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| **STANDARD OPERATING PROCEDURE for Nigerian PreP Study** |
| **Study Site:**  | **SOPs Number** :CA-206 |
| **Title****STUDY VISITS AND MISSED VISITS** |
| **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**

Compliance to study visits are essentially for efficient and proper study conduct and completion. Monitoring the outcomes of a research intervention requires the periodic observation of participants because of the economic and logistical challenge of prolonged facility admission of participants for these observations. Participants after enrolment are appointed to visit the study site for periodic evaluation and assessment. Adequate scheduling and follow up of appoints are important for the success of any research study.

The Principal Investigator and research staff will coordinate and perform the required evaluations for assigned research protocols in accordance with the protocol, ICH guidelines, regulatory authorities, sponsor, and institutional review/ethics boards guidelines and regulations.

1. **Objectives**

Designed to educate, train, and be used as a reference for the site coordinator and research team to perform required visit specific study evaluations.

1. **Responsibility**

 Principal Investigator, Site Coordinator, Co-Investigator, Study Nurse, Pharmacist, Data Manager and designee.

1. Definitions

 **Screening Identification (SID) Number**. A unique number that is assigned by the PI or designee to each participant that presented for screening before the determination of eligibility. The SID will be in the format XXX-001. The first participant screened in Jos, the SID will be JOS-001, for Enugu= ENU-001 and Calabar = CAL-001.

 **Participants Identification (PID) Number:** A unique identifier number that is assigned by the PI (or designee) to each participant participating and in a format (NPD-0X-00XA or NPD-0X-00XB NPD= Nigeria PreP Demonstration; 0X= Site code (01= Jos, 02 = Enugu; 03= Calabar; A for HIV negative partner and B for HIV Positive partner. The first couple to be enrolled in study in various sites will bear the number (NPD-01-001A; NPD-01-001B). A PID is used to protect the subject’s identity and confidentiality in the research file.

PID is used in lieu of the individual’s name when the investigator reports adverse events and/or other trial-related data, and on all research documents that go to the sponsor, or outside of the Institution where the research is being conducted.

While a participant that was screened and found ineligible will have only SID, those enrolled into the study will have both SID and PID. However once enrolled into the study only the PID will be used.

1. Procedures

**1. Screening and/or Pre-entry visits:** The Site coordinator (or designee) will implement screening and/or pre-entry visits as specified in the protocol including implementation of the informed consent process. (See Informed Consent and recruitment Process SOP.)

**a. Informed Consent:** The Site coordinator (and designee) will verify the completion of the informed consent document including correct date and signatures PRIOR to performing any screening procedures for anticipated enrolment.

**b. Clinical Evaluations:** The Site coordinator (or designee) will perform the required clinical evaluations for the assigned protocol including, but not limited to physical assessment, medical history, medication history, and laboratory tests and/or procedures.

**c. Study Procedures and Laboratory Analysis:** The Site coordinator (or designee) will assure that all necessary research procedures and laboratory analysis are obtained as outlined in the protocol AFTER the subject has provided written informed consent. No study procedures may be obtained prior written consent. The Site coordinator (or designee) will coordinate with the head of site laboratory to ensure that the correct procedures and specimens are labeled, collected, and that laboratory staff are available to receive and process study specimens. All study test results and procedures will be reviewed, signed and dated by the Principal Investigator. Abnormal results will be graded and if clinically significant must be documented, including action taken. The research team will verify protocol required action, and assure compliance. (Refer to AE/SAE Reporting SOP)

**d. Eligibility Checklist:** The Site coordinator (or designee) will use an eligibility checklist to verify that all inclusion criteria are met and that no exclusion criteria exist. The Site coordinator and Principal Investigator will confirm each participant’s eligibility prior to enrolment .

**e. Return Visits:** The Site coordinator (or designee) will submit an appointment return with the study nurse for a return study visit as outlined in the protocol. The Site coordinator (or designee) will verify that visits occur within the protocol specified time frame (window). The Site coordinator (or designee) is responsible for notifying the study participant and research team, including, data management, receiving laboratories, and pharmacy (if applicable) of the anticipated enrolment date. The Site coordinator (or designee) will keep a schedule of anticipated study visits.

Missed study visits must be followed up and documented. (See Missed Study Visit SOP).

**g. Source Documentation:** The Site coordinator (or designee) will complete the source documentation for the appropriate study visit and submit it to the Principal Investigator for review and signature. All signed source documentation must be filed in the office or medical records chart for the study patient. Hard copy laboratory or procedure results may be filed in the office chart or participant research binder but should be consistent throughout the study. If filed in the participant research binder, only SID and PID identifiers should be used.

**h. Case Report Forms (CRF):** The Site coordinator (or designee) will complete CRFs as required by the assigned protocol and the data management center and submit them to site data management with 3 working days. (Refer to Data Management SOP for required timeline.)

**2. Enrolment Visit:** After eligibility has been confirmed by the PI and Site coordinator, the Site coordinator (or designee) will schedule and implement the enrolment visit within the protocol specific timeline and conduct the enrolment visit as noted in the protocol.

**b. Clinical Evaluation:** The Site coordinator (or designee) will perform the required enrolment evaluations including, but not limited to physical assessment, review of signs/symptoms, diagnoses, medical and medication history, coordinate laboratory tests and/or procedures .

**c. Medications:** The Site coordinator (or designee) will record all study and concomitant medications in the flow sheet or medication log as required by the protocol at the enrolment visit. The Investigational drug is then prescribed and participant is sent to the adherence counselling for Prep drug adherence counselling (see adherence counselling SOP). The adherence counselor thereafter hands the participant to the pharmacist for PreP dispensing. Original entries and changes to the medication log should be reviewed, signed and dated by the Principal Investigator.

**d. Study Procedures and Laboratory Analysis:** The Site coordinator (or designee) will assure that all necessary research procedures and laboratory analysis are obtained as outlined in the protocol AFTER the subject has provided written informed consent. No research procedures may be obtained prior written consent. The Site coordinator (or designee) will coordinate with the head of site laboratory to ensure that the correct procedures and specimens are labeled, collected, and that laboratory staff are available to receive and process study specimens. All study test results and procedures will be reviewed, signed and dated by the Principal Investigator. Abnormal results will be graded and if clinically significant must be documented, including action taken. The research team will verify protocol required action, and assure compliance. (Refer to AE/SAE Reporting SOP)

**e. Pharmacy:** The site coordinator (or designee) will coordinator with the pharmacy and refer all enrolled participants to the pharmacist for consultation/counseling regarding the initiation of PreP and possible side effects for protocols that include study medication. The agent, route, dose and frequency of all study medications (or changes) must be recorded in the source documents flow sheet, record, or study medication log.

**e. Return Visits:** The site coordinator will submit an appointment return with the study nurse for a return study visit as dictated by protocol. The site coordinator is responsible for notifying the participant of the return date and keeping a schedule of anticipated study visit returns in order to be aware of anticipated return study visits. Missed visits must be followed up and documented. (Refer to Missed Visit SOP).

**f. Source Documentation:** The Site coordinator (or designee) will complete the source documentation for the appropriate study visit, containing all protocol specified events occurring at that visit. The site coordinator (or designee) will submit the source document to the Principal Investigator for signature. All signed source documents must be filed in the office record. Hard copy lab or test results may be filed in the office record or participant research binder, file but must be consistent throughout the study. If filed in the participant research binder, PID identifiers should be used.

**i. Case Report Forms (CRF):** The Site coordinator (or designee) will complete CRFs as required by the protocol and the data management center and submit them to site data management within 5 business days of the actual study visit.

**j. Data Management:** The site coordinator (or designee) will collaborate with data management to ensure that all collected data are entered in a timely fashion. The site coordinator (or designee) will complete CRFs as required per protocol and the data management center. Completed flow sheets and CRFs will be submitted to data management. (Refer to Data Management SOP for required timeline.)

**3. Follow-Up Visit(s):** The study requires scheduled multiple follow up visit. The PI or site coordinator must ensure that this visit happen as at when due.Additionally, participants with ongoing adverse events (AE) even at study discontinuation need to be followed up until the event has resolved, if causality of the AE to study participation is suspected.

**Clinical Evaluation:** The site coordinator (or designee) will perform and document the required follow up evaluations for the study, including, but not limited to physical assessments, review of signs and symptoms, new diagnoses, hospitalizations, SAE, medication changes, status of ongoing AE, and laboratory tests and/or procedures. (Refer to AE/SAE Reporting SOP.)

**b. Study Procedures and Laboratory Analysis:** The site coordinator (or designee) will ensure that all necessary research procedures and laboratory analysis are obtained as outlined in the protocol. The site coordinator (or designee) will coordinator with the receiving laboratories to assure that the correct procedures and specimens are collected, and that laboratory staff are available to receive and process research specimens.

All research test results and procedures will be reviewed, signed and dated by the Principal Investigator. Abnormal results will be graded and if clinically significant must be documented, including action taken. The research team will verify protocol required action, and assure compliance. (AE/SAE Reporting, and Healthcare Management SOPs.)

**4. Missed Study Visits:** Anticipated study visits that are missed or out of the protocol specified time-frame (window) must be documented as missed study visits. The site coordinator (or designee), together with research team will attempt to contact/locate the study participant and bring the him/she back into the study. If the study participant wishes to discontinue study prematurely, then a discontinuation visit will be scheduled. (See Study Discontinuation Visit for details.) All attempts and action to locate and bring the study participant back into care or for study discontinuation must be documented and filed as source documentation. If the study person chooses to discontinue prematurely, the study team, including data management and pharmacy, and the sponsor must be notified of the premature discontinuation visit. If the study participant has missed two consecutive study visits and all attempts to locate the study subject are unsuccessful, the study participant may be prematurely discontinued as lost to follow-up. Participants should not be discontinued as lost to follow-up until all efforts to locate and bring them back into study have been exhausted.

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

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