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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Blood Sampling** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

1. **Purpose/scope**

To describe the procedure for taking blood samples in clinical trials conducted by the [institution/group]

1. **Templates/forms**

CL06.1 Guideline for blood sampling by cannula or venepuncture

1. **Glossary/definitions**

None

1. **Responsibilities and procedure**
   1. The Principal Investigator (PI) will delegate responsibility for blood sampling (phlebotomy) to team members according to their qualification, training and experience. Depending on the visit schedule and number of participants admitted at a particular time, this could include investigator(s), the study coordinator (SC), research nurse(s) and/or phlebotomist(s).
   2. The trial team member taking blood samples will in general:

* Review the necessary equipment according to the protocol or trial-specific instructions.
* Check that tubes are correctly labelled for the participant and time point/sample.
* Take the sample as per current guidelines (an example is provided in CL06.1). The arm used for blood sampling should not be used for other assessments such as blood pressure.
* Process the sample according to protocol or laboratory-specific instructions.
* For timed samples, record the exact time of the end of sampling in the source document or CRF (as per the protocol) noting any reason for delay and initialling the entry. NB In complex trials recording may be performed by a second team member who observes the sampling.
* Remind the participant of the time of the next sample/visit.
* Prepare equipment for the next sample.

**Troubleshooting**

* 1. If blood is slow to flow:
     + Check the tube is securely fitted to the adaptor.
     + Encourage the participant to open and close his/her hand or straighten their arm. Then, if necessary, massage the arm, ask the participant to make a fist or adjust the tourniquet.
     + Use a fresh tube, as the vacuum of the first tube may be compromised (be sure to label the spare tube correctly if necessary).
  2. If blood still will not flow, it may have to be drawn using a syringe.
     + Affix the tip of the syringe to the opening of the cannula and slowly draw out the required volume of blood, steadying the cannula.
     + Transfer the blood to a protocol-specified tube immediately, as clotting occurs quickly.
  3. If blood still will not flow, an investigator will decide whether to draw blood using venepuncture.
  4. Every effort should be made to prevent delays to other/subsequent time-dependent samples. Should there be a delay the investigator or other designee will arrange for a replacement trial team member to step in.

1. **Document history:**

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| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
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