

STANDARD OPERATING PROCEDURE

Collection of Venous Blood Samples from Adult Research Study Participants using a Venous Catheter

SOP ContAct-004

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A. PURPOSE AND BACKGROUND

Performing a procedure on tissue below the dermis is considered a [controlled act](#). This SOP describes the procedures for phlebotomists to collect venous blood samples using an over the needle catheter from adult study participants (i.e., age 17 and older). This technique is used when repeated blood sampling will occur over a number of hours. A separate SOP is to be followed for youth and children.

B. PROCEDURES/STUDY PROTOCOL

1. If fasting blood samples are to be taken, the phlebotomist verbally confirms the participant did not eat and drink for 12 hours prior to the blood draw. If these criteria are not met, the phlebotomist follows the study protocol to either include or exclude the participant or reschedule the blood draw for another day.
2. The phlebotomist to perform the venous blood draw will inspect the participant's arms and hands for a vein of a reasonable size. This is most often the medial cubital vein, although other veins on the forearm and back of the hand can be used.
3. Once a suitable vein has been selected by the phlebotomist, the participant will be asked to sit or lie down in a position that provides the phlebotomist access to the vein and that is comfortable for the participant.
4. The skin superficial to the vein will be cleaned with an alcohol wipe and allowed to dry. The alcohol needs to dry to ensure the area is disinfected and less discomfort for the participant (i.e., stinging feeling).
5. A tourniquet will be applied 5 to 10 cm above the intended site of the venous puncture.
6. Puncture Step: The catheter-over-needle is unsheathed and inserted through the skin and into the vein at an angle of 15 to 30 degrees. On insertion into the vein, a flash of blood will be observed in the needle flash chamber.

7. Upon completion of the puncture step, the tourniquet will be removed.
8. Catheter Positioning: The phlebotomist will gently advance the catheter portion forward 1 cm into the vein, sliding it over the needle in a practiced, smooth motion.
9. Needle Removal: The phlebotomist will gently press on the vein below the puncture with his/her fingertips to slow the flow of blood up the arm. The phlebotomist will swiftly remove the needle (by pulling back) and immediately connect a sterile stopcock to the open catheter. The needle will be disposed of in a sharps container.
10. The catheter and stopcock will be secured with Tegaderm (medical adhesive sheets) or transpore tape (medical skin tape).
11. A single-use syringe may be connected at this point and the stopcock opened to draw blood into the syringe. Timing and volume of blood drawn will depend on the procedure.
12. Blood will be transferred from the syringe(s) to prepared tubes that contain the required anticoagulants/additives as appropriate for the analysis of the blood.
13. Sterile saline will be drawn up into another sterile, single-use syringe and pushed into the stopcock and catheter to replace the blood. The amount will be carefully monitored and the transparent catheter observed carefully so that only the exact amount of saline is inserted. The purpose of the saline is to prevent blood clotting. Saline will not be injected into the participant.
14. Following each sample collection, the stopcock is turned off, and the syringes are disposed of in the biohazard waste containers. The stopcock only is flushed with sterile saline drawn up into another sterile, single-use syringe to make the stopcock ready for subsequent use.
15. The stopcock is cleaned with an alcohol swab for 30 seconds before next use.
16. The catheter will remain in the arm vein for the duration of the study session, usually an hour or two, while blood draws are repeated at intervals as required by the study. The catheter itself is soft, flexible Teflon and the participant may move his/her arm without pain or discomfort.
17. Next blood draw: Always using a fresh syringe, the phlebotomist will first draw out the saline and discard. Then additional blood may be drawn up into another syringe and transferred to waiting tubes for processing, as before.
18. When the last blood draw is complete, the tape securing the catheter will be removed and the catheter portion will be withdrawn from the vein quickly.
19. Cotton will be pressed on the site of venous puncture.

20. Participant will be asked to sit still and apply pressure to stop the bleeding and reduce the risk of bruising.
21. The phlebotomist will dispose of the catheter directly into the sharps disposal.
22. Once the bleeding has subsided or stopped (approximately 2 to 3 min), a bandage will be applied over the puncture and the participant will be asked to sit quietly for up to 10 minutes.
23. The phlebotomist will inform the participant there may be bruising at the site of the puncture for the next few days, to keep the puncture area clean and dry to promote rapid healing, and no heavy lifting for 24 hours to prevent further bruising.
24. The participant will be thanked for his/her participation.
25. Participants who have fasted prior to the session will be offered a beverage (choice of apple or orange juice) and a small snack (for example bagels, breakfast bars).

C. EQUIPMENT

- Over-the-needle catheter for each participant
- Appropriate sized (1,3 or 5ml) sterile needle-less syringes for each participant
- Sterile saline single-use size bottles (10 ml) for each participant
- Blood collection tubes for each participant
- Tourniquet
- Box of nitrile/vinyl gloves (Do not use latex gloves due to allergies/sensitivities.)
- Alcohol wipes
- Cotton balls/swabs
- Bandages
- Pillow/pad for raising arm to comfortable elevation
- Apple/orange juice and snacks for fasting participants
- Disposable, single use materials or equipment are to be used whenever possible
- Any reusable materials or equipment must be cleaned and disinfected with alcohol-based sanitizers before use with another participant

*Disposable, single use materials or equipment are to be used whenever possible and any reusable materials or equipment must be cleaned and disinfected with alcohol-based sanitizers before use with another participant.

D. DESCRIPTION TO STUDY PARTICIPANTS

1. Each individual (i.e., study participant) is to be asked in-person, by telephone, or by email if they are:
 - comfortable having blood drawn, and
 - allergic/have sensitivities to rubbing alcohol.
2. Individuals who indicate in any way they are uncomfortable with the procedure and/or are allergic/sensitive to rubbing alcohol will be asked not to participate in the study.

3. In the information-consent letter participants must be informed:
 - a. the catheter insertion and blood draw will only be carried out by a trained and experienced phlebotomist who has been delegated to conduct the procedure by a physician.
 - b. the phlebotomist will insert a needle into a vein in their arm similar to giving a blood sample in a lab that may be requested by their family physician/doctor during a routine physical or a check-up.
 - c. the procedure requires wiping an area of the skin with rubbing alcohol and puncturing a suitable vein on the inside surface of their elbow with a 21 gauge needle.
 - d. to wear a loose shirt or a short sleeve shirt as the most commonly used vein for blood collection is located on the inside surface of their elbow.
 - e. they can ask any questions that they may have about the procedures at any time or ask to stop the procedure at any time.
4. If fasting blood samples are required, participants are informed in-person, by telephone or email to avoid eating and drinking except for water for 12 hours before coming to the lab for the blood draw and this information is to be reiterated in the information-consent letter.

E. RISKS

1. PARTICIPANTS

- Bruising at site of needle puncture.
- Feelings of lightheadedness or fainting.
- Risk of infection if puncture site is not kept clean.

2. RESEARCHERS

- In the event of a mucous membrane blood exposure or needle stick injury, UWaterloo Health Services' posted procedures for post exposure management for blood-borne pathogens will be followed:
<http://www.healthservices.uwaterloo.ca/menu/occupationalhealth/bloodexposure.htm>

F. SAFEGUARDS/SAFETY PROCEDURES

- Phlebotomist is to have completed:
 - First Aid/CPR training
 - UWaterloo Safety Office lab safety training: See <https://uwaterloo.ca/safety-office/training/training-programs>
- Universal precautions are to be applied at all times. Refer to the Canadian Public Health Association universal precautions guidelines: <http://www.cpha.ca/uploads/portals/idp/19661e.pdf>

- Phlebotomist must follow UWaterloo Safety Office guidelines on use of personal protective equipment and specifically use of gloves. See <https://uwaterloo.ca/safety-office/programs-and-procedures/personal-protective-equipment>
- A new pair of disposable nitrile/vinyl gloves are used with each participant. Gloves are for single-procedure use only. Gloves should always be removed using a glove-to-glove or skin-to-skin technique to prevent contaminating the hands. Gloves are to be disposed in an appropriate container.
- The use of gloves does not replace the need for hand hygiene. Hands are to be properly washed before the gloves are put on and after the gloves are removed. Hand hygiene is also needed before and after the replacement of gloves during a procedure or in between tasks.
- It is recommended the phlebotomist has protective eyewear, a mask or face shield, and a gown during any procedure where droplets of blood or other body fluids may be produced.
- Participants will be asked to sit still and apply pressure to stop the bleeding and reduce the risk of bruising.
- Participants will be asked to sit quietly for up to 10 minutes to reduce the risk of lightheadedness or fainting.
- Participants are reminded to do no heavy lifting for 24 hours.

G. REFERENCES

- Public Health Ontario (2013). *Best Practices for Cleaning Disinfection and Sterilization of Medical Equipment/Devices in all Health Care Settings, 3rd edition*. Retrieved on July 16, 2015
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