|  |  |  |
| --- | --- | --- |
| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** :CA-203 |
| **Title**  **VERIFICATION OF ELIGIBLITY** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

|  |  |  |
| --- | --- | --- |
| **Review date** | **Revision Date** | **Signature** |
|  |  |  |
|  |  |  |

**Document History**

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

**Distribution List**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name/Location** | **No of copies** | **Name/Location** | **No of copies** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Introduction**

Eligibility criteria for clinical trials are designed to ensure the safety of research participants and reflect the objectives of a study. Automated eligibility determination systems are the ideal method as it help strengthen the enrolment process by standardizing decisions. It so that study personnel do not influence the selection process. However, in most clinical trials, investigators or their designees determine whether individual participants meet selection criteria, a process vulnerable to selection bias because of subjective interpretations and the personal views of study personnel. Eligibility criteria are thus predetermined to reduce this individual bias and facilitate consistent decision-making and avoid enrolment error, thereby reducing the opportunity for participant risk.

1. **Objectives**

To establish a standardized procedures for the verification of participants eligibility for the Nigeria Prep Study.

1. **Responsibility**

* This SOP applies to all study staff involved in determining participant eligibility for Nigeria PreP study.
* Study staff members designated to assess and/or confirm eligibility are responsible for doing so in accordance with this SOP.
* PI/Designee is responsible for training study staff to assess and/or confirm participant eligibility in accordance with this SOP and for day-to-day oversight of study staff to ensure that this SOP is followed.
* PI is ultimately responsible for ensuring that all applicable study staff follow this SOP and that only participants who meet protocol-specified eligibility criteria are enrolled.
* Internal and external monitor must verify and confirm the eligibility of all individuals enrolled in the study. When individuals are erroneously enrolled S/He must ensure remedial actions are instituted as in SOP CA 209 (protocol deviation and management).

**4. Procedures**

Eligibility Criteria: The eligibility criteria for Nigeria PreP study are specified in protocol Section ??. Always refer to the current version of this section of the protocol when determining eligibility, including any protocol Clarification Memos and Letters of Amendment.

Assessing Eligibility: It is the responsibility of PI/Designee to perform all assessments required to determine eligibility for the study. These assessments include reviewing available medical records; collecting and reviewing medical/medications history information; performing physical examinations and reviewing the findings thereof; and performing laboratory evaluations and reviewing the results thereof. In addition, documentation of written informed consent must also be reviewed.

Study staff will perform assessments required to determine eligibility in accordance with their roles and responsibilities as designated on the study staff roster and document the outcome of these assessments in accordance with site SOPs for source documentation. As part of this process, if any study staff member identifies any eligibility-related issues, questions, or concerns, he or she will document these and obtain further review and input from the PI or designee. If needed, input will also be sought from the study safety physician , with documentation thereof printed and filed in participant study CRF.

Confirming Eligibility: Before proceeding to enrolment , on the day of enrollment, Site Coordinator will review all available information and verify whether all eligibility criteria have been met. If the reviewer is not able to make a final eligibility determination, he or she will consult with the PI or designee as needed. Any such consultations, and the reviewer’s eligibility determination, will be documented in accordance with site SOPs for source documentation.

Proceeding to Enrollment: Assuming the potential participant is determined to be eligible, he or she will be enrolled according to SOP for enrolment. .

Note: In the event that any study staff determine that an ineligible participant has been enrolled, the PI or designee will immediately be informed and remedial action instituted as in SOP CA 210 (Protocol deviation and management).

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Date** | **Name** | **Date** |
|  |  | 8. |  |
|  |  | 9. |  |
|  |  | 10. |  |
|  |  | 11. |  |
|  |  | 12. |  |
|  |  | 13. |  |
|  |  | 14. |  |