A Demonstration Project of Antiretroviral-based HIV-1 Prevention Among High-risk HIV-1 Serodiscordant Couples in Nigeria (Nigeria PreP study)



STANDARD OPERATING PROCEDURES

**Version 1.0**

**Approved to be in compliance with the protocol and Good Clinical Practice**

**Approved by**

|  |  |  |  |
| --- | --- | --- | --- |
| **Professor John Idoko** | **Principal Investigator** | **Signature** | **Date** |
| **Site PI** (enter name here) | **Site PI (Nnewi)** | **Signature** | **Date:** |
| **Site PI** (enter name here) | **Site PI (Jos)** |  |  |
| **Site PI** (enter name here) | **Site PI (Calabar)** |  |  |
| **Oliver Ezechi** | **Internal Monitor** | **Signature** | **Date:** |

##### Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Type of revision** | **Effective Date** |
| Version 1 | Creation of SOP | 28th February 2015 |
|  |  |  |
|  |  |  |
|  |  |  |

STANDARD OPERATING PROCEDURES NIGERIA PreP STUDY

##### Purpose

The International Conference on Harmonization (ICH) defines Standard Operating Procedures (SOPs) as "detailed, written instructions to achieve uniformity of the performance of a specific function.

##### Objectives

This document describes Standard Operating Procedures (SOPs) related to the activities needed to conduct the Nigeria PreP study, “A Demonstration Project of Antiretroviral-based HIV-1 Prevention among High-risk HIV-1 Serodiscordant Couples in Nigeria”

##### Applicability

Principal Investigator (PI, Site PI, Site coordinators , Co-Investigators, Data Manager, Study site facilitator, Study physicians, Safety Monitor, Internal and External Monitor, Anesthesia, HIV and antiretroviral drug adherence counsellor and study nurses, Data entry Clerks, Pharmacy technician, Pharmacist and other study staff .

# TABLE OF CONTENTS

SOP NO Title

Study Administration

SA-101 SOPs Preparation, Maintenance and Training

SA-102 Attendance Policy and Management

SA-103 Procurement and Shipping

SA-104 Sponsor Responsibility and delegation

SA-105 Training and Education

SA-106 Study Document development and change

Clinical Activities

CA-201 Participant Handling and Work Flow on erollment Day

CA-202 Screening and enrollement of Participants

CA-203 Verification of Eligibility

CA-204 Obtaining informed consent

CA-205 Couple Counselling

CA-206 Participants follow up

CA-207 Monitoring, recording and reporting AEs

**Laboratory procedures**

LP-301 Blood specimen collection

LP-302 Specimen receipt and handling procedures

LP-303 HIV Counselling and Testing

LP-304 Enumeration of CD4+ T lymphocyte

LP-305 HIV 1 Viral Load analysis

LP-306 Hepatitis B surface antigen (HBsAg testing)

LP-307 Creatinine testing and determination of Creatinine clearance

**Drug Administration**

DA-401 Investigational drug management

DA-402 Dispensing of investigational drug

DA-403 Investigational Drug Adherence counselling

**Data management**

DM-501 CRF Completion and Correction

DM-502 CRF Data Entry `

DM-503 Data Query Resolution

DM-504 CRF Filing

DM-505 CRF Quality Assurance

DM-506 Data Security

DM-507 Data Retention.

**Quality Assurance**

QA-601 Monitoring Visit

QA-602 Third Party Audits