Title	Blood Collection for Clinical Trials
SOP Code	SOP203_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) describes how blood should be drawn to ensure collection of high quality and high integrity specimens. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals.

2.0 SCOPE

Blood specimens may be required to be collected for a clinical trial. Blood specimens are drawn from participants that have been through the informed consent process and agreed to participate in a clinical trial. Blood and blood components can be used in clinical trials for establishing the pharmacokinetic profile of a drug, pharmacodynamics, or pharmacogenomics.

3.0 RESPONSIBILITIES

This SOP applies to clinical research personnel involved in blood collection. Roles and responsibilities may vary at specific sites. Personnel must follow institutional guidelines and other applicable rules and regulations.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Timing for Blood Collection

5.1.1 Perform blood collection at the time points established in the protocol.

5.1.2 Identify the person responsible for processing the blood.

5.1.3 Ensure that arrangements are made before, or immediately after, blood collection to achieve timely processing of the specimen(s).

5.2 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 Assemble blood collection tubes and supplies required.

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

5.3 Venipuncture

5.3.1 Confirm participant's identity.

5.3.2 Place participant in a sitting or supine position.

5.3.3 Hyperextend the participant's arm, and apply tourniquet to expose veins. Do not apply too tightly. If superficial veins are not readily 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.

5.3.4 Select suitable site for venipuncture. Avoid areas with excessive scars or haematomas. Note: Hand and wrist veins are acceptable, however, antecubital veins are optimal.

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

5.3.6 Anchor the vein, and swiftly insert the needle into the lumen of the vein, at a 15-30° angle with the surface of the arm. Avoid excessive probing and trauma to the

site.

5.3.7 Draw blood in the required type/number of tubes, and to the recommended volume, as identified in the study protocol, or other study document.

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

5.3.9 Remove the needle, and apply gauze and adequate pressure to the venipuncture site, to avoid haematoma formation.

5.3.10 Mix tubes by inverting each one, 6-8 times.

5.3.11 Label tubes promptly, Ensure that the matching information is recorded on the blood specimen requisition. Record date and time of collection on the blood specimen requisition.

5.3.12 Dispose of needles and supplies in a safe manner.

5.4 Transport of Blood Specimen to Laboratory for Processing

5.4.1 Ensure that responsible personnel transport labelled tubes to the blood processing laboratory/area, within the time frame specified in the protocol, or other study document.

5.4.2 Transport specimens in secondary packaging, such as a biospecimen bag or box, within the institution.

5.4.3 Transport tubes at room temperature, or on ice, as specified in the protocol, or other study document.

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
SOP203_01	01-Aug-2012	Original version