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| Title | Blood Collection for Biorepositories |
| SOP Code | SOP110_02 |
| Effective Date | 04-Jan-2016 |

Site Approvals

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

The purpose of this Standard Operating Procedure (SOP) is to outline standardized procedures for biorepositories to follow for blood collection from participants who have given informed consent and agree to participate in the biorepository program.

2.0 SCOPE

The SOP describes how blood should be drawn. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals

3.0 RESPONSIBILITIES

The policy applies to all personnel responsible for performing venipuncture to obtain blood from the consented participant. Blood samples are obtained by personnel qualified to draw blood from patients in the cancer centre, hospital or in the physician's office.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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.

5.1 Timing for Blood Collection

- 5.1.1. Blood collection should be done as close as possible to the time when the biospecimen is donated to the repositories. To minimize discomfort for the participant an alternate time when other blood work is being done may be chosen. An alternative time may be chosen if appropriate for the research study.
- 5.1.2. Identify the person responsible for processing the blood.
- 5.1.3. Contact this person before or soon after blood collection to arrange timely processing of the sample.

5.2 Blood Collection Procedure - Preparation

- 5.2.1. Blood collection must be performed by personnel qualified.
- 5.2.2. Fill out the required patient information on the blood specimen requisition.
- 5.2.3. Assess patient's physical and mental disposition and determine if this is the appropriate time to draw blood.
- 5.2.4. Assemble proper equipment to draw blood.

5.3 Blood Collection Procedure – Drawing Blood

- 5.3.1. Position the participant comfortably and ensure the arm is supported
- 5.3.2. Place a tourniquet around the arm and assess the veins as they distend. Do not place the tourniquet too tightly.
- 5.3.3. 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.
- 5.3.4. Cleanse the site with an alcohol swab.

- 5.3.5. 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.
- 5.3.6. Draw blood into the appropriate evacuated blood collection tube. Record the date and time of blood draw.
- 5.3.7. When the last tube to be drawn is filling, remove the tourniquet.
- 5.3.8. Remove the needle from the patient and apply a gauze and adequate pressure to the site of venipuncture to avoid hematoma formation.
- 5.3.9. Dispose of needles and supplies in a safe manner.
- 5.3.10. Mix by inverting tubes 6-8 times or as indicated in the laboratory manual and/or manufacturer's guidelines.
- 5.3.11. Label tubes promptly and appropriately with the labels and make sure that the appropriate matching information is recorded on the blood collection worksheet.

5.4 Transport of Blood Sample to Pathology or Biorepository Lab for Processing

- 5.4.1. Verify patient information (in keeping with privacy and ethical policies) and ensure that it corresponds with the information on blood collection tube labels.
- 5.4.2. Transport specimens in secondary packaging, such as a biospecimen bag or box, within the institution.
- 5.4.3. Responsible personnel or technician should transport labeled tubes to the pathology lab or specified area at the repository for processing blood samples.
- 5.4.4. Should samples be coming from a location distant to the repository, they should be shipped express using an appropriate courier.
- 5.4.5. Transport tubes at room temperature. Do not allow the samples to freeze or be exposed to an ambient temperature of greater than 25° C.

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 |
|-----------|----------------|---|
| SOP110_01 | 01-Aug-2012 | Original version |
| SOP110_02 | 04-Jan-2016 | 1.0 Purpose, 3.0 Responsibilities: Added wording to clarify application for informed consent and qualified personnel. 5.1.1: Removal of “preferably”; allowance for alternative timing added. 5.3.1, 5.3.2, 5.3.4, 5.3.10, 5.4.1: Additional instructions added for clarity. 5.4.2: Instruction for transport added. Updated references. Removed OTRN logo. |
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