

Clinical S.O.P. No.: 4
Version 1.1

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DOCUMENT HISTORY

Version	Detail of purpose / change	Author / edited	Date edited
number		by	
1.0	New SOP	Shona Brearley	
1.1	Minor changes made to SOP.	Louise Greig	June 2012

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1. Introduction

Blood sampling for biochemical and genetic analysis is a necessary procedure in most studies. The risks to the patient associated with this procedure include discomfort, bruising and infection. It is therefore vital that the technique be carried out efficiently by trained research nurses.

2. Objectives

To describe the procedure for taking blood samples for biochemical and genetic analysis and to promote uniformity within the SDRN in accordance with ICH GCP guidelines.

3. Responsibility

Only research nurses who have attended and successfully completed the appropriate training session will be responsible for blood sampling of patients as per ICH GCP guidelines.

4. Equipment

- Tourniquet
- 21G Butterfly needle (preferably) or 18g green needle (compatible with vacutainer/ vacuette systems)
- Alcohol impregnated skin wipe
- Vacutainer / vacuette bottles
- Vacutainer guard/holder
- Materials tray (Disposable or autoclavable)
- Appropriate blood specimen tubes
- Sharps bin
- Disposal gloves (recommended but optional)
- Gauze squares
- Plasters
- Chair or couch

5. General Points

- Inform patient of need for procedure and obtain verbal consent before obtaining blood samples.
- Enquire if patient has been fasting, and if so, for how long.
- Enquire if participant has had any previous experience of adverse reaction to needle/sight
 of blood etc. (if so, then offer to carry out procedure while patient lies down on bed or
 couch)
- Keep a regular check on the patient throughout the process to check for pallor/sweating which may indicate a tendency to faint.

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- Ensure the patient is sitting/lying comfortably with arm supported.
- All specimens of blood should be taken using a good aseptic technique. The following
 information should provide some guidance to those individuals who are less familiar with
 the standard procedure and revision for those already competent.
- All blood should be considered potentially infectious and handled accordingly.

6. Procedure

- Wash your hands prior to commencing the procedure. Follow the hand hygiene policy and use an alcohol rub/gel.
- It is highly recommended that a correctly fitting pair of disposable gloves be worn.
- Have at hand, the tray with all required equipment, blood bottles, sharps bin etc.
- Apply tourniquet to upper arm.
- After identifying a suitable vein (generally the best vein to use is sited in the anticubital fossa), wipe the skin with alcohol swab and allow to dry naturally prior to venepuncture.
- Take blood using vacutainer system either butterfly or needle attached to holder.
- The blood tubes should be filled in order of priority (in general, gold tops, then purple, then grey then blue)
- When the correct volume of blood has been collected into the appropriate bottles apply a
 clean gauze swab over the needle tip. Remove the needle and <u>then</u> apply direct pressure
 on the puncture site (applying pressure before the needle has been removed will cause
 tissue damage and pain/discomfort to patient).
 - If more than one sample of blood is required then after the first specimen has been collected release the tourniquet pressure slightly, collect the remaining specimens of blood then remove the tourniquet. (See point 7 additional information.
- Some tubes may need to be inverted, such as purple tops or those containing lithium/heparin – blue/green tops. Invert gently as vigorous shaking destroys the blood composition.
- Label the tubes immediately.
- Pressure should be applied for a few minutes till the bleeding stops (patient can do this
 for themselves and it may take longer than usual if patient is on anticoagulation/
 aspirin therapy)
- If there is no allergy, apply a small plaster if requested.
- Ensure all sharps are placed immediately into a designated sharps bin and all other materials are disposed of appropriately.



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• The research nurse must document in the CRF which blood samples have been successfully obtained in accordance with ICH GCP guidelines.

7. Additional information

- The tourniquet should not be applied for longer than 1 minute. If sufficient blood has not been collected in that time, it should be released. The subject should be encouraged to clench and unclench their fist for a few minutes. Depending on the volume of blood still required, it may be necessary to reapply the tourniquet to gain the requisite amount.
- If the patient feels faint during the procedure, STOP immediately. Lay him/her flat and elevate legs. Stay with them until they feel well again. Arrange to take the sample at a later time or date. (Document Adverse Event)