SOP 002_09

Title	Management of Investigational Products
SOP Code	SOP 002_09
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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 investigational products, regardless of the source (e.g., includes commercially available products). This SOP describes receipt, labelling, storage, distribution, accountability, and return or authorized destruction. Investigational products include drugs, biological products, natural health products, radiopharmaceuticals, and medical devices.

2.0 SCOPE

This SOP is applicable to all clinical studies undertaken at the site (Erie Shores Health Care), and to those clinical research personnel responsible for managing investigational products for a clinical study.

The study protocol should outline specific procedures for handling the investigational product/s. The term investigational product, as used in this SOP includes drugs, biological products, natural health products, radiopharmaceuticals, and medical devices, as necessary.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that investigational products are managed according to 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 Receipt and Inventory of Investigational Products

4.1.1 Review the shipping documentation upon receipt of the investigational product /s. Inventory the products received in order to ensure that the information on the shipment invoice corresponds to the products sent and received, including the quantity and lot number, if applicable. Record any damages and/or discrepancies. Document the result of the inventory, and retain with the essential study documentation.

4.1.2 Communicate any inconsistency to the Sponsor or Sponsor-Investigator, as soon as possible. Document and retain with the essential study documentation

4.1.3 Retain all documentation related to transportation and receipt of the investigational products throughout the study, with the essential study documents.

4.2 Labelling and Coding of Investigational Products

4.2.1 The manufacturing, labelling, packaging and shipping of investigational product (including active comparator(s), placebos, and devices, as applicable) is the responsibility of the Sponsor or Sponsor-Investigator.

4.2.2 Ensure that the label on investigational products is not hidden/covered, withdrawn, or modified without the authorization of the Sponsor/Sponsor-Investigator.

4.2.3 Apply an additional label, if required by the protocol or institution (e.g., participant name, institution name, etc). Do not cover the original label of the investigational product.

4.2.4 No participant-identifying information (nominative data) must remain/appear on container or devices labels, when/if medication or device is returned to the Sponsor or Sponsor-Investigator, in order to respect participant confidentiality.

4.3 Storage of Investigational Products

4.3.1 Store investigational products in a secure environment (e.g., locked room) with controlled access restricted to authorized personnel. Refer to special storage conditions for biologics, radio-pharmaceuticals, or devices, as needed.

4.3.2 Ensure that the storage location has appropriate and controlled temperature/humidity, as stated in the protocol or other written information provided by the Sponsor or Sponsor-Investigator.

4.3.3 Monitor the temperature/humidity conditions, and record regularly, either manually or by an automatic device. Be prepared to move the product to an alternate storage area, if problems arise. Document any storage issues.

4.3.4 Keep storage records within easy access of the investigational product, and have it available for monitors, auditors, etc., if requested.

4.3.5 File temperature records with essential study documentation at the end of the clinical trial.

4.4 Distribution/Dispensing the Investigational Product

4.4.1 Use the investigational product only in accordance with the approved protocol. Document any use of the investigational product not in accordance with the approved protocol. Report to Sponsor or Sponsor-Investigator, as required.

4.4.2 Maintain a Dispensing Log (provided by Sponsor or Sponsor-Investigator, or equivalent) to document assignment of investigational product to specific study participants.

4.4.3 Inform each study participant about the correct use of the investigational product/s. Inform the participant of his/her responsibility to return all unused devices (if applicable), medication and medication packaging (bottle, container, syringe, etc.), even if empty, as specified in the protocol. Document this interaction in the source documents.

4.4.4 Assess participant compliance with the instructions at intervals appropriate for the trial/protocol.

4.5 Accountability for Investigational Products

4.5.1 Document the return of all devices (if applicable), investigational products and/or containers by participants.

4.5.2 Perform a participant or pharmacy follow-up in the event of accounting inconsistency, for the safety of the participant. Document this inconsistency.

4.5.3 Maintain documentation of all investigational products and/or empty containers returned by participants, with the essential study documents.

4.5.4 Never give investigational product assigned to a participant and not used, to another study participant, to a participant outside the study, or to another site.

4.6 Return/Destruction of Investigational Products

4.6.1 Return investigational products left after study completion to the sponsor/distributor, or follow the instructions in the protocol or other study document, as required.

4.6.2 Obtain written authorization from the Sponsor or Sponsor-Investigator for destruction of product at the study site, if applicable.

4.6.3 Ensure that the institution/pharmacy has appropriate procedures for the destruction of investigational products, and that the destruction is performed in accordance with those procedures.

4.6.4 Return or destroy defective or outdated products in the same manner, unless otherwise requested by the Sponsor or Sponsor-Investigator.

4.6.5 File return and/or destruction documentation with essential study documents.

4.7 Randomization Procedure

4.7.1 Follow the randomization procedures as described in the protocol.

4.7.2 Retain all documents relating to randomization by external sources, such as an Interactive Voice Response System (IVRS).

4.7.3 Ensure that the randomization code is broken only in accordance with the protocol.

4.7.4 File randomization documentation with essential study documents.

4.8 Blinded Trials Only: Unblinding Procedure

4.8.1 Confirm that the coding system for the investigational product/s includes a mechanism that permits rapid identification of the product/s in case of a medical emergency, but does not permit undetectable breaks of the blinding.

4.8.2 Follow the protocol-specific requirements for unblinding the investigational product.

4.8.3 Promptly document and explain to the Sponsor or Sponsor-Investigator any premature unblinding of the investigational product/s such as, accidental unblinding or unblinding due to a serious adverse event/drug reaction. Inform REB/IEC as per their procedures.

4.8.4 File unblinding documentation with the essential study documents.

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.

Government of Canada, Medical Devices Regulations, SOR/98-282, May 7, 1998; last amended December 16, 2011, current to February 4, 2015.

Government of Canada, Natural Health Products Regulations, Part 4 Clinical Trials Involving Human Subjects, SOR/2003-196, June 5, 2003; last amended June 1, 2008, current to February 4, 2015.

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.

Health Products and Food Branch Inspectorate, Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines: Drugs Used in Clinical Trials, December 1, 2009.

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).