

STANDARD OPERATING PROCEDURE

Collection of Venous Blood Samples from Research Study Participants

SOP ContAct-001	
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A. PURPOSE AND BACKGROUND

This SOP describes the procedures for researchers to perform the [controlled act](#), performing a procedure on tissue below the dermis, by collecting venous blood samples from study participants.

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 this criteria is 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.
5. A tourniquet will be applied 5-10 cm above the intended site of the venous puncture.
6. Blood samples will be collected using a closed, vacutainer system. The grey rubber end of the vacutainer needle is exposed and screwed onto the vacutainer tube holder. The needle is then unsheathed and inserted through the skin and into the vein at an angle of 15-30 degrees.
7. Blood tubes can then be inserted into the tube holder and onto the hold. The vacuum in the tube will draw the blood. A full tube can be disengaged and a new tube can be added. The number of tubes to be used varies depending on the number and type of analyses to be performed. Most studies require one to two 10 mL tubes, however three

to four tubes may be used, particularly when different blood matrixes are required (i.e., serum, heparinized plasma, plasma prepared with EDTA, plasma prepared with sodium citrate).

8. Upon completion of the blood draw, the tourniquet will be removed and the needle will be withdrawn from the vein quickly.
9. Cotton will be pressed on the site of venous puncture.
10. Participant will be asked to sit still and apply pressure to stop the bleeding and reduce the risk of bruising.
11. The phlebotomist will disengage the needle from the holder directly into the sharps disposal.
12. If a plasma sample is being collected the blood samples will be gently inverted to mix anticoagulant.
13. Once the bleeding has subsided or stopped (approximately 2-3 min), a bandage will be applied over the puncture and the participant will be asked to sit quietly for up to 10 minutes.
14. 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.
15. The participant will be thanked for their participation.
16. 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

- 21 gauge needle for each participant with closed vacutainer system
- 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

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 blood will only be drawn 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

1. PARTICIPANTS

- Universal precautions are to be applied at all times. Refer to the Canadian Public Health Association universal precautions guidelines. See <http://www.cpha.ca/uploads/portals/idp/19661e.pdf>
- A new pair of disposable latex/vinyl gloves are used with each participant. Gloves are to be for single-procedure use only. Gloves should always be removed using a glove-to-glove or skin-to-skin technique which will prevent contaminating the hands.
- The use of gloves does not replace the need for hand hygiene. Hands should 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.
- Participants are reminded to do no heavy lifting for 24 hours.
- Phlebotomist is to have completed:
 - First Aid/CPR training
 - UWaterloo Safety Office lab safety training. See <https://uwaterloo.ca/safety-office/training/training-programs>

2. RESEARCHERS

- 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>
- Protective eyewear, a mask, or face shield and a gown during any procedure where droplets of blood or other body fluids may be produced is recommended.
- After completing the blood draw and handling of the vacutainers, the phlebotomist disposes of gloves in an appropriate container and washes hands thoroughly with soap and warm water.

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 http://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf

Public Health Ontario. (2015). Infection Prevention and Control for Clinical Office Practice. Retrieved on July 16, 2015 http://www.publichealthontario.ca/en/eRepository/IPAC_Clinical_Office_Practice_2013.pdf