**Cornell University Standard Operating Procedure (SOP) - Venipuncture**

**PROTOCOL TITLE:** Click here to enter text.

**PI NAME:** Click here to enter text. **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Definition:** Venipuncture is the collection of blood from a vein, usually for laboratory testing.

**Possible Risks to Participants:** Drawing blood from a vein may cause discomfort, bruising, excessive bleeding or infection at the site of puncture. Light-headedness or fainting may occur.

**Equipment and Supplies:** Non-Latex Exam Gloves, Alcohol Swab/Pad, Vacutainer(s), Sterile Double-Ended Safety Needles or Butterfly Needles, Non-Latex Tourniquet, Gauze and Tape or Band-Aid, and Sharps Container.

Any individual performing venipuncture must:

1. be approved to conduct venipuncture in the HMRU;
2. be current in Bloodborne Pathogen Training provided by Environmental Health and Safety;
3. be current in CPR/AED Training or have someone current in CPR/AED Training present in the HMRU to provide assistance, if needed;
4. have another individual present in the HMRU to provide assistance, if needed;
5. have completed Cornell University’s Human Subjects training (www.irb.cornell.edu)

**Procedures:**

1. Assemble all equipment and supplies (see Equipment and Supplies above) including vacutainer tubes labeled with participant identifier numbers and a list of participants with their associated identifier number.
2. Wash hands thoroughly and put on exam gloves. When multiple participants are having venipuncture, exam gloves should be changed between participants, and hand sanitizer should be used each time gloves are changed.
3. Confirm the identity of the participant by asking their name and/or their study ID number.
4. Explain the procedure and that the participant can end the procedure at any time for any reason.
5. Position the participant so that they are seated or reclined comfortably with their arm extended to form a straight line from the shoulder to the wrist. In either situation the participant’s arm and elbow should be firmly supported and not bent.
6. Check both arms to identify a vein, preferably one which runs along the inner part of the forearm close to the surface of the skin. Use of the median cephalic vein or median basilic vein is preferable. Select the larger and fuller vein.
7. Palpate and trace the path of the vein several times with your index finger.
8. Open packaged equipment and supplies in the presence of the participant so that they can see that these items come from original packaging.
9. Tap the vein at the site of the draw with your index finger and third finger; this will help the vein to dilate.
10. Apply tourniquet above the desired site of puncture.
11. Ask participant to form a fist holding it tightly. They should avoid opening and closing the fist.
12. Clean the draw site with an alcohol swab (70% isopropyl alcohol) in a circular motion from the center of the area and allow the alcohol to dry. DO NOT touch the venipuncture site again.
13. Using a sterile needle, gently insert the needle into the vein at an angle roughly 15 degrees parallel to the vein making sure that the bevel of the needle is pointing up. To prevent a hematoma from forming only, the uppermost wall of the vein should be punctured. It’s important to be sure that the needle completely penetrates the uppermost wall of the vein. Failure to do this may allow blood to leak into the soft tissue surrounding the vein by way of the needle bevel. Engage the person in conversation as the needle is inserted and throughout the procedure to create a diversion. \*\*At this point and throughout the procedure verify that the participant feels well. If the participant does not feel well, immediately end the procedure (see steps 17-20) then follow the steps outlined in the SOP for Dealing with Lightheadedness or Fainting\*\*.
14. Push the vacutainer tube into the holder and repeat as necessary. As each tube is removed from holder, gently rotate tube to mix blood with additive in tube.
15. Vacutainers should be used in the following sequence, based on Clinical and Laboratory Standards Institute guidelines, to limit contamination of tube additives from tube to tube, which may cause erroneous result with some tests: Blood Culture, Royal Blue, Red (No additive), Light Blue (Sodium Citrate), Serum Separation, Green (Sodium Heparin), Yellow (ACD Solution), Pink (TMS), Pearl, and then Lavender (EDTA).
16. If the venipuncture is not successful, a second attempt can be made on the other arm. If the second attempt is not successful, the procedure should be terminated.
17. When the last vacutainer tube is filling, release the tourniquet. Remove the collection tube from the holder. Remove the needle at the same angle it was inserted.
18. Discard the needle in the designated sharps container.
19. Using gauze, apply firm pressure to the venipuncture site for 2 minutes or until bleeding stops.
20. Apply tape and gauze or a Band-Aid to the venipuncture site and discard used gauze in the sharps biohazard container.
21. Remove gloves.
22. Wash hands.
23. Provide a Venipuncture Information Sheet (Take home sheet).
24. Advise participant to consult with primary care provider and inform the investigator if any complications develop at the site of venipuncture.

**Dealing with Lightheadedness or Fainting:**

Individuals having venipuncture may experience lightheadedness or fainting (sudden transient loss of consciousness with concurrent loss of postural tone). This usually results from any mechanism that decreases cerebral blood flow. The common faint is often precipitated by fear, anxiety, or low blood sugar levels due to prolonged fasting and may be accompanied by dimming vision, sweating, nausea and loss of balance.

If the participant feels lightheaded or faint:

* Remain with the participant and summon help from a colleague.
* Help the participant lie down on the floor and raise legs above the level of the heart. Do not attempt to move individual to the bed.
* When the participant no longer feels faint, allow the participant to sit up in place.
* When the participant is able to tolerate sitting in place without feeling faint, assist him/her into a chair.
* Offer sips of juice.
* When the participant is able to tolerate sitting in a chair without feeling faint, assist him/her with standing and walking.
* Retain the participant for 15-20 minutes to verify recovery, then allow him/her to leave.

If the participant loses consciousness:

* Remain with the participant and summon help from a colleague.
* Attempt to wake the participant by loudly calling his/her name and briskly tapping shoulder. If the participant is unresponsive and not breathing or not breathing normally (only gasping), have a colleague call 911 and obtain the AED.
* While 911 is being called and the AED being obtained, check for a pulse for no more than 10 seconds.
* If there is no pulse, or are unsure, begin and continue CPR until emergency responders arrive.
* If there is a pulse, begin and continue rescue breathing until emergency responders arrive.
* Aid the emergency responders by providing information as needed until they have assumed responsibility for the participant.

File an Unexpected Event Report:

* If the person performing the procedure is not the PI for the study, they should immediately inform the PI of the incident and ensure that the procedures outlined in the protocol are followed.
* Within 24 hours of the incident, either the person performing the procedure or the PI should complete an Unexpected Event Report and submit it to the IRB (irbhp@cornell.edu) and the medical oversight physician/occupational medicine (gannettoccmed@cornell.edu).
* The physician lead for medical oversight/occupational medicine will assess the provided information and, if indicated, forward the form to the Office of Risk Management and to the consulting physician specialist for review. Telephone contact will be made if there is an urgent need for consultation.
* The medical oversight physician will inform the PI if there is a need for additional follow-up action or for corrective changes in research procedures and/or the handling of the event.

**Dealing with Excessive Bleeding:**

Excessive bleeding at the venipuncture site may occur. Causes include: laceration of the vein, excessive tourniquet pressure, or failure to apply enough pressure after withdrawal of the needle.

1. If excessive bleeding occurs, apply firm pressure at the site for several minutes.
2. If the bleeding is not controlled or if bleeding occurs in spurts (suggestive of arterial bleeding) the person performing venipuncture should:
	1. Call 911 or ask a colleague to call 911 (the individual placing the call should follow the directions for calling emergency responders posted in the room they are calling from. If a colleague is available the colleague should then go to the front of the building to help guide emergency personnel to the room).
3. File an Unexpected Event Report:
* If the person performing the procedure is not the PI for the study, they should immediately inform the PI of the incident and ensure that the procedures outlined in the protocol are followed.
* Within 24 hours of the incident, either the person performing the procedure or the PI should complete an Unexpected Event Report and submit it to the IRB (irbhp@cornell.edu) and the medical oversight physician/occupational medicine (gannettoccmed@cornell.edu).
* The physician lead for medical oversight/occupational medicine will assess the provided information and involve other institutional contacts if necessary. If there is an urgent need for consultation, the participant may be contacted by phone.
* The occupational medicine staff and the IRB will coordinate any follow-ups with the PI and the facility staff, including a need for additional action or corrective changes in research procedures and/or the handling of the event.
* The incident report and any follow-up actions will be presented to the IRB at a convened meeting. The IRB may require further action from the research team or occupational medicine personnel.

**Venipuncture Information Sheet**

\*\*Please keep this information sheet accessible until your venipuncture site has fully healed.\*\*

**Care of the site from which blood was drawn**

Keep the gauze or band-aid on your blood draw site dry for several hours, until the site has had adequate time to heal. You may change this gauze/band-aid if necessary.

**Potential Complications**

**Bleeding --** A small amount of bleeding is normal after blood is drawn, but this bleeding should

stop after firm pressure has been applied for several minutes. If you have continued bleeding from the site, continue to apply firm pressure for a few more minutes. If the bleeding persists, contact your primary care provider for advice. If you do not have a primary care provider, proceed to the emergency room for attention.

**Infection --** The risk of infection following blood draws is minimal, but should be taken seriously.

Signs of infection include:

• Excessive pain, warmth, redness or swelling at the site

• Oozing/drainage from or around the site

• Fever, chills, fatigue, increasing aching or stiffness in your joints

**Nerve irritation—**Irritation of a nerve may occur during blood draws.

Signs of nerve irritation include:

* Localized numbness
* Localized tingling
* Localized weakness

If you experience any of the above signs, you should contact your primary care provider for advice. If you do not have a primary care provider, proceed to the emergency room for attention.

You should also notify the investigator of bleeding or infection problems so that they can file the appropriate reports within Cornell University.