clsa élcv Canadian Longitudinal Study on Aging Étude longitudinale canadienne sur le vieillissement	**Title:**	**Collection of Blood by Venipuncture**		
	Version Date:	2018-APR-09	**Document Number:**	SOP_BCP_0001
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Data Collection Site (DCS)	**Version:**	5.0	**Number of Pages:**	12

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_BCP_0002** – Collection of Random Urine Specimens
- **SOP_DCS_0030** – Handling Adverse Events and Medical Emergencies
- **SOP_DCS_0033** – Reagents and Consumables – Inventory Control and Ordering Information
- **SOP_BCP_0005** – Discard of Collected Specimens upon Withdrawal of Consent
- **SOP_BCP_0007** – Housekeeping – Biospecimen Collection & Processing
- **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
- **MAN_BCP_0217_2** – LabWare Guide
- MSDS

5.0 Definitions:

- **Acid Citrate Dextrose (ACD):** an anticoagulant used 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.
- **Leucosep:** Leucosep tubes are used to separate lymphocytes and peripheral mononuclear cells from human whole blood through density gradient centrifugation.
- **Ethylenediaminetetraacetic Acid** (**EDTA)**: an anticoagulant used 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:

- 2D barcode scanner (Brady Code Reader 3500 or Honeywell); 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.

7.0 Procedure Steps:

8.1 Gather Supplies

8.1.1 Assemble the following items for each participant:

- 1 set of 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 If starting a new lot number of Vacutainers log the participants interview ID in the corresponding *DOC_DCS_0033 - BCP Lot Controlled Consumable Tracker.*

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

8.1.6 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	6	1	6

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–blood collected
- Yellow – urine 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, 9 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;
- Extensive scarring;
- Arms with vascular graft;
- Paralyzed arm from stroke; and,
- Arm with a PICC line.

NOTE: If there is a tattoo on the draw site, allow participants to decide if they want to provide a blood sample.

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.

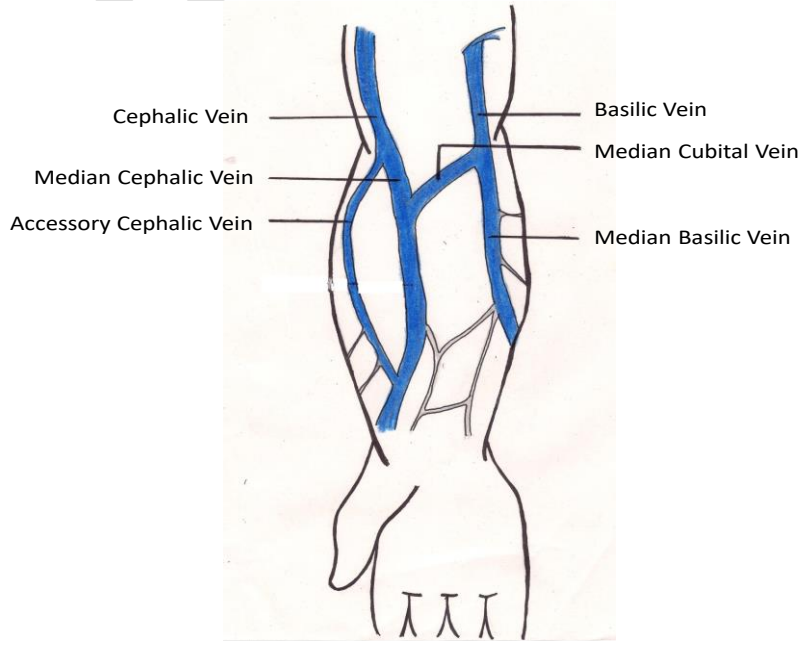
8.5.1 Wrap a tourniquet around the arm approximately 10 cm above the venipuncture site. If there is a skin lesion at this site, move the tourniquet slightly higher or lower to avoid it, OR apply the tourniquet on top of the participant's sleeve or gauze.

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:

8.7.2.1 Safety-Lok Blood Collection Set

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

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

8.7.2.1.3 Remove the needle sheath.

8.7.2.2 Eclipse Blood Collection Needle

8.7.2.2.1 Position the pink safety shield straight back towards the holder.

8.7.2.2.2 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 needle and tourniquet immediately and go to step 8.7.16.

8.7.7 If using the **Eclipse Collection Set**, insert the discard (no additive) tube, and then proceed to step 8.7.8.

If using the **Safety-Lok 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.

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.
6. DO NOT attempt the venipuncture procedure more than twice.

8.7.9 Remove the discard tube carefully and set aside. The needle sleeve will re-cover the tube-piercing point during the exchange of tubes and prevent blood flow.

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.

8.7.18.1 Safety-Lok Blood Collection Set

8.7.18.1.1 Grasp the yellow safety shield grip area and the tubing at the same time.

8.7.18.1.2 Remove the needle from the study participant's vein in a smooth motion.

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

8.7.18.2 Eclipse Blood Collection Needle

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

8.7.18.2.2 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 Leucosep tube and the 15 mL Leucosep 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 Leucosep tubes to prevent mixing up of samples.

8.9.1 In LabWare, in **Assign Sample Labels** tab, click on the **Sample Label Assignment** button. 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);
- Leucosep;
- Leucosep PBS wash conical tube;
- Urine container;
- Serum;
- ACD;
- EDTA, 3 mL;
- EDTA, 6 mL (3x);
- Heparin;
- Citrate (2x); and,
- Citrate PPP – 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.*

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.

8.9.3 In LabWare, in **Assign Sample Labels** tab, click on the View Collection Samples button and open the recent Participant Sample Folder.

8.9.4 In the Participant Sample folder, check that all required tubes are assigned. If they are, click on the CLSA menu button and choose Label Assignment Complete. If any tubes were not collected, LabWare will prompt to enter the reasons.

8.9.5 If the wrong arm was selected, you can modify that by clicking on the CLSA menu item and choosing Sampled Arm Assignment. Refer to *MAN_BCP_0217 – LabWare Guide* for further details.

8.9.6 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.

8.9.7 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

- **DOC_BCP_0001** – Daily Zero Times for Collection of Blood and Urine Sample

- **DOC_DCS_0033** – BCP Lot Controlled Consumable Tracker

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.

F2 Revision History:

New Version #	Revision Date	Revision Author	Content Approval
5.0	2018-APR-09	Chetna Naik	Cynthia Balion
Summary of Revisions			
Added reference to 2D Barcode Scanner in section 6.0, now referring to either the Brady Code Reader or the Honeywell.			

Updated number of tubes: now collecting **three 6 mL EDTA tubes**. Now only collecting 9 tubes total.
Corrected Step 8.7.7 – the Eclipse and Safety-Lok needle references were mixed up – it is the Safety-Lok that has the butterfly.
Removed reference to Buffy Coat in list of tubes at Step 8.9.2.