Title	Specimen Shipping and Transportation
SOP Code	SOP005_02
Effective Date	04-Jan-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines processes for shipping samples within Canada and internationally. The SOP specifies considerations such as specimen classification, packaging, and documentation that should be followed to ensure appropriate packaging and shipping of the samples.

2.0 SCOPE

Biospecimens collected for clinical trials will require shipping to different laboratories for analysis. During the shipping process, care should be taken to protect and maintain sample quality and integrity.

3.0 RESPONSIBILITIES

This SOP applies to clinical research and biorepository personnel involved in shipping specimens. Personnel must be certified in Transportation of Dangerous Goods. Roles and responsibilities may vary at specific sites.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Packaging and Shipping Conditions

5.1.1 Note: IATA defines a 'patient specimen' as material collected directly from human or animals for diagnostic, treatment, prevention, investigational or research purposes.

A Category B substance (UN3373) is "an infectious substance which does not meet the criteria for inclusion in an infectious material". Typical clinical research human specimens are Category B substances for shipment.

5.1.2 Ensure that packaging is appropriate for the transportation of perishable goods. Contents of the package may be categorized as being dangerous or biohazardous; therefore packaging must conform to transportation regulations. Consult www.iata.org for required labelling and packaging.

5.1.3 Pack specimens for shipping in a leakproof primary container, a leakproof secondary container, with absorbent material between the two, and an outer package.

5.1.4 Ship all frozen products in cryovials and frozen sections (in slide shippers) on dry ice. Dry ice is classified as a dangerous substance (UN1845) and needs to be sent in a double insulated shipper (styrofoam container in fitted cardboard box). Dry ice must NEVER be placed into a tightly sealed container (explosion hazard); the packaging must allow the release of CO_2.

5.1.5 Ship all refrigerated products on frozen gel packs in insulated shippers.

5.1.6 Ship paraffin blocks and slides with paraffin sections at room temperature.

5.1.7 Insert glass slides into slide shipping cassettes, to prevent breakage and damage.

5.1.8 Ensure that the quantity of samples to be shipped is reflected in the size of the packaging. Add sufficient refrigerant to maintain desired temperature throughout the shipping cycle. Use sufficient dry ice to ensure that the sample will remain frozen even if delayed in transit for 48-72 hours.

5.1.9 Tape and seal the packaging securely to prevent condensation of refrigerant, and to provide additional security for the contents.

5.1.10 Affix appropriate labels required to comply with shipping regulations and to ensure timely and proper shipping protocol, e.g., UN1845 dry ice declaration

sticker, Category B UN3373 sticker, address of shipper and recipient etc.

5.1.11 Place specimen requisitions or listing of shipping contents in the package and retain a copy at the site.

5.2 Supporting Documentation

5.2.1 Contact the courier to establish what supporting documentation is needed to ship the specimen to the specified destination. For international shipments, research any new regulations that may have been adopted or special permits that are needed for that destination.

5.2.2 Complete Shipper's Waybill and three copies of a ProForma Invoice (to provide contact information and to declare nature of contents to customs and regulatory agencies). For shipments to the United States, include a letter to the United States Department of Agriculture (USDA), to declare the presence or absence of possible contamination with any pathogenic agents (if relevant).

5.2.3 Dry ice is a Class 9 dangerous good, and requires completion of a Shipper's Declaration.

5.3 Courier Selection

5.3.1 Select established couriers such as FedEx, Purolator, or World Courier.

5.3.2 Identify and build a relationship with a courier that can consistently deliver frozen shipments within 24 hours.

5.3.3 Choose couriers who routinely and reliably deliver biospecimens, provide online tracking of shipments, and have appropriate customer service measures, such as 'top-up' of dry ice if a delay has occurred.

5.4 Shipping Procedure

5.4.1 Verify that there is an adequate stock of dry ice available, on the day before the shipment is to go out.

5.4.2 Before scheduling a pick-up, assemble packaging material, refrigerants, specimens to be shipped, accompanying study requisitions, and shipping documentation.

5.4.3 Contact shipper to schedule package pick-up. If there is a high volume of shipments, consider arranging a daily pick-up time.

5.4.4 Verify that all shipping information, contacts, and required documents are accurate and complete.

5.4.5 Retrieve specimens from storage and keep frozen on dry ice until packaged.

5.4.6 Use appropriate safety procedures when handling dry ice, or when retrieving specimens from liquid nitrogen containers.

5.4.7 Document specimen retrieval and shipping information, such as shipping date, courier waybill number, and recipient, in the inventory system.

5.4.8 Verify that information on the specimen labels match the study requisitions.

5.4.9 Package specimens, as required.

5.4.10 Contact (call, fax, or e-mail) the consignee to provide the courier waybill number and inform them that package has been shipped, so that they can anticipate arrival of the package.

5.4.11 Track delivery using the online tracking capability of the courier to monitor shipment and expedite specimens, if delayed by customs or regulatory agencies.

5.5 Timing of Shipment

5.5.1 Adhere to shipping timelines, as described in the protocol or Request for Material.

5.5.2 Schedule pick-up early in the day, to ensure that the package goes out on the earliest flight available (if applicable).

5.5.3 Schedule pick-up for early in the week (e.g., Monday or Wednesday) to prevent delays in shipment, or delivery on weekends.

5.5.4 Do not ship just before a holiday and/or long weekend, as delays may occur in transit.

5.5.5 Be aware of public holidays in the province or country of destination to plan for optimal shipping dates.

6.0 REFERENCES

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

International Air Transport Association (IATA)
http://www.iata.org/index.htm

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

2011 NCI Best Practices for Specimen Resources. Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, MD.
http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf

ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research. 3rd Edition, http://www.isber.org

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network,

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP005_01	01-Aug-2012	Original version
SOP005-02	04-Jan-2016	5.1.2, References: Added source for transportation regulations. Updated references. Removed CRTN logo.