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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** :CA-202 |
| **Title**  **SCREENING AND ENROLLEMENT OF PARTICIPANTS** | | |
| **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** |
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1. **Introduction**

The recruitment phase of a clinical study is frequently difficult and challenging. Successfully recruiting subjects involves the development and implementation of a well-coordinated plan that may require the efforts of the entire research team. Once in place, subject recruitment efforts must be constantly assessed, with new strategies implemented as necessary. After potential subjects have been identified through recruitment efforts, the process of subject selection begins.

1. **Objectives**

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in subject recruitment and selection

1. **Responsibility**

This SOP applies to research team involved in conducting clinical study at the Nigeria PreP Study sites. This includes the following but not limited to :

1. Principal investigator
2. Co-investigator
3. Site coordinator
4. Definitions

The following definitions from the International Conference on Harmonisation, Good Clinical Practice Guideline apply to this SOP.

**Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

**Participant/Study participant**: An individual who participates in a clinical study, and receives an intervention (investigational product(s) or any other).

**Vulnerable Participants:** Individuals whose willingness to volunteer in a clinical study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable individuals include persons with incurable diseases, persons in nursing homes, unemployed or impoverished persons, individuals in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent

1. Process overview

* Develop and implement an overall recruitment plan
* Assess the effectiveness of the recruitment plan
* Initiate screening procedures

1. Procedures
2. **Develop and implement an overall recruitment plan**

* The P**I** based upon the specific inclusion/exclusion criteria for this study, identify the target population for potential study Participants. Establish a recruitment timeline. Identify sources of potential participants, engage staff and provide training
* The Site Coordinator or designee determines recruitment methods. Develop recruitment materials and submit to the IRB as appropriate.

1. **Assess the effectiveness of the recruitment plan**

* The PI/Site coordinator orDesigneeMonitor progress and assess results of the recruitment strategy. Develop appropriate alternative strategies, if enrollment projections lag.

1. **Initiate screening procedures**

* The Site coordinatordevelop a screening log based upon the study inclusion/exclusion criteria to collect screening information on all potential Participants (Attachment A, Screening and Enrollment Log). Note if individuals went on to enroll in the study; if they were not enrolled, document the reason.
* The PI or Designee obtains informed consent. Maintain a log of when informed consent was obtained from each subject. Retain all signed informed consent forms from Participants who terminate their participation in the study during the screening process.

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

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