



Standard Operating Procedure

Blood Collection and Delivery

I. POLICY: The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) ensures the safety and well-being of participants in research studies performed in its facilities.

II. PURPOSE: Ensuring the safety and well-being of participants during the collection of blood samples as established in the Federal and institutional regulations.

III. Area(s) of Responsibility: This policy applies to all the personnel responsible for performing venipuncture, clinical staff of the PRCTRC, Principal Investigator, Study Coordinator and other staff members of the protocol.

IV. Procedure Details: Blood samples are obtained by qualified personnel in the PRCTRC, at the University Intramural Practice Plan of the Medical Sciences Campus and/or the community.

1. Blood samples will be drawn from participants that have been signed the informed consent; verify participant identification;
2. Explain the procedure clearly to participant giving time for any questions, ensuring the patient is comfortable about the procedure;
3. Ensure all equipment is ready to hand in a tray next to the participant;
4. Complete the Lab Requisition Form;
5. Use the Personal Protective Equipment (PPE) required;
6. Position the patient, he/she should sit in a chair, lie down or sit up on bed;
7. Hyperextend the patient's arm, identify a good sized vein (Phlebotomy will be done only in the peripheral veins of the upper limbs);
8. Apply a tourniquet proximal to the site of venipuncture to ensure engorgement of vein;
9. Prepare with either a green, black or blue needle depending upon the size of the vein or prepare the vacutainer with a butterfly needle. The type of device used to extract blood is dependent upon operator's preference;
10. Clean the site of venipuncture with an alcohol swab, in a circular movement. Allow to air dry;
11. Insert needle into vein looking for blood flashback in the bevel of the syringe;
12. Blood samples are taken according to the protocol provided by the principal investigator;
13. Once enough blood has been withdrawn, undo the tourniquet with the needle still in place;
14. Take a gauze and place over site of needle insertion (venipuncture) and gently remove the needle;
15. Apply direct pressure with the gauze over the puncture site to stem any

- bleeding. This should be carried out for 2mins, after which the gauze should be removed to ensure bleeding has stopped. If not affix the gauze with gauze tape or a bandage;
16. Dispose of contaminated materials/supplies in designated containers;
 17. Label the tubes promptly and appropriately with the labels that have the patient's ID number and confirm that the appropriate matching information is recorded on the Lab Requisition Form. Subject ID will be assigned by the study coordinator or PI;
 18. Deliver specimens promptly to the PRCTRC laboratory.
 - a. Samples taken at the PRCTRC
 - i. Put the tubes in the plastic biohazard bag and then in the lab basket. Notify the lab technician.
 - b. Samples taken at the University Intramural Practice Plan of the Medical Sciences Campus and/or the community.
 - i. Put the blood samples in two plastic biohazard bags and carry them in a plastic case wearing gloves to the PRCTRC laboratory or call the PRCTRC personnel.

V. Adverse Reactions:

1. If the patient experiences any adverse reactions such as dizziness, sweating or nausea, the procedure must be stopped immediately. The PI and/or Study Coordinator will be notified as soon as possible.
2. If the patient experiences any adverse effects during and/or after the phlebotomy procedure, the research staff will notify the PI and shall observe the participant for 15-30 minutes or until symptoms have disappeared. Vital signs will be taken to verify if they are stable and instructions given by the PI will be followed.
3. If the patient fails to re-establish the normal vital signs, the PI and/or Study Coordinator will be responsible for evaluating him/her. If necessary, the subject will be referred to the emergency room for treatment.