

Category : Study conduct
Title : Procedure for collection of blood samples of trial participants
SOP No. : D 10/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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1. Purpose:

This standard operating procedure (SOP) describes the technique for performing a venipuncture to obtain a blood sample.

2. Scope:

This SOP is limited to the procedure of blood collection in clinical study.

3. Responsibilities:

The Principal Investigator (PI) and the study team members are responsible for the safety and wellbeing of all study participants. The task of performing venipuncture will be delegated to trained personnel in the study team.

4. Applicable rules, regulations and guidelines

- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR (2017)
http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 20 December 2023)
- New Drugs and Clinical Trials Rules, 2019
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed 20th Dec, 2023)
- **Post Exposure Prophylaxis, NACO Guidelines**
<http://naco.gov.in/sites/default/files/1.%20Antiretroviral%20Therapy%20Guidelines%20for%20HIV-Infected%20Adults%20and%20Adolescents%20Including%20Post-exposure.pdf>

5. Reference to other applicable SOPs

- SOP No. D 24/06: Waste management.

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6. Detailed instructions

1. Care must be taken to maintain participant's comfort, integrity of veins during blood collection and good aseptic technique (universal precautions) should be followed to minimize the risk of infection.
2. Prepare the blood collection kit, as follows:
 - i. Vacutainer tubes/ glass bulbs with appropriate anticoagulants
 - ii. Vacutainer holder/syringes
 - iii. Needle (either straight or butterfly with connector)
 - iv. Tourniquet
 - v. Cotton swabs
 - vi. Spirit or 70% alcohol
 - vii. Gloves
 - viii. Sticking plaster
 - ix. Heparin ointment
 - x. Marker pen for labelling
3. Prepare a set of vacutainer and vials or required bulbs for blood investigations as per trial requirement as follows:
 - For complete blood count (CBC), erythrocyte sedimentation rate (ESR): Use ethylene diamine tetra acetic acid (EDTA) bulbs or purple colour capped vacutainer. Use black colour capped vacutainers for ESR.
 - For blood sugar: use vacutainer or bulbs containing sodium fluoride
 - For routine serum biochemical tests: use plain vacutainer (i.e. without anticoagulant)
 - For plasma: use glass bulb with 2-3 drops of heparin (5000 IU) or vacutainers with heparin or EDTA vacutainers

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- For Prothrombin time/ Activated Partial Thromboplastin Time/ International Normalized Ratio (PT/APTT/INR) test: use vacutainer or bulb containing sodium citrate
 - Participant information should be recorded on the vacutainer or glass bulb (Participant's Initial / ID, age, sex, date and time of collection, test to be performed etc.)
4. Ensure adherence to timing of blood collection as mentioned in the protocol (especially in pharmacokinetic studies) to avoid sampling deviation
 5. Ensure that the participant has been informed about the blood collection procedure, purpose of the same and amount of blood to be collected during the consent process, and the same is documented
 6. The participant must be made comfortable prior to the blood collection
 7. Escort participant to the site where the blood will be collected
 8. Enquire participant whether he/she gets lightheadedness before blood collection, and if so, ask them to lie down in supine position for sometime
 9. Precautions to be taken by the technician before the blood collection:
 - Apply antiseptic lotion thoroughly on both the hands
 - For personal protection, use sterile gloves and laboratory coats (Mask should be used whenever necessary).
 - In case of a cut or an injury on hand of the phlebotomist, cover it fully with sterile bandage
 10. Ask the participant to be seated and place his/her arm out, palm up on a flat surface and arm extended completely. Place a tourniquet around one of the participant's arms (slightly above the elbow area). When wrapping the tourniquet, instead of tying it completely, only pull one end to create a loop. This will allow for quick one hand release of the tourniquet

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11. Locate a vein by pressing around the area on the anterior aspect of the elbow (antecubital area). You will be able to locate the vein. If unable to locate, repeat on another arm. You will be able to judge the appropriate area by the firm, bouncy, spongy feeling of the vein.
12. Apply spirit or 70% alcohol swab on the site of blood collection and allow to air-dry, to make the area aseptic.
13. Blood can be drawn using a vacutainer - brand needle, regular straight needle, or a butterfly needle to puncture the vein.
 - a) **Vacutainer- brand needle**
 - The Vacutainer needle has a sharp point at both ends, and is covered by a rubber sheath, with one end being shorter than the other. The long end of the needle is used for penetrating the vein, the shorter end is used to pierce the rubber stopper of the vacuum tube. The sheath makes it possible to draw several tubes of blood by preventing leakage of blood as tubes are changed. If the short end is not covered with a rubber sheath, it is a single sample needle and only one tube of blood can be collected.
 - There are several sizes of vacutainer needles available, the size depends on the length and gauge of the needle. Vacutainer needle lengths range from 1 to 1 ½ inches. One-inch needles are used for routine venipuncture, 1 ½ inch needles are used for patients with very deep veins.
 - When the last tube has been filled, the entire assembly is removed from the patients' arm and the needle is disposed-off (Refer SOP No.: D 24/06, Waste management).
 - b) **Straight needle with syringe**
 - The needle of appropriate size is attached to the syringe. The cover of needle must not be removed until the technician is ready to draw the blood.

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- When ready for use, examine the needle especially the tip and check for any blockage by pressing the piston (The piston will not move freely if needle is blocked). Draw the blood by pulling piston to the appropriate volume.
- c) Butterfly needle:**
- Hold the wings of the butterfly needle with the thumb and index finger. Insert needle into the vein, visualize blood in the tubings of the butterfly needle and subsequently open cap of the rear end of the tubings and attach the sterile syringe (disposable). Draw the blood by pulling the piston to the appropriate volume.
14. Discard tube should be used, if butterfly needle set is used, to check for adequate flow of blood
 15. The gauge of a needle is a number that indicates the diameter of its lumen; the lumen, also called the bore, is the circular hollow space inside the needle. The higher the gauge number of the needle, the smaller is the needle's lumen. The most frequently used gauges for phlebotomy are 20, 21, 22 and 23.
 16. The bevel is the slanted opening at the end of the needle. Ensure that the bevel of the needle is facing upward when the needle is inserted into the vein while performing a venipuncture.
 17. Draw blood using the methods described above for the respective needles. The needle should form a 15–30-degree angle with the arm surface. You have successfully drawn blood if you notice the return from the vacutainer.
 18. Press a piece of sterile dry cotton swab firmly at the puncture area and remove the needle and withdraw the syringe / vacutainer holder from the patient's arm fully avoiding a needle stick injury.
 19. Inform the participant to press the cotton swab with his/her other hand while you discard the needle. (Refer to SOP No. D 24 /06: Waste management).
 20. Ensure that the blood flow has stopped and apply sticking plaster.

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21. In case of hematoma (swelling / bruising), apply heparin ointment.
22. In case of needle stick injury/ spillage or leakage of blood on an intact or broken skin follow post exposure prophylaxis as per National AIDS Control Organization (NACO) guidelines.

8. Abbreviations:

- i. **APTT:** Activated Partial Thromboplastin Time
- ii. **CBC:** Complete Blood Count
- iii. **Co-I:** Co-investigator
- iv. **EDTA:** Ethylene Diamine Tetra Acetic-acid
- v. **ESR:** Erythrocyte Sedimentation Rate
- vi. **INR:** International Normalised Ratio
- vii. **NACO:** National AIDS Control Organization
- viii. **PI:** Principal investigator
- ix. **PT:** Prothrombin time
- x. **SOP:** Standard Operating Procedure

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