible for ensuring all research site personnel delegated tasks related to the management of biological samples is qualified and appropriately trained to conduct their duties. Refer to SOP 201: Delegation of Authority.

### Biological Sample Collection

4.5 The qualified investigator (QI), or delegate, is responsible for ensuring the safety and well-being of study participants is maintained during the collection of biological samples.

4.6 All samples should be labeled with the protocol number, participant ID and the date and time of sample collection.

4.7 The QI, or delegate, should maintain documentation associated with biological samples (e.g. results). Refer to SOP 208: Study Files and Regulatory Documentation.

### Biological Sample Storage and Shipping

4.8 CERU should ensure the QI (and affiliated institution) have a secure and suitable environment for storage of biological samples.

4.9 CERU, or delegated laboratory, should provide instruction regarding sample storage conditions and stability. Storage conditions should be checked regularly. The checks should be documented and filed with the study regulatory files.

4.10 Procedures should be in place concerning backup systems in the event of power failures.

4.11 CERU, or delegated laboratory, should provide research sites with appropriate shipping materials and procedures, including labels, documentation and stability information. All shipping records should be maintained in the study regulatory files.

### Biological Sample Analysis

4.12 Procedures should clearly outline whether samples will be analyzed at the research site local laboratory or at a central laboratory. As well as whether the samples will be analyzed prospectively or at the end of the study.

4.13 Records should be filed in the study regulatory files concerning laboratory reference ranges and accreditation.

4.14 The MC should be informed of any changes to analysis procedures, including but not limited to, reference range changes, changes in calibration of equipment or materials used to analyze samples.

### Data Transfer

4.15 In situations when data is entered into a clinical database at the central lab, procedures should be in place to document transfer of data, including timing and data formats, to CERU for incorporation into the study database.



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4.16 Procedures should be in place to outline the process of merging central lab data with the study database at the coordinating centre.

### Biological Sample Destruction

4.17 Destruction of biological samples should be conducted only under the direction of CERU, or a delegated laboratory.

4.18 The QI, or delegate, at the research site should ensure that destruction records are filed with study regulatory documentation.

## **5. References**

5.1 ICH GCP Section 8.0: Essential Documents for the Conduct of a Clinical Trial

5.2 Health Canada Division 5 Food and Drug Regulations: Drugs for Clinical Trials Involving Human Subjects

5.3 Network of Networks Standard Operating Procedures for Clinical Research ([N<sub>2</sub> organization](#)).