Title	Blood Processing and Storage for Biorepositories
SOP Code	SOP111_02
Effective Date	04-Jan-2016

Site Approvals

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

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to outline standardized procedures for biorepositories to follow for blood processing from patients who have been through the approved informed consent process and have had blood collected by qualified personnel.

2.0 SCOPE

The SOP describes how blood should be processed, accessioned, and stored. The SOP does not cover detailed safety procedures for handling blood.

3.0 RESPONSIBILITIES

The policy applies to all biorepository personnel responsible for the processing of blood to obtain blood products for storage in the biorepository. It also applies to personnel responsible for collection of the blood from the consented participant.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Timing for Blood Collection and Processing

5.1.1. Blood collection should be done pre-operation and as close as possible to the time when the tissue is donated to the biorepositories or at an alternative time, if appropriate for the research study.

5.1.2. Communicate with personnel responsible for blood collection to determine if blood has been collected and needs to be processed.

5.1.3 The time between collection and sample processing depends on the intended use and therefore time to process should be recorded.

5.2 Verification of identification information on tubes.

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

5.3 Separation of Plasma from the Cellular Fraction

The whole blood can be processed directly for DNA or RNA, or processed as described below to obtain a buffy coat fraction and plasma for cryopreservation.

5.3.1. In the area designated by the repository for processing blood, fractionate the whole blood (blood collected in tubes containing an anticoagulant such as EDTA or Heparin) by centrifuging at 1500-2000 x g for 15 minutes at room temperature. 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 or bottom layer is dark red and consists of the erythrocytes or red blood cells.

5.3.2. 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 or buffy coat layer.

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

5.3.4. Aliquot recovered plasma and place into labeled cryovials.

5.3.5. Place the cryovials in dry ice until freezer storage.

5.3.6. Transfer the cryovials to a labelled freezer storage box and place the box immediately in the -80° C freezer or in liquid nitrogen.

5.3.7. Record position and location of the tubes

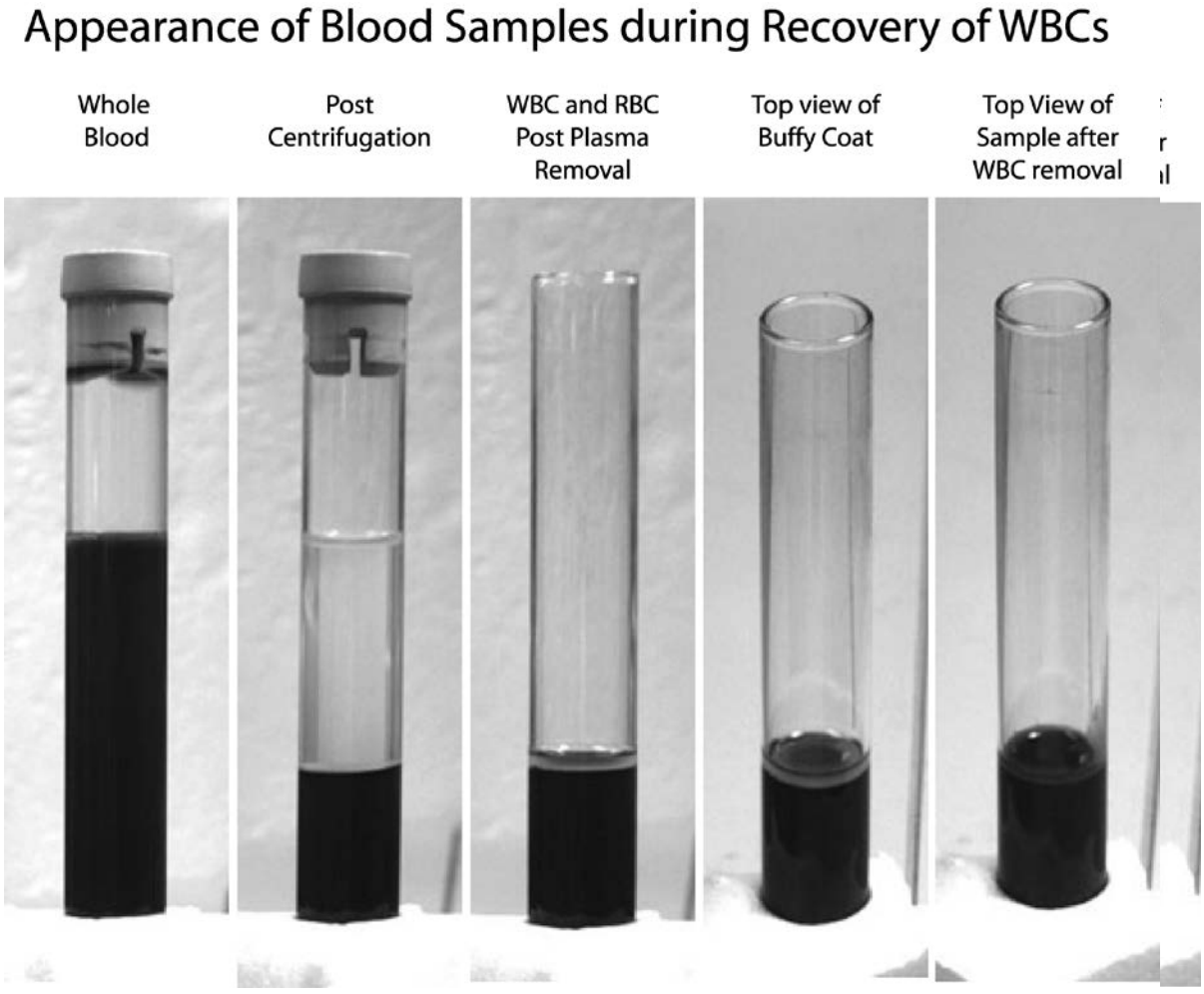

Figure 1: Blood Samples during WBC Recovery

5.4 Recovery of White Blood Cells

5.4.1 After removing the plasma layer, use a new transfer pipette to aspirate all of the

buffy coat layer (usually a volume of 0.5 mL or less from 10ml of whole blood).

5.4.2. Expel the buffy coat into a abelled cryovial(s).

5.4.3. Place the cryovial(s) in dry ice until freezer storage

5.4.4. Transfer the cryovia(s) to a labelled freezer storage box and place the box immediately in the -80° C freezer or in liquid nitrogen.

5.4.5. Record position and location of tubes.

5.5 Separation of serum from blood samples

5.5.1. Collect the whole blood in serum tubes coated with particles such as silica which act as a clotting activator.

5.5.2. Invert the tubes 8 times immediately following collection to ensure proper coagulation as per manufacturer's guidelines.

5.5.3. Incubate the mixed serum tubes for 1 hour at room temperature to ensure complete coagulation.

5.5.4. Following incubation, centrifuge the serum tubes at 1500 g for 15 minutes as per manufacturer's guidelines

5.5.5. Aspirate the supernatant and transfer directly to the required labelled cryovial(s).

5.5.6. Place the cryovial(s) in dry ice until freezer storage

5.5.7. Transfer tubes to a labelled freezer storage box and place the box in a -80° C freezer or in liquid nitrogen.

5.5.8. Record the position and location of tubes.

5.6 Accessioning of samples

5.6.1. Accession plasma, serum, and buffy coat samples into biorepository inventory database system as per established procedure for the site-specific inventory system and affix appropriate labels on the vials.

5.7 **Alternate Processing of Blood Samples**

Blood may be collected in specific DNA or RNA extraction collection tubes. For extraction of DNA or RNA proceed with processing of these collection tubes as per established procedures for DNA and RNA processing and extraction.

6.0 REFERENCES

Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3 http://www.wma.net/e/policy/b3.htm

Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans; Canadian Institute of Health Research; Natural Sciences and Engineering Research Council of Canada; Social Sciences and Humanities Research Council of Canada, December, 2014. http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm

Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf

Best Practices for Repositories Collection, Storage Retrieval and Distribution of Human Biological Materials for Research, 3rd Edition 2012 International Society for Biological and Environmental Repositories (ISBER). http://www.isber.org

National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999. http://bioethics.georgetown.edu/nbac/hbm.pdf

US National Biospecimen Network Blueprint http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

Blood Collection: Routine Venipuncture and Specimen Handling.http://medlib.med.utah.edu/WebPath/TUTORIAL/PHLEB/PHLEB.html

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP111_01	01-Aug-2012	Original Version
SOP111_02	04-Jan-2016	2.0 Scope: Added participant consent and qualified personnel. 5.1.1: Removed preferably. 5.1.3 Moved to 5.1.2 5.1.2, 5.3, 5.4.1, 5.4.2, 5.3.2, 5.5.4: Rewording for clarification. 5.5.2: Spelling correction. 5.7: Addition of alternate process for DNA/RNA extraction. Updated references. Removed OTRN logo.