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| **STANDARD OPERATING PROCEDURE for Nigerian PreP Study** | | |
| **Study Site:** | | **SOPs Number** : LP-301 |
| **Title**  **BLOOD SPECIMEN COLLECTION** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

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| **Review date** | **Revision Date** | **Signature** |
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**Document History**

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| **Version number** | **Reason for change** | **Date** |
| 1.0 | Initial release | 28th March 2015 |
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**Distribution List**

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1. **Introduction**

Accurate documentation of participant and study information, and obtaining sufficient blood for study investigations are essential for quality data and safety of study participants. Specimens should be transported to the lab as soon as possible or properly stored until transport can occur to assure sample integrity.

1. **Objectives**

Procedures for collection and transport of blood specimens for the Nigeria PreP study studies.

1. **Personnel**

* Appropriate staff to undertake venepuncture may include:
* Phlebotomists
* Study Nurse
* Medical Laboratory Scientist/Technicians
* Members of clinical staff trained to take blood, including doctors and nurses so designated.

1. **Standard precautions**

Standard precautions should be observed when obtaining and handling patient samples. Wear gloves to prevent exposure to blood borne pathogens.

1. **Personal injuries**

All injuries incurred with sharps (e.g. needles, lancets, broken specimen bottle etc), no matter how minor, must be reported immediately so appropriate follow-up procedures can be initiated if necessary. Refer to the Integrated National Guideline for HIV Prevention Treatment and Care 2014 for a detailed description of post-exposure procedures.

1. Apply pressure to wound to curtail bleeding if necessary and apply a bandage.
2. Report any injury involving sharps to a site coordinator and report to the sites’ HIV treatment centre for treatment and evaluation for post-exposure prophylaxis.
3. **Lab request form completion**
4. Select appropriate study laboratory request form.
5. Enter participants information on the spaces provided in the :

* Visit date
* Gender
* Screening ID#
* Participant ID#

1. Record Specimen Collection dates.
2. Enter the initials of the staff that made the request and date.
3. **Blood samples - venepuncture**
4. **Materials**

* 70% alcohol solution
* Gloves
* Tourniquet
* Cotton wool balls
* Butterfly needle
* Syringe with needle (5mls, 10mls, and 20mls)
* EDTA (purple top)
* Plain (red top) vacutainer
* Pens for labeling

1. **Preparation of collection tubes**

* Inspect collection containers for breakage
* Refer to the study screening Lab Request Form for the following:
  + Bottles or tubes to be filled
  + Draw priority (order in which bottles/tubes should be filled)
  + Amount of blood required in each tube
* Line up bottles and tubes in the order of draw sequence listed Lab Request Form and mark on each the required volume.
* Enter in the specimen blood the following information
  + Screening ID#
  + Participant ID#
  + Specimen Collection dates.

1. **Participant’s preparation**

* Verify participant’s identity by asking them for the study identification card.
* Explain to the participant why the blood is being drawn and what the procedure will be.
* Have participant sit or lie down for the procedure and make them feel comfortable.
* Explain possible side effects of the procedure e.g. pain on needle insertion, bruising.

1. **Venepuncture procedure:**

***NOTE: If at any time during the venepuncture procedure the patient displays any adverse reaction (e.g. light-headedness, fainting, nausea, convulsions) discontinue the procedure immediately and contact the nearest Nurse/Medical Doctor and Site coordinator.***

1. Put on gloves.

2. Apply a tourniquet 3-4 inches above the site selected. Ideally, the tourniquet should not be applied for longer than 1-2 minutes. Leaving it on for an extended period may result in localized stasis and hemoconcentration that can cause erroneous results for some laboratory tests.

3. Find a suitable vein. Having the participant squeeze their fist to increase the blood accumulation may help in locating a suitable site.

NOTE: Antecubital veins are the preferred choice but blood may also be collected from veins on the hand, wrist or lower on the arm. If a suitable vein is not available, contact site coordinator.

4. Soak a cotton ball with 70% alcohol and scrub the venepuncture site vigorously for 30 seconds.

5. Position the arm so it is resting on a table or bed alongside the participant. The arm should be supported firmly and not bent at the elbow. If necessary, place a pillow under the arm to provide additional support.

6. Remove the butterfly from the package and attach the syringe to the butterfly.

7. Anchor the vein by using thumb to draw the skin taut, about 1-2 inches below the site.

8. Smoothly insert needle with the bevel side up.

9. If blood does not flow, calmly make the following adjustments:

* Change the position of the needle; pull back if it has penetrated too far, or advance the needle if it is not fully inserted in the vein.
* Make sure the bevel of the needle is up.
* Loosen the tourniquet which may be on too tight stopping the blood flow.

NOTE: If first attempt is unsuccessful repeat the process on another site using a NEW butterfly. A clean, sterile needle must be used for each new collection attempt. If the second attempt fails, do not attempt another. Contact the site coordinator for assistance with the venepuncture.

1. Release the tourniquet as soon as the blood begins to flow. Do not allow the tourniquet to be continuously in place more than 2 minutes.
2. Collect the proper amount of blood for tests.
3. Gently invert EDTA tubes to mix anticoagulant and prevent clotting.
4. Remove the needle and apply pressure to the site with a cotton ball. The patient may also apply pressure while elevating the arm to assist clotting.
5. Check site to make sure that bleeding has stopped and apply a bandage.
6. Discard syringe/butterfly in appropriate Sharps container. **NEVER RECAP NEEDLES.**
7. Discard other materials in appropriate trash receptacle.
8. While still with the participant confirm that the information on the Lab request form and specimen collection blood is the same. If same initial the specimen collection bottle.
9. Before leaving the patient make sure the patient is stable and shows no sign of distress following the procedure.

**This SOP has been read and understood by:**

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