



Blood Specimen Collection

Section:	Biobank - OHIRC	SOP No:	B-3-001.00
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1. PURPOSE

This SOP outlines standardized procedures for UOHI personnel to follow for the collection of blood samples for the Biobank. This SOP is intended to ensure that blood samples will be obtained from consented participants in a consistent, safe and efficient manner while eliminating the risks of contamination. This SOP does not cover detailed safety procedures for handling blood; personnel must follow institutional bio-safety guidelines. This SOP has been adapted for the UOHI Biobank use from the CTRNet Standard Operating Procedure: Blood Collection.

2. INTRODUCTION

Blood products are a precious resource in the Biobank and procedures must be followed to obtain products with high integrity and quality. Blood samples are drawn from patients and visitors who have been through the informed consent process and agreed to participate in the UOHI Biobank program ("participants"). Blood samples are obtained in accordance with the Biobank Medical Directive for Blood Collection, by personnel qualified to draw blood.

3. ROLES AND RESPONSIBILITIES

Personnel	Responsibility / Role
Chief Scientific Officer / Biobank Principal Investigator	Provide medical directive for blood specimen collection in consented Biobank participants
Biobank Manager / Research Coordinator / Research Assistant	Obtain participant consent
Phlebotomist / Venipuncture nurse / Biobank Manager (nurse) / Research Coordinator (nurse)	Understand Biobank Medical Directive for Blood Collection Draw blood from participant
Biobank Laboratory Technician / Biobank Manager / Research Coordinator / Research Assistant	Transport and Process blood

4. SUPPLIES

Biobank blood collection kits pre-labelled with unique participant ID containing the following items:
Evacuated blood collection tubes (2 x 6ml or equivalent) for serum (e.g. Red top tube such as BD 367815, with silica clot activator)
Evacuated blood collection tubes (3 x 6ml or equivalent) for plasma (e.g. Lavender top tube with K2 EDTA such as BD 367863)
Blood Collection and Processing Worksheet (see Appendix A for sample form)
Extra blood collection tubes and labels, in case replacements are needed in above kits.
Blood collection set with safety engineering (e.g. BD Vacutainer Push Button Blood Collection Set) of appropriate gauge number, 19 G to 23 G
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 participant and phlebotomist

5. PROCEDURES

5.1 *Timing for Blood Collection*

- 5.1.1 Preferably, blood collection should be done pre-operation and as close as possible to the time when the tissue is donated (if applicable) to the biobank. To minimize discomfort for the participant an alternate time when other blood work is being done may be chosen.
- 5.1.2 Contact the person responsible for blood processing and arrange for timely processing.

5.2 *Blood Collection Procedure – Preparation*

- 5.2.1 Identify participant and check that informed consent has been obtained.
- 5.2.2 Verify participant information (in keeping with privacy and ethical policies). Ensure that it corresponds with the participant ID number on the blood collection tube labels and on the Blood Collection and Processing Worksheet.
- 5.2.3 Assess patient's physical and mental disposition and determine if this is the appropriate time to draw blood. Take a history to identify participants on anticoagulants, with anemia or mastectomy.
- 5.2.4 Clean work surfaces with disinfectant as needed, before and after procedure.
- 5.2.5 Perform hand hygiene: wash hands or use alcohol based hand rub prior to and after patient or environment contact.
- 5.2.6 Assemble equipment to draw blood (See Section 4).

5.3 Blood Collection Procedure – Drawing Blood

- 5.3.1 Participant should be in a sitting or supine position. Fully extend the participant's arm, with the hand in a lowered position relative to the shoulder.
- 5.3.2 Apply tourniquet to upper arm to expose veins. Do not place too tightly. If superficial veins are not easily apparent, massage the arm from wrist to elbow, tap the site with index and second finger, apply a warm, damp cloth to the site, or lower the extremity further to allow veins to fill.
- 5.3.3 Select appropriate site for venipuncture. Avoid areas with edema, infection, wounds, scars or hematomas, or side with mastectomy. While hand and forearm veins are acceptable it is optimal to select an antecubital vein.
- 5.3.4 Apply gloves.
- 5.3.5 Prepare the participant's arm using alcohol swab. Cleanse in a circular fashion, beginning at the site and working outward. Allow to air dry.
- 5.3.6 Assemble the blood collection set as per package insert. Remove needle sheath.
- 5.3.7 Anchor the vein and swiftly insert the needle (upwards 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.
- 5.3.8 Follow order of draw: 2 red top tubes followed by 3 purple top tubes.
- 5.3.9 Draw blood into the evacuated blood collection tube(s). Fill tubes completely. When the last tube to be drawn is filling, remove the tourniquet.
- 5.3.10 Remove the needle from the participant and apply a gauze and adequate pressure to the site of venipuncture to avoid hematoma formation.
- 5.3.11 Retract the needle as per package insert. Dispose of needles in sharps container and supplies in appropriate manner.
- 5.3.12 Mix all tubes by inverting 8 times.
- 5.3.13 If any pre-labelled collection tubes were replaced (e.g. no vacuum), promptly label replacement tubes with the matching participant ID number from pre-labelled blood collection tubes and Blood Collection and Processing Worksheet.

5.4 Transport of Blood Sample to Biobank Lab for Processing

- 5.4.1 Transport labelled tubes to the specified biobank lab area for processing blood samples.
- 5.4.2 Do not allow the samples to freeze or be exposed to ambient temperature greater than 25°C.
- 5.4.3 Transport tubes at room temperature (or on wet ice if temperature approaches 25°C).

6. ACRONYMS

OHIRC - Ottawa Heart Institute Research Corporation
SOP- Standard Operating Procedure
UOHI - University of Ottawa Heart Institute

7. RELATED REGULATIONS AND/OR POLICIES

References:

- 7.1 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/>

- 7.2 ICH Guidance E6: Good Clinical Practice: Consolidated guideline
<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php>
- 7.3 Declaration of Helsinki. <http://www.wma.net/en/30publications/10policies/b3/index.html>
- 7.4 WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy
<http://www.ncbi.nlm.nih.gov/books/NBK138665/>
- 7.7 CTRNET Standard Operating Procedures, Canadian Tumour Repository Network
<http://www.ctrnet.ca/operating-procedures>
- 7.8 OTRN OICR Standard Operating Procedures for Biorepositories, Ontario Tumor Repository Network/Ontario Institute for Cancer Research
http://oicr.on.ca/search/apachesolr_search/SOPs%20for%20Biorepositories
- 7.9 Blood Collection: Routine Venipuncture and Specimen Handling
<http://library.med.utah.edu/WebPath/TUTORIAL/PHLEB/PHLEB.html>

Associated OHIRC SOPs:

UOHI Biobank SOP No: B-3-004.00 – Medical Directive for Blood Specimen Collection

8. APPENDICES

8.1 Appendix A – Blood Collection and Processing Worksheet Example

9. HISTORY

SOP #	Effective Date	Review Date	Summary of Changes

Appendix A – Blood Collection and Processing Worksheet Example

Phlebotomy Date: ___/___/___ Time: ___:___
Day Month Year hh:mm

Last consumed calories Date: ___/___/___ Time: ___:___
Day Month Year hh:mm

Last Moderate/Vigorous Exercise, Sustained ≥ 30 minutes: None in last 7 days or Date: ___/___/___ Time: ___:___
Day Month Year hh:mm

Order of draw:	1) <input type="checkbox"/> 6 ml red top #1	2) <input type="checkbox"/> 6 ml red top #2	3) <input type="checkbox"/> 6 ml EDTA #1	4) <input type="checkbox"/> 6 ml EDTA #2	5) <input type="checkbox"/> 6 ml EDTA #3
	<input type="checkbox"/> hemolyzed	<input type="checkbox"/> hemolyzed	<input type="checkbox"/> hemolyzed	<input type="checkbox"/> hemolyzed	<input type="checkbox"/> hemolyzed

Phlebotomist: Biobank staff initials: _____ UOHI Phlebotomist initials: _____ UOHI research coordinator initials: _____

Needle Gauge: 21G 23G Site: superficial vein, antecubital fossa other venous site _____

CRF Completed by: _____

Samples Received in Laboratory: ___/___/___ Time: ___:___
Day Month Year hh:mm

Purple top tube		
Centrifugation Time	Speed	Temperature
___:___ <small>hh:mm</small>	<input type="checkbox"/> 1500 x 15 minutes	<input type="checkbox"/> 4°C

Plasma and Buffy Coat		
Aliquoting Time	Stored in – 80° C freezer Time	
___:___ <small>hh:mm</small>	___:___ <small>hh:mm</small>	
Number of Plasma Aliquots (purple) _____	Number of Buffy Coat Aliquots (white/DNA) _____	Number of Buffy Coat & TRIzol Aliquots (light blue/RNA) _____

Red top tube		
Stand room temperature	Speed	Temperature
	<input type="checkbox"/> 60 minutes	<input type="checkbox"/> 90 minutes (participant on anticoagulant)
___:___ <small>hh:mm</small>	<input type="checkbox"/> 1500 g x 15 minutes	<input type="checkbox"/> 4°C

Serum		
Aliquoting Time	Stored in – 80° C freezer Time	Number of Serum Aliquots (red)
___:___ <small>hh:mm</small>	___:___ <small>hh:mm</small>	_____

Completed by: _____