SOP 002_10

Title	Management of Biological Specimens
SOP Code	SOP 002_10
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the management of biological specimens obtained from clinical research participants. Processes include collection, processing, storage, and handling from collection to destruction, within the institution (Erie Shores Health Care).

2.0 SCOPE

This SOP applies to all clinical studies undertaken at the site, and to those clinical research personnel responsible for biological specimen handling.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that the specimen handling processes meet all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), sponsor, and local requirements.

Any or all parts of this procedure may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the Sponsor-Investigator or Qualified Investigator (QI)/Investigator.

4.0 PROCEDURE

4.1 General

4.1.1 Obtain detailed instructions for specimen management from the Sponsor or Sponsor-Investigator and/or central laboratory prior to study activation. Ensure that all supplies are available.

4.1.2 The protocol, laboratory manual, or other documentation should include:
• laboratory contact information (for central laboratories),
• requirements for specimen collection, labelling, processing and storage,
• supplies, and
• packaging and shipping specifications.

4.1.3 Ensure that equipment such as centrifuges, storage refrigerators and freezers are calibrated and checked on a regular maintenance schedule. Retain any documentation connected with maintenance of the equipment with the essential study documentation.

4.1.4 Prepare an emergency response plan to ensure the integrity of the biological specimens.

4.1.5 Arrange/perform specimen collection, as required by the protocol.

4.1.6 Identify specimens according to the specifications in the protocol.

4.1.7 Document the collection, storage, and shipping (as applicable), and file records with the essential study documentation.

4.2 Biological Specimen Storage

4.2.1 Ensure that biological specimens are stored in a secure and suitable environment, in compliance with the requirements of the protocol, or other study documentation. Establish and maintain controlled access for authorized personnel.

4.2.2 Ensure adherence to the storage time for biological specimens, as defined in the protocol, or other study documentation.

4.2.3 File storage records with the essential study documentation.

4.3 Biological Specimen Destruction

4.3.1 Destroy biological specimens, according to the requirements of the protocol, and of the institution.

4.3.2 File destruction records with the essential study documentation.

5.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

Transport Canada, Transportation of Goods Act (1992) and Regulations (and subsequent amendments).

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

- Part 11, Electronic Records; Electronic Signatures, (21CFR11).
- Part 50, Protection of Human Subjects, (21CFR50).

- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).