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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** :SA-108 |
| **Title**  **PROTOCOL DEVIATION AND MANAGEMENT** | | |
| **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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**Distribution List**

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1. **Introduction**

A protocol that has received ethics approval and regulatory approval is a formal document defining what can and cannot be done as part of a research project and must be adhered to so that participant safety and research integrity can be maintained. In some circumstances it may be necessary to deviate from protocol to protect the safety of a research participant, which is classed as an urgent safety measure. Most deviations from protocol relate to variance from the defined inclusion and exclusion criteria or changes to protocol defined processes.

1. **Objectives**

To establish the process for reading and implementing a clinical research protocol.

1. **Responsibility**

The Principal Investigator and all research staff involved with the performance of a protocol are responsible for reading and implementing the protocols once approved by all necessary regulatory authorities in accordance with Federal, International, Sponsor and Institutional guidelines and regulations.

1. **Definitions**

**Approval:** The affirmative decision of the ethics committee (EC) that the study has been reviewed and may be conducted at the institution’s site within the constraints set forth by the EC, the Institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

**Clinical Study:** Any investigation in human participants intended to discover, prevent, control, diagnose or treat illness, including: verify clinical, pharmacological, and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

**Multi-Center Study:** A research study conducted according to a single protocol at more than one site, and, each site having separate site leadership ie Principal Investigator.

**Protocol:** A document that describes the objective(s), design, methodology, statistical considerations, and organization of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.

**Protocol Amendment:** A written description of a change(s) to a protocol or formal clarification of a protocol.

**Participant/Trial Participant:** An individual who participates in a clinical study.

**Study Site:** The location(s) where study-related activities are actually conducted.

**Clarification Memo:** A memo designed to clarify a specific part of the protocol. A clarification memo does not officially change the protocol.

**Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical study that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of study participants are protected.

**Institutional Review Board (IRB) and Institutional Ethics Committee (IEC)**:An independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial participants.

**Investigational Product:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

1. **Procedures**

**Reading the protocol:** The site coordinator will be responsible for reading the assigned research protocol in its entirety including but not limited to the schema, study design, study treatment, inclusion/exclusion criteria, required evaluations, laboratory tests/procedures, toxicity management, clinical/laboratory endpoints, the schedule of events, appendices and the informed consent.

**Informed consent document:** The site coordinator will be responsible for reading and understanding the informed consent document prior to reviewing it with a potential study candidate.

**Information**: The site coordinator will be responsible for reviewing all communication and documents pertaining to the protocol, including but not limited to correspondence, clarification memos, and protocol amendments.

**Communication**: The site coordinator will communicate with the protocol team regarding all questions, issues or problems with the research protocol.

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

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