Title	Blood Processing and Storage for Clinical Trials
SOP Code	SOP204_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) describes how blood should be processed and stored to ensure high quality and high integrity specimens for research. This SOP does not describe detailed safety procedures for handling blood.

2.0 SCOPE

Blood specimens are drawn from patients 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 pharmacokinetics profile of a drug, pharmacodynamics, or pharmacogenomics.

3.0 RESPONSIBILITIES

This SOP applies to clinical research personnel involved in blood processing and storage. Roles and responsibilities may vary at specific sites. Blood specimens must be processed by qualified personnel. Personnel must follow institutional biosafety guidelines.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Blood Processing - General

5.1.1 Collect blood into required type and number of tubes, as per protocol or other study document, and record the time of collection

5.1.2 Verify that the specimens are adequately labelled, prior to processing.

5.1.3 Take samples to designated processing area.

5.1.4 Record time blood processing, and aliquot freezing, and note any deviations from the protocol. This information may be required for downstream analysis of blood components.

5.1.5 Process all samples as per protocol or study document/guidelines.

5.1.6 Follow the processing steps described below, unless otherwise specified in the protocol, or other study document.

5.2 Separation of Plasma

5.2.1 Fractionate the whole blood, collected in tubes containing an anticoagulant such as EDTA or Heparin, as per protocol.

5.2.2 This will separate the blood into three visible layers (see Figure 1):

- The upper layer is generally clear and pale yellow in colour.
- The second layer is a narrow grayish white interface band representing the“buffy coat” or leukocyte fraction.
- The third/bottom layer is dark red, and consists of the erythrocytes (red blood cells).

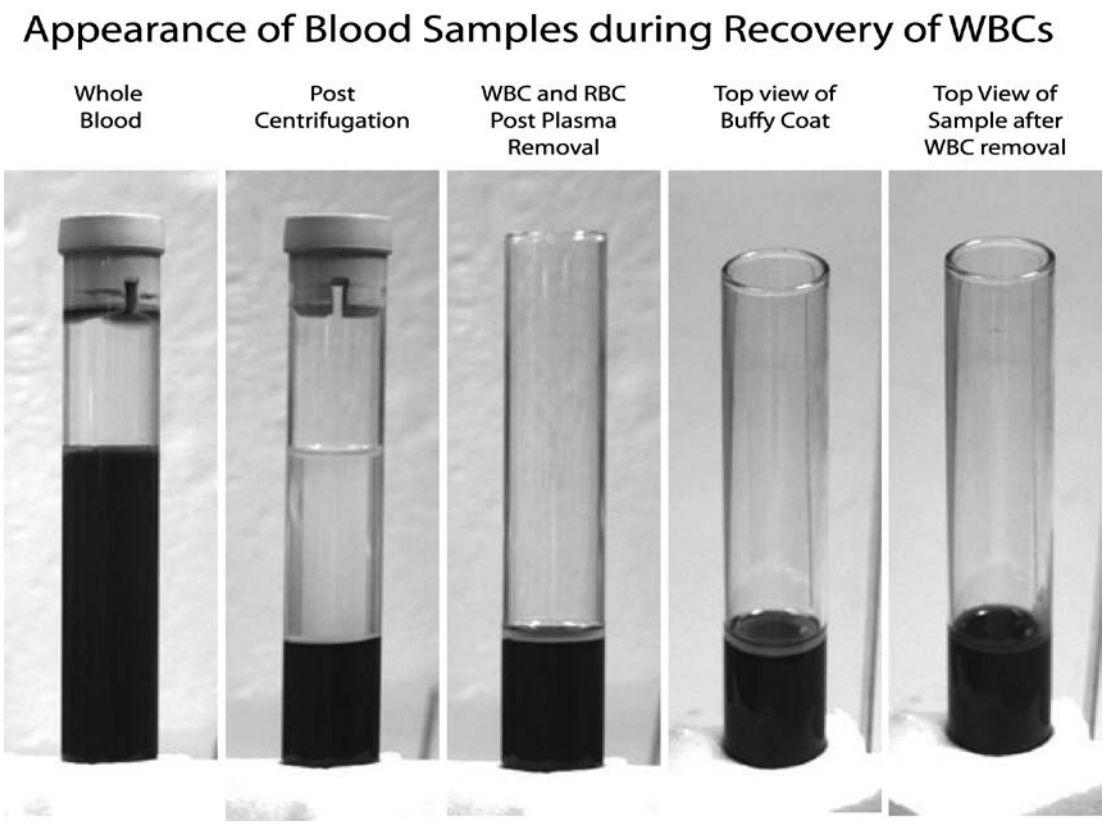

Figure 1: Blood Separation for White Blood Cells in Buffy Coat.

5.2.3 Using a disposable transfer pipette, aspirate off the plasma layer down to approximately 1 mm from the buffy coat layer. Take care not to disturb the leukocyte/buffy coat layer.

5.2.4 Expel all plasma from the pipette into a plasma collection tube.

5.2.5 Aliquot recovered plasma into labelled cryovial(s).

5.2.6 Place the cryovial(s) in dry ice until freezer storage or as per protocol or other study documents.

5.2.7 Transfer the cryovial(s) to a labelled freezer storage box, and place the box immediately in the -80° C freezer or in liquid nitrogen or as per protocol or other study documents.

5.2.8 Record exact storage location of the cryovial(s) as per institutional guidelines.

5.3 Recovery of White Blood Cells (aka, Leucocyte or Buffy Coat)

5.3.1 After removing the plasma layer, use a new transfer pipette to aspirate all of the buffy coat layer (usually 0.5 mL or less from 10ml of whole blood). Minimize aspiration of red blood cells.

5.3.2 Expel the buffy coat into required cryovials as per protocol or other study documents.

5.3.3 Store cryovial(s) or as per protocol or other study documents..

.

5.3.4 Record the exact storage location of cryovial(s), as per institutional guidelines.

5.4 Separation of Serum

5.4.1 Collect the whole blood in serum collection tubes as per protocol or other study documents.

5.4.2 Invert the tubes 8 times immediately following collection, or as per protocol or other study documents.to ensure proper coagulation.

5.4.3 Incubate the mixed serum tubes for one hour at room temperature, or as per protocol or other study documents, to ensure complete coagulation.

5.4.4 Following incubation, centrifuge the serum tubes at 1500 g for 15 minutes, or as per protocol or other study documents.

5.4.5 Aspirate the supernatant, and transfer directly into labelled cryovial(s).

5.4.6 Place the cryovial(s) on dry ice until freezer storage or as per protocol or other study documents.

5.4.8 Record the exact storage location of cryovial(s) as per institutional guidelines.

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, 3rd Edition, 2012, http://www.isber.org

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP204_01	01-Aug-2012	Original version
SOP204_02	04-Jan-2016	5.1.1, 5.1.3, 5.1.4, 5.1.5, 5.1.6: rewording and reordering for clarity. 5.1.5, 5.3.2, 5.3.3, 5.3.4, 5.4.1: Replacement of specific instruction with reference to protocol/study guidelines. 5.2.6, 5.2.7, 5.2.8, 5.4.1-5.4.6: Allowance for use of alternative procedures according to protocol, study, institutional guidelines 5.3.1: changed from used to new pipette. Updated references. Removed OTRN logo.