Title	Blood Collection for Biorepositories
SOP Code	SOP110_01
Effective Date	01-Sep-2012

Site Approvals

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

1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines standardized procedures for biorepositories to follow for blood collection. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals.

2.0 SCOPE

This procedure is intended to ensure that blood samples will be obtained from consented participants in a safe and efficient manner, while eliminating the risks of contamination.

3.0 RESPONSIBILITIES

All biorepository personnel responsible for performing venipuncture to obtain blood from the consented participant, must follow this procedure.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Timing for Blood Collection

5.1.1 Preferably, blood collection should be done pre-operation, and as close as possible to the time when the biospecimen is donated to the repositories. To minimize discomfort for the participant an alternate time when other blood work is being done may be chosen.

5.1.2 Identify the person responsible for processing the blood.

5.1.3 Contact this person before, or soon after blood collection, to arrange timely processing of the sample.

5.2 Blood Collection Procedure - Preparation

5.2.1. Ensure that blood collection is performed by qualified personnel.

5.2.2. Complete the required participant information on the blood specimen requisition.

5.2.3. Assess participant's physical and mental disposition, and determine if this is the appropriate time to draw blood.

5.2.4. Assemble proper equipment to draw blood.

5.3 Blood Collection Procedure – Venipuncture

5.3.1. Place participant in a sitting or supine position.

5.3.2. Hyperextend the participant's arm, and apply tourniquet to expose veins. Do not place too tightly. If superficial veins are not easily apparent, force blood into the vein by massaging the arm from wrist to elbow, tap the site with index and second finger, apply a warm, damp cloth to the site or lower extremity to allow veins to fill.

5.3.3. Select appropriate site for venipuncture. Avoid areas with excessive scars or hematomas. While hand and wrist veins are acceptable, it is optimal to select an antecubital vein.

5.3.4. Prepare the participant's arm using an alcohol prep. Cleanse in a circular fashion, beginning at the site and working outward. Allow to air dry.

5.3.5. Anchor the vein and swiftly insert the needle (at a 15-30 degree angle with the surface of the arm) into the lumen of the vein. Avoid excessive probing and trauma to the site.

5.3.6. Draw blood into the appropriate evacuated blood collection tube. Record the date and time of blood draw.

5.3.7. Remove the tourniquet, when the last tube to be drawn is filling.

5.3.8. Remove the needle from the participant and apply a gauze and adequate pressure to the site of venipuncture to avoid hematoma formation.

5.3.9. Dispose of needles and supplies in a safe manner.

5.3.10. Mix by inverting tubes 6-8 times.

5.3.11. Label tubes promptly and ensure that the appropriate matching information is recorded on the blood collection worksheet.

5.4 Transport of Blood Sample to Pathology or Biorepository Lab forProcessing

5.4.1. Verify participant information (in keeping with privacy and ethical policies) and ensure that it corresponds with the information on the labels on blood collection tubes.

5.4.2. Responsible personnel or technician: Transport labelled tubes to the pathology lab or specified area at the biorepository for processing blood samples.

5.4.3. Ship samples express using a qualified courier, if samples are coming from a location distant to the repository.

5.4.4. Transport tubes at room temperature. Do not allow the samples to freeze or be exposed to an ambient temperature of greater than 25° C.

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.

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. Cell Preservation Technology 6(1), 3-58, 2008 http://www.isber.org/Pubs/BestPractices2008.pdf

CTRNET Standard Operating Procedures, Canadian Tumour Repository Network, http://www.ctrnet.ca/operating-procedures

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP110_01	01-Sep-2012	Original version