

Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures			
SOP #103 Revision #	TITLE: Venipuncture - 2 years & older for Phlebotomy		Page 1 of 10
Approved By: ORC Director <i>Chris Haydon</i>	Signature <i>Chris Haydon</i>	Date <i>June 21, 2019</i>	Date First Effective: <i>July 1, 2019</i>
Approved By: Biomedical IRB Chair	Signature <i>[Signature]</i>	Date <i>July 1, 2019</i>	Revision Date:
Approved By: Social / Behavioral IRB Chair	Signature	Date	Revision Date:
Expiration Date	<i>July 1, 2022</i>		

Please note: At least one IRB Chair and the ORC Director must review, approve and sign-off on the SOP for it to be in effect. Following review the SOP will be approved with a three (3) year expiration date.

OBJECTIVE

To describe the policies and procedures for the proper and safe collection of blood samples for laboratory testing in individuals two years of age and older. This SOP does not cover venipuncture for intravenous access, insertion of a saline lock, or blood sampling from a saline lock.

GENERAL DESCRIPTION

- a. *Brief description of the technique or procedure that could be used in the Project Outline Form.*
Blood will be collected by an individual trained in the procedure (see Training section below) using aseptic technique and following principles to avoid exposure to bloodborne pathogens. A total of [insert number] mL of blood will be drawn from a peripheral vein. This procedure will be repeated # times, at visit number, time points.
- b. *Brief description of the technique or procedure that would be used in the Consent Form.*
Someone trained to draw blood will use a sterile needle to get [# mL, # tablespoons or teaspoons or some other familiar reference volume] from a vein in your forearm or hand. This will be done again at visit # or at time point x. Your body will replace the amount of blood taken. You should let the study team know ahead of time if you have ever had problems getting your blood drawn before, such as passing out or feeling faint, or if you are not comfortable having this

**Ohio University Office of Research Compliance and Institutional Review Board
Standard Operating Procedures**

SOP #103
Revision #

**TITLE: Venipuncture- 2 years &
older for Phlebotomy**

Page 2 of 11

done, or if you are taking medications such as blood thinners that may make you bruise more easily. Risks include feeling light-headed, fainting, bruising at the site where the needle goes into the skin, bleeding afterwards, or seizures. We will make every attempt to keep these events from occurring. There is also a possibility that the staff member is not able to obtain enough blood. If this happens, you will be asked to give permission for a second attempt. A maximum of (insert the max #) blood draws will be attempted with the permission of the participant.

c. *Brief description of the technique or procedure that would be used in the Assent Form.*

A blood draw is a test to check your blood and see how your body is working. A tourniquet will be used and it looks like a long, rubber band. It is used to help see your veins better. It will feel like a tight squeeze on your arm or hand. Then we make sure everything is very clean. A small area of your skin will be washed with a wipe, which may be smelly. It may feel cold and wet. You will then have your arm pricked by a needle so that we can draw blood. Some kids say they feel a little pinch when it goes in. A small amount of blood is taken from your vein (the blue lines in your hands or arms). Your blood then goes into a special tube to keep it safe from germs. Once done, a cotton ball will be placed where the blood was taken and tape or a bandage will be put on the cotton ball to keep it in place.

d. *Brief description of the technique or procedure that would be used in the Parental Consent Form.*

Someone trained to draw blood will use a sterile needle to get [# mL, # tablespoons or teaspoons or some other familiar reference volume] from a vein in your child's forearm or hand. [This will be done again at visit # or at time point x.] Your child's body will replace the amount of blood taken. You should let the study team know ahead of time if your child has ever had problems getting blood drawn before, such as passing out or feeling faint, or if you are not comfortable having this done, or if your child is taking medications such as blood thinners that may make your child bruise more easily. Risks include feeling light-headed, fainting, and bruising at the site where the needle goes into the skin, bleeding afterwards, or seizures. We will make every attempt to keep these events from occurring. There is also a possibility that the staff member is not able to obtain enough blood. If this happens, you will be asked to give permission for a second attempt. A maximum of (insert the max #) blood draws will be attempted with the permission of the participant.

e. *Confirm the target age range for the technique or procedure, as needed.*
This SOP is for individuals two years of age and older.

Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures		
SOP #103 Revision #	TITLE: Venipuncture- 2 years & older for Phlebotomy	Page 3 of 11

TRAINING

In Ohio, under proper supervision, personnel can draw blood from individuals regardless of previous experience or education. Drawing blood and handling specimens does not require a license in Ohio. The person performing the procedure must first complete the OU Bloodborne Pathogens Training before attempting phlebotomy, and refresher training as required by the OU Environmental Health and Safety Office. The person drawing blood will be supervised or personally approved by a licensed or certificated health professional (e.g., physician, nurse, certified medical assistant) who is experienced in drawing blood before their first attempt on a research subject.

RESPONSIBILITY

The Principal Investigator (PI) or delegated study staff are responsible for performing proper and safe venipuncture. Venipuncture and documentation will be performed as specified by the study protocol. If the study protocol does not specify particular requirements, then the PI or delegated study staff will follow the procedure below.

PROCEDURES

- a. *Detailed description of the list of steps needed to use the technique or complete the procedure.*

SAFETY

Specialized clothing or equipment is required for protection against infectious materials. Personalized Protective Equipment (PPE) for venipuncture will include gloves and lab coats.

Special considerations for a child

- Good communication is necessary
- Positive body language (cheerful/relaxed)
- Soft voice
- Eye to eye contact
- Listen
- Demonstrate sensitivity to child's wishes
- Involve child with procedure if age appropriate
- Be honest

Challenges: Age-specific behavior should be considered prior to collection:

**Ohio University Office of Research Compliance and Institutional Review Board
Standard Operating Procedures**

SOP #103
Revision #

**TITLE: Venipuncture- 2 years &
older for Phlebotomy**

Page 4 of 11

Psychological

- Fear of strangers
- Limited language use
- Fear of pain
- Separation anxiety

PROCEDURE

Preparation: Assemble Supplies

Chux or other drape to cover work surface

Needles, 19-23 gauge, multi-sample or wing-tipped (butterfly) (Note - gauge depends on many factors, including size of vein and protocol)

Single use, needle holder for evacuated system

Tourniquet

Alcohol prep pads

Gauze pads

Adhesive band aids

Disposable latex-free gloves

Blood collection tubes

Sharps container

Cavi-wipes or other disinfectant for clean-up

Other Supplies As Needed:

Blood collection tube labels

Laboratory requisition

Biohazard bags (for transport of collection tubes)

Centrifuge

Pipettes (for drawing off serum and plasma)

Plastic transfer tubes (for serum and plasma)

Preparing for Venipuncture

- After assembling equipment, ensure all information for sample processing has been reviewed and needed supplies are on hand (e.g., dry ice, coolers for sample transfer, centrifuges, availability of refrigerators/freezers, shipping materials, etc.).
- Greet the individual and introduce yourself.
- Identify the individual.
- Verify diet restrictions and time requirements.
- Position the individual comfortably in a chair or lying back on a bed.
- Explain the procedure as needed.

**Ohio University Office of Research Compliance and Institutional Review Board
Standard Operating Procedures**

SOP #103
Revision #

**TITLE: Venipuncture- 2 years &
older for Phlebotomy**

Page 5 of 11

- Assemble supplies. Check the expiration date on each collection tube, put on gloves, apply tourniquet and palpate venipuncture site for vein before cleansing.
- Select the venipuncture site. The most frequently used veins are the superficial veins located in the forearm and hand. Commonly used are the median cubital vein and cephalic vein. Other veins in the anterior surface of the forearm, as well as on the back of the hand are acceptable sites. **Lower extremities, legs, feet, ankles and underside of wrist are not acceptable.**
- Remove tourniquet.
- If palpation and/or visualization is difficult, consider the following actions:
 - 1) Consult with another phlebotomist, if available.
 - 2) Use a vascular visualization device, if available.
 - 3) Use a heating pad to warm the extremity if not contraindicated.
 - 4) Have subject drink water to increase hydration if not contraindicated (i.e. fasting).

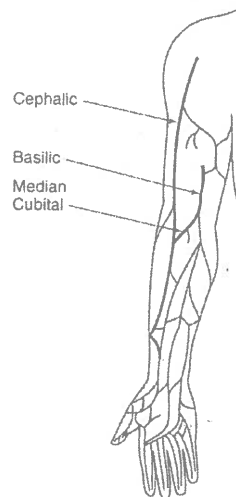


Figure 4-3 Major veins of the arm.

Performing Venipuncture (Evacuated System)

- Open alcohol pad, gauze pad, and organize supplies on protected work surface.
- Apply tourniquet.
- Put on protective gloves.
- Special considerations for child: If required, have an assistant hold child. The assistant places one hand, palm up, under the child's elbow. The other hand is placed palm down on the child's wrist. The assistant's fingers should be placed in such a manner as to allow the child to squeeze the fingers.
- Cleanse venipuncture site with alcohol pad, moving pad in a circular motion from the center to the periphery, and allow to dry (residual alcohol may cause

Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures		
SOP #103	TITLE: Venipuncture- 2 years &	Page 6 of 11
Revision #	older for Phlebotomy	

hemolysis of specimen as well as a stinging sensation when skin is punctured).

- After inspecting the needle for hooks/barbs, anchor the vein and, with the bevel of the needle directed up, perform venipuncture (approximately at a 15-30 degree angle).
- Holding the needle steady, push collection tube into vacutainer needle and allow the tube to fill. Once filled, remove the tube. If multiple tubes are required, insert each tube using the correct order of draw. Mix tubes with additives immediately by gently inverting them 4-5 times. Do not shake tubes vigorously.

NOTE: Recommended order of draw unless specified by the study protocol:

- 1) Blood Culture tube
- 2) Blue (Citrate)
- 3) Serum tube with or without gel (Red, Gold or SST)
- 4) Green (Heparin)
- 5) Lavender (EDTA)
- 6) Gray (Oxalate/Fluoride)

- Release tourniquet.
- Fold gauze into quarters (to act as a pressure bandage) and place over venipuncture site.
- Remove needle by withdrawing slowly. Safely dispose of needle immediately in appropriate sharps container to prevent accidental needlestick injury.
- Apply pressure to venipuncture site until bleeding has stopped.
- Apply band aid. **Note:** Some individuals may be allergic to adhesives on band aids. Always ask before applying band aid.
- Special considerations for a child: Give rewards and praise.

Procedural Notes:

- Blood samples should not be drawn from an arm receiving IV fluids.
- Do not perform venipuncture on the arm on the side on which a mastectomy has been performed or lymph nodes removed.
- Do not collect samples from an area with a hematoma.
- Avoid scar tissue and areas with extensive burns.
- Do not obtain samples from edematous extremities (arms or hands).
- Do not obtain samples from thrombosed veins.
- Do not obtain samples from a cannula or fistula (e.g. a surgically created connection between an artery and vein).
- Do not obtain samples through tissue that is infected, e.g. with an abscess or more diffuse redness and thickening of the skin (cellulitis).

**Ohio University Office of Research Compliance and Institutional Review Board
Standard Operating Procedures**

**SOP #103
Revision #**

**TITLE: Venipuncture- 2 years &
older for Phlebotomy**

Page 7 of 11

Specimen Labeling

- Complete laboratory requisition per study lab manual.
- Label each specimen tube as required per study lab manual (e.g., Study, Subject ID#, Subject Initials, Date of Collection, and Time of Collection).
- Prepare specimens for shipment per study lab manual.

b. *Description of calibration steps needed to check the performance of the device or instrument and documentation that it is maintained.*
Not applicable.

c. *Description of cleaning needed to maintain and / or sterilize the device or equipment.*

Clean-up

Clean area with Cavi-wipes or other disinfectant.
Dispose of contaminated material in a biohazard bag.
Dispose of needles and syringes in a sharps container.

d. *Brief summary of the procedure that would be used for the Project Outline Form.*
See General Description section a, above.

e. *Brief summary of the procedure that would be used for the Consent Form.*
See General Description section b, above.

RISK

a. *Description to be used for the Project Outline Form.*

POTENTIAL COMPLICATIONS

Pre-fainting Symptoms (increased nervousness, increased respiration, a slow and weak pulse, pallor, mild sweating, nausea, or vomiting).

Treatment:

Stop procedure

Immediately remove tourniquet and needle

Speak calmly and have individual lower head to a position no higher than their heart and breathe slowly and deeply. Feet should be elevated to a position higher than the heart.

Take vital signs (blood pressure, pulse, respiratory rate, oxygen saturation)

**Ohio University Office of Research Compliance and Institutional Review Board
Standard Operating Procedures**

SOP #103
Revision #

**TITLE: Venipuncture- 2 years &
older for Phlebotomy**

Page 8 of 11

Apply cool compress to the head

Offer juice or water

Provide a basin and tissues if nausea/vomiting is present. Notify available medical personnel (i.e. study physician, nurse or other first responder) and PI.

Fainting (Syncope)

Treatment:

Prevent or break fall

Stop the procedure

Call for help

Place the individual in a reclining or Trendelenburg position (laid flat on the back with the feet higher than the head by 15-30 degrees)

Loosen clothing

If the subject is choking, perform a Heimlich maneuver.

If the subject is vomiting or bleeding from their mouth, turn them on their side.

Take vital signs (blood pressure, pulse, respiratory rate, oxygen saturation)

Apply cool compress to the head

Offer juice or water

Notify available medical personnel (i.e. study physician, nurse, or other first responder) and PI. If the subject struck their head in the course of fainting, inform the medical provider of this, too.

Call 9-1-1 if:

1. The lips or face are blue
2. There is an irregular or slow pulse (i.e. 50 beats per minute or fewer)
3. There is chest pain.
4. The subject has difficulty breathing or breathes noisily.
5. The subject does not waken within one minute.
6. It is difficult to awaken the subject.
7. The subject acts confused, or answers incorrectly to:
 - a. What is your name?
 - b. Where are you now?
 - c. How old are you?
8. The subject experiences unusual symptoms such as blurred vision or difficulty talking.

Assessing Recovery

1. Keep the subject recumbent with or without legs elevated for at least 5 minutes after:
 - a. They are awake and not confused (see above).
 - b. Their pulse is at least 51 beats per minute and their systolic BP is at least 95 mm of mercury.

**Ohio University Office of Research Compliance and Institutional Review Board
Standard Operating Procedures**

SOP #103
Revision #

**TITLE: Venipuncture- 2 years &
older for Phlebotomy**

Page 9 of 11

2. If symptoms recur upon attempts to sit or stand, repeat #1 but for 10 minutes.
3. If symptoms recur upon a second attempt to sit or stand, then seek medical guidance.

Convulsions

Treatment:

Help individual to floor

Turn the subject on their side so that vomit and other fluids will drain out of the mouth and not be aspirated into the lungs.

Prevent individual from injuring himself/herself, including cradling or cushioning the head to avoid it striking a hard object.

Loosen tight clothing, such as scarf, necktie, or belt

Do not insert objects or fingers into the mouth.

Call for help, including 9-1-1.

Take vital signs (blood pressure, pulse, respiratory rate, oxygen saturation)

Notify the PI, but someone should remain with the subject.

Hematomas (swelling due to ruptured blood vessels, bruising will occur)

Treatment:

Stop procedure

Immediately remove tourniquet and needle

Apply pressure to venipuncture site until bleeding has stopped

Cold packs can be applied to reduce bruising and pain

Notify available medical personnel (i.e study physician, nurse, or other first responder) and PI.

Excessive bleeding after venipuncture (may be seen in individuals on anticoagulant therapy, medications containing aspirin, or clients with low platelet counts).

Treatment:

Prepare to apply pressure on venipuncture site for longer period of time

Do not leave individual until bleeding has stopped

Infection at the venipuncture site (redness or swelling in the vein or tissue below the skin surface accompanied by a fever)

Prevention:

Properly cleaning the site prior to pricking the skin.

Treatment:

Check the individual's temperature.

Instruct the individual to seek care by a medical professional if a fever of over 101.5 degrees Fahrenheit or above is present.

Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures		
SOP #103 Revision #	TITLE: Venipuncture- 2 years & older for Phlebotomy	Page 10 of 11

Notify available medical personnel (i.e. study physician, nurse, or other first responder) and PI.

Inability to Collect Sample

If the blood sample cannot be obtained following two attempts, another person trained in phlebotomy may attempt venipuncture. However, this is ultimately at the discretion of the individual participant. If samples cannot be obtained, document and notify the PI. Rescheduling the blood draw will be done at the discretion of the PI and participant. A maximum of (insert the max #) blood draws will be attempted with the permission of the participant.

Special considerations for a child: For children 9 years old and above, three venipuncture attempts may be made, but no more than twice by the same individual (study personnel). If the first two attempts are unsuccessful, another trained study personnel, if available, should attempt a final time, if the child and their parent permits. If another trained study personnel is not available, a third stick should not be attempted. Attempt only two venipunctures on a children 8 years of age and younger. If the child (any age) or their parent is not agreeable to more than one needle stick, do not make any further attempts. If the blood sample is unable to be collected, document and inform the PI.

b. *Description to be used for the Consent Form.*

Because this study involves drawing blood, you should not consider participating if you are not comfortable with having your blood drawn. We will try to keep your stress as low as possible when drawing your blood. Your blood will be obtained by a person specifically trained to do so, using approved methods and sterile needles.

Common discomforts of having blood draw include:

- Pain or discomfort at the needle insertion site.
- Redness, swelling, or bruising where blood was taken.
- Feelings of being scared or nervous.
- Feeling dizzy.
- Fainting.

Difficulty getting enough blood

The person drawing your blood will watch carefully for any redness, bleeding, bruising, or pain during and after your blood sample is taken. It is not uncommon to have a small amount of bruising or mild pain following blood collection. However, if the bruising or pain gets worse or continues beyond a couple of days without any signs of getting

Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures		
SOP #103 Revision #	TITLE: Venipuncture- 2 years & older for Phlebotomy	Page 11 of 11

better, or if you suspect that the site of blood collection has become infected, then you should immediately seek medical attention. Signs of infection at the site include swelling, redness, warmth, pain, or red streaks above or below the site.

Sometimes it is difficult to obtain a blood sample. If that occurs we may have a different person attempt to get your blood or take some other measures to help us get your blood easier, such as having you drink water or change positions.

If you feel faint or feel like you may pass out you should notify a study team member right away. This is an uncommon occurrence with having blood drawn and can usually be managed by having you lie down.

REFERENCES

CLSI 2011 Standards. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard, Sixth Edition, December 2010
<http://96.36.117.186/NewsLetter.pdf>

Davis, Bonnie K., Phlebotomy: A Client-Based Approach. 1997

<http://www.austincc.edu/health/phb/documents/PHBLec8ComplicationsinBloodCollectionSum04.pdf>

http://www.ehow.com/list_6742839_ohio-phlebotomist-regulations.html

<https://www.nlm.nih.gov/medlineplus/ency/article/003423.htm>

SUBMITTER

Please note that the name of the submitter of the SOP is provided for a reference for follow-up, as needed.

Lee Ann Williams, MEd, CCRP, Associate Director, Clinical Research Operations, Clinical & Translational Research Unit, Ohio University Heritage College of Osteopathic Medicine.