CTRNet Standard Operating Procedure Blood Collection			
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Approved By:	CTRNet Management Group (CMG)	01-June-2012
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1.0 PURPOSE

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

2.0 SCOPE

This standard operating procedure (SOP) describes how blood should be drawn. This SOP does not cover detailed safety procedures for handling blood, and personnel must follow institutional bio-safety guidelines. When blood collection is subcontracted, the subcontractor must follow institutional guidelines.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

3.1 *CTRNet Policy: POL 5 Records and Documentation*
3.2 *CTRNet Policy: POL 2 Ethics*
3.3 *CTRNet Policy: POL 4 Privacy and Security*
3.4 *CTRNet Policy: POL 7 Material and Information Handling*
3.5 *CTRNet Standard Operating Procedure: SOP 08.01.002 Biohazardous Material Waste Management*
3.6 *CTRNet Standard Operating Procedure: SOP 08.01.001 Labeling and Tracking Materials*
3.7 *CTRNet Standard Operating Procedure: SOP 08.02.002 Blood Processing and Storage*

4.0 ROLES AND RESPONSIBILITIES

The SOP applies to all personnel from CTRNet member biobanks that are responsible for performing venipuncture to obtain blood from the consented participant.

Tumour Biobank Personnel	**Responsibility/Role**
Consent Nurse	Obtain Patient Consent
Phlebotomist/ Venipuncture nurse	Draw Blood from patient and read and understand product inserts
Laboratory Technician/Technologist	Transport and Process blood

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list 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)
Evacuated blood collection tubes for plasma (e.g. Lavender top tube with EDTA)	
Evacuated blood collection tubes (e.g. Tube for separating serum)	
Tube for extraction of nucleic acids from blood (e.g. Paxgene tube)	
Needles of appropriate gauge number	
Appropriate size holder/adapter for use with the evacuated collection system (such as system from Becton Dickinson)	
Tourniquet	
Alcohol wipes (70%) isopropyl alcohol	
Gauze sponges for application to site from which needle has been withdrawn	
Adhesive bandages/tape to protect venipuncture site after collection	
Needle/sharps disposal unit	
Gloves (non-latex recommended) worn to protect patient and phlebotomist	
Syringes that may be used in place of evacuated collection tubes in certain circumstances.	
Sufficient appropriate labels (see *CTRNet SOP 08.01.001)* for collection tubes and Blood Collection/Processing Worksheets	
Blood Collection/Processing Worksheets (see Appendix A for sample form)	

6.0 DEFINITIONS

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

7.0 PROCEDURES

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.

Blood products are a precious resource in the tumour biobank and procedures must be followed to obtain products with high integrity and quality.

7.1 Timing for Blood Collection

7.1.1 Preferably, 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.

7.1.2 Identify the person responsible for processing the blood collection and arrange for timely processing (Refer to *CTRNet SOP 08.02.002 – Blood Processing and Storage* for further details).

7.2 Blood Collection Procedure - Preparation

7.2.1 Personnel qualified by training to draw blood must perform blood collection.

7.2.2 Start filling out the blood collection worksheet. Identify the patient, verify identification, and check that informed consent has been obtained.

7.2.3 Assess patient's physical and mental disposition and determine if this is the appropriate time to draw blood.

7.2.4 Be courteous, professional, and sensitive to the patient's needs. Ensure that all communications are discreet and respectful of patient confidentiality.

7.2.5 Assemble proper equipment to draw blood. (See Section 5.0.)

7.3 Blood Collection Procedure – Drawing Blood

7.3.1 Provide for the patient's comfort as much as possible, and gain the patient's cooperation. Position the patient. The patient should sit in a chair, lie down or sit up in bed. Hyperextend the patient's arm.

7.3.2 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.

7.3.3 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.

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

7.3.5 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.

7.3.6 Draw blood (4-5ml is the recommended minimum volume) into an evacuated blood collection tube. Fill in additional appropriate tubes for DNA and RNA extraction if relevant.

7.3.7 When the last tube to be drawn is filling, remove the tourniquet.

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

7.3.9 Dispose of needles and supplies in a safe manner.

7.3.10 Mix by inverting tubes 6-8 times.

7.3.11 Label tubes promptly and appropriately with the labels and make sure that the appropriate matching information is recorded on the blood collection worksheet.

7.4 Transport of Blood Sample to Pathology or Biobank Lab for Processing

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

7.4.2 Responsible personnel or technician/technologist should transport labelled tubes to the pathology lab or specified area at the biobank for processing blood samples.

7.4.3 Should samples be coming from a location distant to the biobank, they should be shipped express using an appropriate courier.

7.4.4 Transport tubes at room temperature or if appropriate on wet ice. Do not allow the samples to freeze or be exposed to an ambient temperature of greater than 25° C.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Declaration of Helsinki.
http://www.wma.net/en/30publications/10policies/b3/index.html

8.2 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, December 2010.
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

8.3 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics
http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

8.4 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).
http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories

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

8.6 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

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

9.0 APPENDICES

9.1 Appendix A– Blood Collection and Processing Worksheets

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
LP 001.001	2005	JdSH	CTRNet Generic SOP for Blood Collection and Processing

8.2.001 e1.0	2007	JdSH	Revised to cover blood collection only.
8.2.001 e1.0	JUNE	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 2.0: Added “When blood collection…” • Section 3.0: Added SOP 08.02.002 Blood Processing and Storage. • Section 7.1.2: Added reference of SOP 08.02.002 • Section 7.1.3: Deleted

Blood Collection and Processing Worksheets

The Blood Collection/Processing Worksheet can be customized by specific sites to capture information relevant to the site. The following may be used as a guide for relevant sets of information to record:

Blood Collection

Collection Site	
Date Blood is Drawn	
Time Blood is Drawn	
Date Sample Received by Processing Laboratory	
Time Sample is Received by Processing Laboratory	
Name of Person Drawing Blood	
Additional Collection Notes:	

Sample (tube) Information

Tube Label (Unique identifier)	Tube Type	Tube Lot#	Volume (ml)

DNA Filter Card (if used)

Unique identifier	Card type	Laboratory Technician/ Technologist	Date and Time Created	Card Lot#	# of spots

Plasma Processing
Processed by: Technician/Technologist name
Centrifugation: Duration of spin, G Force, Temperature
Time stored in Transporter:
Plasma Tubes Obtained:

Processed Plasma tube number	Tube 1	Tube 2	Tube 3	Tube 4
Volume				
Storage Location				

Serum Processing
Processed by: Technician/Technologist name
Centrifugation: Duration of spin, G Force, Temperature
Time stored in Transporter:

Serum Tubes Obtained:

Processed Serum tube number	Tube 1	Tube 2	Tube 3	Tube 4
Volume				
Storage Location				

Buffy Coat Processing
Processed by: Technician/Technologist name
Centrifugation: Duration of spin, G Force, Temperature
Time stored in Transporter:
Buffy Coat (White Blood Cell) Tubes Obtained:

Buffy Coat tube number	Tube 1	Tube 2	Tube 3	Tube 4
Volume				
Storage Location				