QCC Standard Operating Procedure Blood Collection and Transportation			
SOP Number:	08.02.001	Version:	e1.0
Supersedes:	NA	Category:	Material Handling and Documentation - Blood

Approved By:	QCC Working Group Per: Insert signature	Date of approval DD-MM-YYYY

Fields in green should be modified according to your biobank and institution

1.0 PURPOSE

Blood samples are drawn from participants who have been through the informed consent process and have agreed to participate in the tumour biobank program. Blood samples are obtained by personnel qualified to draw blood from participants in the hospital or in the physician's office. The purpose of this document is to outline standardized procedures for QCC biobanks to follow for blood collection.

2.0 SCOPE

- This standard operating procedure (SOP) describes how blood should be drawn and transported. Blood products are a precious resource in the tumour biobank, and procedures must be followed to obtain products with high integrity and quality.

- This SOP does not provide details on security measures essential for biological material handling. Please refer to institution biosafety guidelines (reference - to add in the table point 3.0). Personnel should have received an institutional training for biosafety and waste management. Access to the SIMDUT database (state location in your institution) and an information document on biosafety measures (indicate location) should be available.

3.0 REFERENCE TO OTHER SOPS OR POLICIES

Biobank or Institutional SOP	
Biohazardous Material Waste Management	TBD
Biosafety procedure	TBD
CTRNet SOP and Policies **h**ttp://www.ctrnet.ca/	
Ethics	POL.002
Privacy and Security	POL.004
Records and Documentation	POL.005
Material and Information Handling	POL.007
Labelling and Tracking Materials - Biobank ID	SOP 08.01.001

Coding of Biological Specimens	SOP 08.01.008
QCC SOPs	
Blood Processing - Serum and Storage	SOP 08.02.002
Blood Processing - Plasma, Buffy Coat and Storage	SOP 08.02.003
Blood Processing - Plasma, PBMC and Storage	SOP 08.02.004

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all biobank personnel that are responsible for performing venipuncture to obtain blood from consenting participants.

Personnel	Responsibility/Role
Nurse or Biobank staff	Obtain participant consent
Phlebotomist/ Venipuncture Nurse	Draw blood from participants, and read and understand product inserts
Laboratory Technician/Technologist	Verify specimen identification Transport and process blood Record information related to blood collection in the **Blood Collection and Processing Worksheet** and in ATiM

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed below are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	**Materials and Equipment (Site-Specific)**
4 BD Medical 367874 Vacutainer® Plus Plastic Heparin Blood Collection Tubes with Sodium Heparin for Plasma Determination, 16 x 100mm, 10mL Draw Volume, **Green** Conventional Closure (Cat # BD367874) – Suitable for PBMC isolation and functional assay	
1 BD Vacutainer® Plastic Plus EDTA Blood Collection Tubes, 16 x 100mm, 10mL Draw Volume, **Lavender** Hemogard™ Closure (Cat # BD366643) – Suitable for Sequencing (PBMC or Buffy Coat)	
1 BD Vacutainer® Plus Plastic SST™ Blood Collection Tubes with Polymer Gel for Serum Separation, 13 x 100mm, 5mL Draw Volume, **Gold** Hemogard™ Closure (Cat # BD 367986)	
Needles of appropriate gauge number (ex. Becton; Vacutainer Blood Collection Set Cat. # BEC367253)	
Needle holder/adapter for use with the evacuated blood collection system (such as system from Becton Dickinson Cat. #BD364815)	
Tourniquet (MEDJPS16332)	
Alcohol wipes (70%) isopropyl alcohol (LP 103-03)	

Gauze sponges for application to venipuncture site when needle is withdrawn	
Adhesive bandages/tape to protect venipuncture site after collection	
Needle/sharps disposal unit	
Gloves (non-latex recommended) to protect participant and phlebotomist	
Syringes that may be used in place of evacuated collection tubes in certain circumstances (BD 309659)	
Plastic bag (Fisher #2980110)	
Cooler for secure transportation	
Sufficient appropriate labels for collection tubes	
Permanent marker to label tubes	
Blood Collection and Processing Worksheet (see Appendices for sample form)	Version # 1.1

6.0 DEFINITIONS

See the CTRNet Program Glossary: http://www.ctrnet.ca/education/glossary

7.0 PROCEDURES

7.1 Timing for Blood Collection

7.1.01 Blood collection should be done pre-operation and as close as possible to the time when the tissue is donated to the biobank or at an alternative time, if appropriate for the research study. Suitable time points should be listed in the **Timing of Blood Collection** (refer to Appendix).

7.1.02 If the person who will process the blood is different from those involved in this SOP, inform this person Name and extension/email and arrange for timely processing.

7.2 Blood Collection Procedure - Preparation

7.2.01 Only qualified personnel trained in drawing blood must perform blood collection. If this person is part of the hospital setting, biobank personnel must inform the person drawing the blood that the participant consented to participate in the biobank. (add specification for your setting - which service, which location, etc)

7.2.02 Biobank personnel will label **6** blood collection tubes with the participant identification number (or less if this amount of blood is not available) (SOP 08.01.001 or the Participant initials and RAMQ number). All tubes are gathered in a plastic bag labelled with the participant RAMQ number tube label - see table below) and order of collection. The plastic bag is placed in the location defined by hospital where the collection will take place. All materials for collection are provided by the hospital/pre-admission clinic.

Tube (order of collection)	Label	Volume
1	EDT-1	10
2	SST-1	5
3	HEP-1	10
4	HEP-2	10
5	HEP-3	10
6	HEP-4	10

7.2.03 Biobank personnel will fill out the **Blood Collection and Processing Worksheet**. Identify the participant, verify identification, and check that informed consent has been obtained.

7.2.04 The person who will draw blood should assess the participant's physical and mental disposition and determine if this is the appropriate time to draw blood. Be courteous, professional, and sensitive to the participant's needs. Ensure that all communications are discreet and respectful of participant confidentiality.

7.3 Blood Collection Procedure – Drawing Blood

7.3.01 Assemble proper equipment to draw blood (See Section 5.0). If the clinical personal is performing the blood draw, they may use their own procedure. However, you will need to compare it with this one and note major differences.

7.3.02 Make the participant feel as comfortable as possible and gain the participant's cooperation. The participant should sit in a chair, lie down or sit up in bed. Hyperextend the participant's arm.

7.3.03 Apply the tourniquet to expose veins. Do not tie it too tightly. If superficial veins are not readily apparent, force blood into the vein by massaging the arm from wrist to elbow, tapping the site with index and second finger, and applying a warm, damp cloth to the site or lower extremity to allow veins to fill.

7.3.04 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.

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

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

7.3.07 Draw blood into an evacuated blood collection tube (refer to step 7.2.02 for appropriate order of collection). Pay close attention to filling the tube to the appropriate volume.

Note: **8-9 ml is the recommended minimum volume for 10 ml tubes**.

7.3.08 When the last tube is filling with blood, remove the tourniquet.

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

7.3.10 Dispose of needles and supplies in a safe manner.

7.3.11 Mix by inverting tubes 6-8 times.

7.3.12 Add all collection tubes into the pre-labeled plastic bag.

7.3.13 The bag containing blood collection tubes is rapidly transferred to the biobank personnel.

7.4 Transport of Blood Samples to Biobank Lab for Processing - Biobank Staff

7.4.01 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. Ensure that the appropriate matching information is recorded on the **Blood Collection and Processing Worksheet**.

7.4.02 Transport labelled tubes to the specified area at the biobank for processing blood samples.

7.4.03 If samples are coming from a distant location, they should be shipped express using an appropriate courier.

7.4.04 Transport tubes at room temperature. Do not allow the samples to freeze or be exposed to an ambient temperature of greater than 25°C for more than 5 minutes.

7.4.05 Store tubes at room temperature and process them within 4 hours after blood collection.

Note: Cell degradation will occur if tubes are stored for more than 4 hours

7.4.06 The **Blood Collection and Processing Worksheet** should always be completed and kept with collection tubes. All information should be recorded in ATiM.

7.4.07 Proceed with blood processing SOP

08.02.002	Blood Processing - Serum and Storage
08.02.003	Blood Processing - Plasma, Buffy Coat and Storage
08.02.004	Blood Processing - Plasma, PBMC and Storage

8.1 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.2 Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects

8.3 Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, 2018. https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

8.4 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/

8.5 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). https://www.isber.org/page/BPR

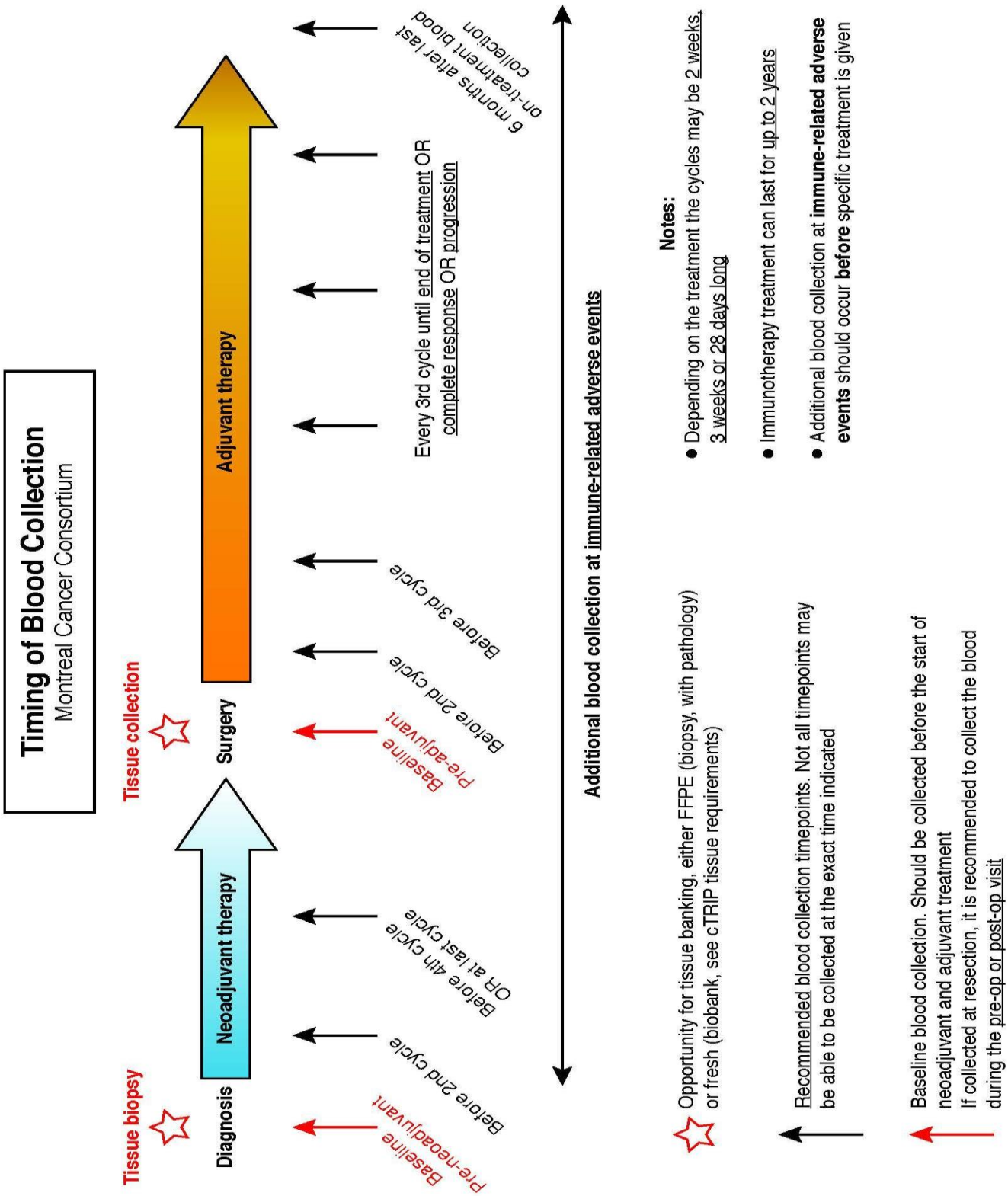
8.6 US National Biospecimen Network Blueprint http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

8.7 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

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

9.1 APPENDICES

Timing for Blood Collection


Timing of Blood Collection
Montreal Cancer Consortium
Tissue biopsy
Diagnosis
Neoadjuvant therapy
Tissue collection
Surgery
Adjuvant therapy
Pre-neoadjuvant
Baseline
Before 2nd cycle
Before 4th cycle OR at last cycle
Pre-adjuvant
Baseline
Before 2nd cycle
Before 3rd cycle
Every 3rd cycle until end of treatment OR complete response OR progression
6 months after last on-treatment blood collection
Additional blood collection at immune-related adverse events
Notes:
• Depending on the treatment the cycles may be 2 weeks, 3 weeks or 28 days long
• Immunotherapy treatment can last for up to 2 years
• Additional blood collection at immune-related adverse events should occur before specific treatment is given
Opportunity for tissue banking, either FFPE (biopsy, with pathology) or fresh (biobank, see cTRIP tissue requirements)
Recommended blood collection timepoints. Not all timepoints may be able to be collected at the exact time indicated
Baseline blood collection. Should be collected before the start of neoadjuvant and adjuvant treatment
If collected at resection, it is recommended to collect the blood during the pre-op or post-op visit

Blood Collection and Processing Worksheet

Blood Collection and Processing Working Sheet1
Version 1.1

Biobank ID: _____

Date of Collection: _____

Timepoint - for details, please refer to the worksheet entitled 'Timing Blood Collection'		
☐ Adjuvant (following Sx) A	☐ Pre-treatment B	☐ at complete response CR
☐ Neo-adjuvant (prior to Sx) N	☐ Prior to cycle ____ C#	☐ at progression P
	☐ at end of treatment EC#	☐ at immune related adverse event (Cycle ___) AEC#
	☐ 6 months after last treatment 6 M	

Time (hh:mm, 24h) of Collection (blood drawn - end) ____ : ____										Time (hh:mm, 24h) of collection tubes are received in the laboratory ____ : ____							
	Lot# / Expiry date	Hemolysis?	Volume of blood in collection tube (mL)		Time (hh:mm, 24h)		MCC Assay			Aliquot ID cryovial	Volume (mL) in cryovial	From tube with hemolysis? (Y)	Time -80 C	Storage of 2mL cryovials			
					tubes at 4C	Centrifugation start	Assay	PI	Amount required					Freezer	Shelf	Box	Position
Lavender K2-EDTA (10mL)		☐yes ☐no	EDI-1				Bio banking			PLAE-1							
							CM	Bernier	2mL	PLAE-2							
							Bio banking			PLAE-3							
							C	IW	0.2mL	BFC-1							
							Bio banking			BFC-2							
Golden - SST (5 mL)		☐yes ☐no	SSI-1				Bio banking			SER-1							
										SER-2							
										SER-3							
Green - Sodium Heparin (10mL tubes)		☐yes ☐no	HEP-1				A.I	BL	1mL	PLAH-1							
							Bio banking			PLAH-2							
		☐yes ☐no	HEP-2							PLAH-3							
										PLAH-4							
		☐yes ☐no	HEP-3							PLAH-5							
										PLAH-6							
		☐yes ☐no	HEP-4							PLAH-7							
										PLAH-8							

PBMC Isolation process		MCC Assay		Aliquot ID	Amount Required	PBMC in cryovial		Time at -80 C	Storage of 1.5 mL cryovials			
		Assay	PI						Freezer	Shelf	Box	Position
Volume of Blood Processed (remaining fraction after removing plasma)	mL	Banking		PBMC1	1 cryovial	5	X 10^6					
		A.II	BL	PBMC2	1 cryovial	5	X 10^6					
Volume of cells resuspended prior counting (mL)	mL	A.III	BL	PBMC3	1 cryovial	5	X 10^6					
		E.I	LB	PBMC4	1 cryovial	5	X 10^6					
Number of PBMC in 1 (small (=1 large) square from hemocytometer count		B.I	IW	PBMC5	1 cryovial	5	X 10^6					
		Banking		PBMC6			X 10^6					
Total number of PBMC		Banking		PBMC7			X 10^6					
		Banking		PBMC8			X 10^6					
	X10^6	Banking		PBMC9			X 10^6					

Comments :

☐ All M completed

Note : Aweil mixing tubes with hemolysis with the others . For MCC project, when possible share material from tubes without hemolysis
Labelling: Ideally, indicate bio bank ID, Timing of collection, Aliquot ID, Date

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions