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| **STANDARD OPERATING PROCEDURE for Nigerian PreP Study** | | |
| **Study Site:** | | **SOPs Number** : CA-201 |
| **TITLE**  **CLINIC FLOW** | | |
| **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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1. **Introduction**

Clinical studies are often conducted in busy public health facility. If the flow of the Participants are not clearly delineated it could impact on participants satisfaction, compliance to the study activities and loss of essential man hours. The clinic flow should be known by the participants and staff alike.

1. **Objective**

This document describes the clinic flow of a study participant at various sites during the Nigeria PreP Study.

1. **Responsibility:**

The PI and Site Coordinator are responsible for ensuring that this procedure is followed.

1. **Process**

* The study participants check in with the study nurse at study site waiting room.
* Nurse confirms the willingness of the couple to be part of the study/verifies appointment and pages the site coordinator and/or clinician.
* Participants wait in waiting room.
* Clinic intake nurse obtains vital signs of participants and return them to the waiting room.
* Study Coordinator receives study form with vital signs and meets with study Participants prior to blood draw to ensure that consent has previously been obtained and to ensure no challenge that would preclude obtaining blood samples.
* Study Coordinator provides research phlebotomist with appropriate study visit kit, pre-labeled and with requisition completed.
* Phlebotomist verifies Participants identity prior to blood draw
* Phlebotomist draws required samples according to Study Standard Operating Procedure for venipuncture and order of draw.
* Phlebotomist completes processing of study specific labs and prepares for shipment, including notification to receiving lab.
* Study Coordinator or designee meets with the study participant and updates medical history, any changes, medications and any other pertinent information and updates these findings on the study CRF.
* Study Coordinator assesses patient. Abnormal findings are immediately referred to PI or Sub-Investigator for clinical exam. Study visits requiring physical exam are completed by the PI or Sub-Investigator.
* Study Coordinator or designee assesses patient for drug adherence (if applicable) and social needs, including: any emotional or psychological issues. Issues identified are addressed.
* The Study Coordinator/Designee signs out the pharmacist dispensed study medication and gives it to the study participant. Any study medication questions are referred to the research pharmacist. All components of this process are documented on the study specific form by the Study Coordinator.
* Study Coordinator talks with the participant about the next study visit and sets a dates and time with the participant, noting this date and time on the study form.
* Study Coordinator provides the participant with travel reimbursement (as per study agreement) and has patient initial receipt which is returned to PI. Receipt of travel reimbursement is captured on the study specific form.
* The study participant checks out with the study nurse who enters the next scheduled appointment.

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

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