 clsa élcv Canadian Longitudinal Study on Aging Étude longitudinale canadienne sur le vieillissement	Title:	Collection of Blood by Venipuncture		
	Version Date:	2015-JAN-21	Document Number:	SOP_BCP_0001
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Data Collection Site (DCS)	Version:	4.0	Number of Pages:	11

1.0 Purpose:

The purpose of this document is to describe the standardized procedure for the collection of blood samples by venipuncture from a study participant. The procedure provides instruction on greeting the study participant, confirming participant identification to verify blood collection.

2.0 Scope:

This document is to be used by all DCS laboratory staff when drawing blood by venipuncture.

3.0 Responsibilities:

It is the responsibility of DCS laboratory staff to perform procedures as described in the current and approved version of the standard operating procedure, to use standard precautions and follow applicable safety regulations.

4.0 Related Documents:

- **SOP_DCS_0030** – Handling Adverse Events and Medical Emergencies
- **SOP_BCP_0005** - Discard of Collected Specimens upon Withdrawal of Consent
- **SOP_BCP_0007** - Housekeeping – Biospecimen Collection
- **SOP_BCP_0406** – Site Specific - Waste Disposal SOP
- **SOP_BCP_0031** - Code Reader 3500 - Operation, Maintenance & Calibration
- **SOP_BCP_0405** – Site Specific – Needlestick Injury SOP
- **DOC_BCP_0001** - Daily Zero Times for Collection of Blood and Urine Samples
- **MAN_BCP_0217** – LabWare Guide

5.0 Definitions:

- **Acid Citrate Dextrose (ACD):** used as an anticoagulant in the yellow stoppered BD Vacutainer tube.
- **Antecubital Fossa:** the large anterior area of either arm that is in front of and slightly below the crease/bend of the elbow. This is an area where large veins lie near the skins surface.
- **Cell Preparation Tube (CPT):** a blue and black stoppered BD Vacutainer tube containing sodium citrate anticoagulant and Ficoll density gradient medium.

- **Ethylenediaminetetraacetic Acid (EDTA):** used as an anticoagulant in the lavender stoppered BD Vacutainer tube.
- **Fistula:** permanent abnormal passageway between an organ, vessel or intestine and another structure. It can result from injury, surgery, infection or inflammation.
- **Hematoma:** A localized swelling that is filled with blood caused by a break in the wall of a blood vessel, also referred to as a bruise.
- **Peripherally Inserted Central Catheter Line (PICC line):** a long, thin, flexible tube inserted in to one of the large veins near the crease/bend of the elbow. It is then slid in to the vein until the tip sits in a large vein just above the heart.
- **Petechiae:** small red spots or a pinpoint red rash on the skin resulting from blood leaking from tiny capillaries under the skin.
- **Vascular Graft:** transplanted or prosthetic blood vessels.
- **Venipuncture:** the puncture of a vein for collecting blood specimens.

6.0 Equipment:

- Brady Code Reader 3500; and,
- LabWare.

7.0 Supplies:

- BD Vacutainer Eclipse Blood Collection Needle with pre-attached holder, 21 gauge disposable;
- BD Vacutainer Safety-Lok Blood Collection Set with pre-attached holder (butterfly);
 - 21 gauge disposable;
 - 23 gauge disposable;
- BD Vacutainer tubes (see **Table 1**);
- Barcode labels;
- Cotton balls;
- Gauze;
- Disinfectant disposable wipes;
- Hand sanitizer;
- Gloves, non-latex disposable;
- Isopropyl alcohol wipes, 70%;
- Paper tape;

- Sharps disposal container;
- Sterile bandages, non-latex; and,
- Tourniquet, non-latex.

8.0 Procedure Steps:

8.1 Gather Supplies

8.1.1 Assemble the following items for each participant:

- 1 set of 15 barcode labels;
- Tubes (see **Table 1**);
- 21 or 23 gauge BD Vacutainer Safety-Lok Blood Collection Set with pre-attached holder;
 - **For most participants** use a 21 gauge Vacutainer Safety-Lok Blood Collection Set;
 - **For small veins** use a 23 gauge BD Vacutainer Safety-Lok Blood Collection Set;
 - **For an obese participant** use a 21 gauge BD Vacutainer Eclipse Blood Collection Needle;
- 1 cotton ball;
- Bandage;
- Alcohol wipe;
- Tourniquet; and,
- Non-latex gloves.

8.1.2 Place all supplies on a table near/ the phlebotomy chair so that they are within easy reach during venipuncture. Be certain that the supplies are safe and will not roll away or fall over.

8.1.3 Check expiry dates on the tubes. **Do not use expired tubes.**

8.1.4 Place the tubes on the table in the planned order of draw. Refer to **Table 1**.

8.1.5 Tap all of the tubes to ensure any additives are at the bottom of the tubes to facilitate immediate mixing as blood is collected.

Table 1. Blood collection tubes and order of draw

Draw Order	Tube Type	Additive	Closure Color	Tube Volume (mL)	Number of Tubes	Total Volume (mL)
1	No Additive	None	Red & Grey			
2	Citrate	3.2% buffered sodium citrate solution, 0.109 M	Light Blue	2.7	2	5.4
3	Serum	Spray coated silicone and micronized silica particles	Red	10	1	10
4	Heparin	Lithium heparin, 90 USP	Green	10	1	6

5	EDTA	Spray coated K ₂ EDTA, 10.8 mg	Lavender	3	1	3
6	EDTA	Spray coated K ₂ EDTA, 10.8 mg	Lavender	6	3	18
7	ACD	Trisodium citrate, 13.2g/L; citric acid, 4.8 g/L; and dextrose 14.7 g/L, 0.4 mL	Yellow	3	1	3
8	CPT	Sodium citrate 0.45 mL 0.1 M and Ficoll medium	Blue & Black	8	1	8

8.2 Greet and Identify the Participant

8.2.1 Greet the participant, identify yourself and check if consent has been given for blood and urine collection by checking for a coloured dot sticker on the participant interview ID badge.

- Red – both blood and urine collected
- Yellow – urine only collected
- Blue – no samples will be provided

If the study participant has not consented, direct them back to Reception.

8.2.2 Ask the study participant to sit in the phlebotomy chair. Provide assistance if requested. Use the reclining position only if it is impossible for the participant to sit upright during the procedure. Take note of participant position in phlebotomy chair for Onyx after blood collection.

8.2.3 Ask the participant for their interview ID barcode, which may be in a plastic sleeve. Scan their interview ID barcode into Onyx. Verify that the blood stage in Onyx is available. If blood collection is contraindicated, continue to *SOP_BCP_0002 – Collection of Random Urine Specimens* for urine collection instructions.

8.2.4 Ask the participant to swallow any food or drink in their mouth before continuing. Chewing gum or any other object should also be discarded. **Nothing should be in the participant's mouth at the time of venipuncture.**

8.2.5 Open the blood stage and scan participant interview ID barcode.

8.2.6 Ask the participant the questions shown in Onyx pertaining to consent, food, drink, caffeine, tobacco and alcohol consumption. Enter the participant's answers in Onyx.

8.2.7 Wash hands, scrubbing vigorously with soap and water for 15 seconds, or alternately sanitize hands with waterless hand sanitizer.

8.2.8 Return to the participant to begin blood collection.

8.3 Explain the Blood Collection Procedure

8.3.1 Explain the following to the study participant:

- You will be placing their arm on a pillow for added support (if required).
- You will select a vein and disinfect the area using an alcohol wipe.

- The tourniquet that you will be using is new and will be discarded after use or disinfected after use depending on the type of tourniquet being used.
- The tourniquet will be wrapped around the arm approximately 10 cm above the selected venipuncture site.
- The needle being used is new and will be disposed of following the blood draw.
- A small volume of blood (about 1 mL) will be drawn to prime the blood collection system. This tube of blood will be discarded.
- After the discard tube, 10 tubes of blood will be collected.
- The total quantity of blood to be collected is approximately 50 mL or slightly more than 3 tablespoons.

8.3.2 Ask the study participant if there are any questions and answer them according to the CLSA specific information.

8.3.3 Ask if the study participant is ready to proceed.

8.4 Selection of Venipuncture Site

8.4.1 Ask the participant to extend both arms so that the veins are accessible.

8.4.2 Observe both arms for the following contraindicated conditions:

- Casts or prosthetic arms;
- Surgery of arm, breasts, or both sides of chest within the last 3 months, or arteriovenous shunt/fistula;
- Severe swelling, open sores, wounds, infection or burns;
- Hematoma of any size;
- Sclerotic, hard veins;
- Fibrosed, inflamed or fragile veins;
- Red, swollen veins;
- Sites showing petechiae;
- Tattoos;
- Extensive scarring;
- Arms with vascular graft;
- Paralyzed arm from stroke; and,
- Arm with a PICC line.

8.4.3 In Onyx, record any of the conditions observed in 8.4.2 for both arms, and do NOT draw blood from the arm(s) where any of these conditions are present.

8.4.4 Select a site for venipuncture.

8.4.5 Offer the participant a pillow to support their arm if required.

8.4.6 Hold the pillow and ask the study participant to place their arm in a downward position on the pillow. The pillow will support and help maintain arm position, preventing backflow from the tube into the vein.

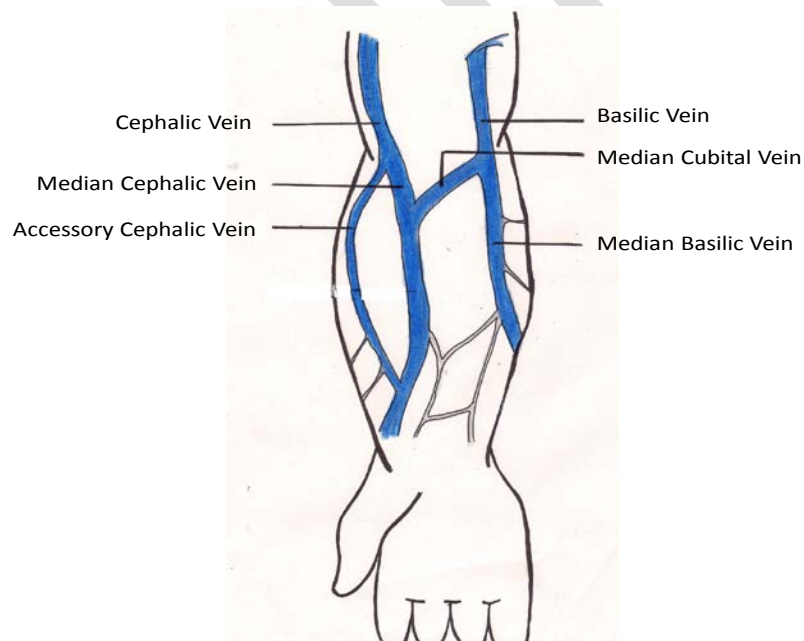
8.4.7 Ask the study participant to extend and externally rotate their arm (turning the palm upward toward the ceiling) in a straight line from shoulder to wrist, exposing the veins.

8.5 Selection of Vein

NOTE: During vein selection, **the maximum time for tourniquet application is 1 minute.** If it takes longer than this to make the vein selection and insert the needle, then release the tourniquet and reapply after 2 minutes.

- 8.5.1 Wrap a tourniquet around the arm approximately 10 cm above the venipuncture site. If there is a skin lesion at this site, move the tourniquet slightly higher or lower to avoid it, OR apply the tourniquet on top of the participant's sleeve or gauze.
- 8.5.2 Ask the participant to clench their fist, but to avoid vigorous hand pumping.
- 8.5.3 Feel for a vein in the antecubital fossa using your index or middle finger. Refer to **Figure 1, including the preferred order of veins to use.**
- 8.5.4 Assess vein depth and size, using your index or middle finger, and make selection.

Figure 1. Vein Selection



The preferred order of vein selection is:

1. Median cubital vein
2. Median cephalic and median basilic veins
3. Cephalic and accessory cephalic veins
4. Dorsal veins on the back of the hand – use only as a last resort and only if the study participant is willing.

Avoid:

1. Veins from the inner wrist
2. Basilic vein

8.6 Prepare the Puncture Site

8.6.1 Put on non-latex gloves.

8.6.2 Open the 70% isopropyl alcohol wipe and clean the selected venipuncture site from the centre outward using a circular motion. Discard the wipe, ensuring that you do not touch the side of the skin wipe that was in contact with the study participant's arm.

8.6.3 Allow the area to air dry. **Do not blow on the area or wipe dry.** Do not touch the selected puncture site after disinfection.

8.7 Perform Venipuncture

8.7.1 Open the needle package.

8.7.2 Prepare the needle for venipuncture according to needle type:

i. Safety-Lok Blood Collection Set

Step 1: Check that the needle and holder of the "butterfly" blood collection set are securely attached.

Step 2: Hold the blood collection set so that the wings of the "butterfly" are gently pushed together.

Step 3: Remove the needle sheath.

ii. Eclipse Blood Collection Needle

Step 1: Position the pink safety shield straight back towards the holder.

Step 2: Twist and pull the colored needle cap straight off. DO NOT twist, rotate or pull off the pink safety shield.

8.7.3 Hold the study participant's arm and fix the vein by gently pulling the skin taut approximately 5 cm below the site of entry.

NOTE: Do not anchor the vein above the puncture site as this increases the possibility of needle stick injury.

8.7.4 Position the needle bevel up at a 15 to 30 degree angle with the vein. This angle reduces the possibility of puncturing through the vein.

8.7.5 Inform the participant the venipuncture is about to occur. Carefully observe the participant for any adverse reactions i.e., dizziness or fainting, and respond according to *SOP_DCS_0030 – Handling Adverse Reactions and Medical Emergencies*.

NOTE: In the case of a needlestick injury, please refer to *SOP_DCS_0405 – Site Specific – Needlestick Injury SOP*.

8.7.6 Push the needle, with a smooth motion, into the vein.

ALERT: If a study participant is experiencing an intense shooting electrical pain sensation, tingling or numbness, this indicates nerve involvement. Remove the tourniquet immediately and go to step 8.7.16.

- 8.7.7** If using the **Safety-Lok Blood Collection Set**, insert the discard (no additive) tube, and then proceed to Step 8.7.8.

If using the **Eclipse Blood Collection Needle with butterfly** release the wings with care and pierce the discard tube. The tube must be held lower than the needle. Hold the flanges of the tube holder for added stability.

- 8.7.8** Draw blood until the tubing of the blood collection set is filled. There will be approximately 1 mL of blood in the discard tube. Make certain that the blood collection tube remains angled downward to prevent reflux.
- 8.7.9** Remove the discard tube carefully and set aside. The needle sleeve will recover the tube-piercing point during the exchange of tubes and prevent blood flow.

If blood is not flowing try one or more of the following steps

1. Pull gently back a small amount on the needle, if the needle has gone through the vein.
2. Push gently in a small amount on the needle, if the needle has not penetrated to the middle of the vein.
3. Tube may be vacuum defective. If so, replace the blood collection tube with a second tube.
4. Remove the tourniquet and go to step 8.7.17.
5. Select another vein/site and re-attempt venipuncture procedure with the participant's permission.

- 8.7.10** Insert the Citrate tube. Allow blood to fill the tube.

- 8.7.11** Have the study participant open and close their hand slowly and gently to allow blood to flow.

- 8.7.12** Remove the tube carefully once the vacuum is exhausted and blood flow into the tube stops.

NOTE: Tubes may not fill completely as per manufacturer's specifications.

- 8.7.13** Immediately mix the Citrate tube by gently inverting 5 to 10 times. Avoid vigorous shaking to prevent blood hemolysis. Carefully set the filled tube to the side.

- 8.7.14** Insert the next tube according to the order of draw in **Table 1**.

- 8.7.15** Repeat procedure steps 8.7.10 to 8.7.15 until all tubes have been filled.

- 8.7.16** Remove the tourniquet.

- 8.7.17** Place a clean cotton ball loosely over the puncture site and lightly apply pressure to hold the cotton ball in place.

8.7.18 Remove the needle using one of the safety procedures outlined below.

Safety-Lok Blood Collection Set

Step 1: Grasp the yellow safety shield grip area and the tubing at the same time.

Step 2: Remove the needle from the study participant's vein in a smooth motion.

Step 3: Close the yellow safety shield with thumb and index finger until a click is heard and the shield is locked, covering the needle tip.

Eclipse Blood Collection Needle

Step 1: Place your thumb on the pink safety shield thumb pad and push the safety shield forward to cover the needle.

Step 2: Lock the safety shield in place. Do not press the safety shield against a hard surface.

8.7.19 Discard the used blood collection set and holder directly in the sharps container. Place the needle in the sharps container first and allow the tube holder to drop after.

8.7.20 Continue to apply firm pressure to the cotton ball covering the venipuncture site and keep the participant's arm straight. Allow the participant to apply pressure if they agree and are comfortable doing so.

8.7.21 In Onyx, complete the "inspect the draw site questions" as to which arm was chosen, the needle type used, whether the participant is sitting or reclining, if the blood was collected and the number of attempts.

8.8 Complete the Venipuncture

8.8.1 Check the venipuncture site to be sure that a clot has formed and the bleeding has stopped. Continue to apply pressure, or have the participant continue to apply pressure, until bleeding has stopped.

8.8.2 Apply a bandage or a strip of paper tape over the cotton ball once bleeding has stopped. Recommend to the study participant that the bandage or paper tape be kept in place for a minimum of 15 minutes.

8.9 Label Biospecimen Tubes

General Instructions

- **Label** all biospecimen tubes while the participant is still seated.
- Align the barcode label lengthwise along the axis of the tube.
- Apply label so the surface is free of wrinkles and the barcode is clearly visible.
- Ensure that **only one column** of labels is used for each participant.
- **NOTE:** It is important to label the CPT tube and the 15 mL CPT PBS wash conical tube with sequential labels from one column of labels for a single participant (e.g., 70029 & 70030). This is necessary for processing multiple CPT tubes to prevent mixing up of samples.

8.9.1 In LabWare, in **Assign Sample Labels** tab, click on the **Sample Label Assignment** title. This will generate a dialog box. Scan the participant's interview ID. The time that blood collection started will automatically populate in the Time Zero information window. When urine is collected prior to blood collection enter in the time written on *DOC_BCP_0001 - Daily Zero Times for Collection of Blood and Urine Samples*. Answer the questions "Blood collected?" and "Urine collected?"

8.9.2 Label and scan all tubes in the order listed below.

- Discard tube (no additive);
- CPT;
- CPT PBS wash conical tube;
- Urine container;
- Serum;
- ACD;
- EDTA, 3 mL;
- EDTA, 6 mL (3x);
- Heparin;
- Citrate;
- Citrate PPP – 5 mL round bottom tube; and,
- Buffy Coat – 5 mL round bottom tube.

NOTE: If any tube is not collected you will not have any tube for that sample to scan (due to lack of blood drawn, etc). Refer to *MAN_BCP_0217 - LabWare Guide*.

8.9.3 In LabWare, in **Assign Sample Labels** tab, click on the **Citrate Platelet Poor Plasma (PPP)** button.

8.9.4 Scan the label on the Citrate PPP - 5 mL round bottom tube to assign it to PPP test.

8.9.5 In LabWare, in **Assign Sample Labels** tab click on **Buffy Coat** button.

8.9.6 Scan the Buffy Coat – 5 mL round bottom tube to assigning it to buffy coat test

All samples must be labeled in LabWare for a current participant before starting the next step, Check by viewing the LabWare Sample Folder for that participant.

8.9.7 Ask the study participant if they are feeling light-headed or dizzy.

- **IF YES:** Keep the study participant seated until capable of standing and proceeding. The phlebotomy chair may also be reclined.
- **IF NO:** Thank the participant. Proceed to *SOP_BCP_0002 – Collection of Random Urine Specimens* for urine collection instructions or direct the participant to the reception if urine has already been collected or will not be collected.

8.9.8 Move the labeled tubes to the processing bench or biosafety cabinet.

8.10 Clean Phlebotomy Station

- 8.10.1 After each participant, wipe the blood collection station, including the pillow and anything that comes in contact with the participant's arm with approved disinfectant wipes.
- 8.10.2 Wipe the chair with a disinfectant wipe if visibly soiled and at the end of each day. Refer to *SOP_BCP_0007 -Housekeeping - Biospecimen Collection*.

9.0 Documentation and Forms:

- CRF_BCP_0001 – Blood and Urine Collection Case Report Form
- LabWare Laboratory Information Management System (LIMS)

10.0 References:

- Clinical and Laboratory Standards Institute (CLSI) H3-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard Sixth Edition. Vol.27 No. 26.
- BD Vacutainer Evacuated Blood Collection System Product Insert, 11/2010.

Baseline Revision History:

New Version #	Revision Date	Revision Author	Content Approval
4.0	2015-Jun-26	Chetna Naik	Cynthia Balion
Summary of Revisions			
Added MAN_BCP_0217 – LabWare Manual to Related Documents section.			
Various sections were reorganized and edited to make the steps and instructions clearer.			
Sections 'Greet the Participant' and 'Identify the Participant' combined into one, 8.2 Greet and Identify the Participant. Steps reordered.			
In Table 1 , corrected ACD tube volume to 2.7.			
Added reference to the Site Specific - Needlestick Injury SOP to Step 8.7.5 and to Related Documents .			
Completed sentence in ' If blood is not flowing ' box under Step 8.7.9, Step 3 : Tube may be vacuum defective. If so, replace the blood collection tube with a second tube.			
Under Section 8.9 , removed 'Scan linear barcode' from the list of General Instructions .			
Under Section 8.9 General Instructions , added NOTE : It is important to label the CPT tube and the 15 mL CPT PBS wash conical tube with sequential labels from one column of labels for a single participant (e.g., 70029 & 70030). This is necessary for processing multiple CPT tubes to prevent mixing up of samples.			
Under 8.9.2, edited note: NOTE : If any tube is not collected you will not have any tube for that sample to scan (due to lack of blood drawn, etc). Refer to MAN_BCP_0217 - LabWare Guide . Specify the reason (e.g., collapsed vein, slow bleed) on CRF BCP_0001 – Blood and Urine Collection Case Report Form and press Enter on the keyboard to skip and continue in LabWare.			
Updated Purpose section.			
SOP formatting updated.			
New Version #	Revision Date	Revision Author	Content Approval
3.0	2013-OCT-31	Chetna Naik	Cynthia Balion
Summary of Revisions			
NOTE : Due to clerical error released version 1.0 a second time			
8.2 Added instruction regarding returning for blood on a different date than urine donation			

New Version #	Revision Date	Revision Author	Content Approval
3.0	2013-JUN-14	Lori Dewar	Cynthia Balion
Summary of Revisions			
Section 4.0 Added time zero to document			
Section 5 added definition for CVS and hematoma and vascular graft			
Section 6 added 2D scanner and Brady code reader to the equipment			
8.1.1- Moved needle size recommendation			
8.3.3 - Added info for contraindications to be checked			
8.4.1 -Removed tourniquet cannot be reused info			
8.5.2 - Added info to check for exclusions			
8.8.6 – Added collection of time zero information			
8.8.9 – Removed the blood not flowing recommendation info			
8.9.4 to 8.9.7 – Label Vacutainers and using information added			
8.9.8 – Added direct the participant to the reception			
8.10 Addition of instructions for labeling biospecimens and scanning into LabWare.			
8.11 – Renumbered section for completing the interview			
8.12 – Renumbered cleaning the bleeding station section			
New Version #	Revision Date	Revision Author	Content Approval
2.0	2012-JUN-12	Lori Dewar	Cynthia Balion
Summary of Revisions			
Updated table 1			
New Version #	Revision Date	Revision Author	Content Approval
1.0	2012-MAY-03	Lori Dewar	Cynthia Balion
Summary of Revisions			
NOTE: Due to clerical error released version 1.0 a second time			
Added document numbers in section 4.0			
Reworded PICC line definition			
Updated section 7.0			
Updated step 8.1.1, 8.5.2 to correct contain correct consumables			
Updated table 1			
Updated 8.8.1 to include all needle types			
Removed section 8.9 Perform Venipuncture using BD Vacutainer Eclipse Blood Collection Needle with pre-attached holder			
Removed steps 8.10.5 – 8.10-9 and 8.11.1			
Added steps 8.9.6 and 8.9.8			