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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : SA-106 |
| **Title**  **DOCUMENTATION AND RECORDS RETENTION** | | |
| **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**

International and local regulations require documentation of all study-related activities. This standard operating procedure (SOP) describes the steps Nigerian PreP Study follows to fulfil all regulatory and clinical requirements for creating, collecting, reviewing, filing and storing study-related documents and records.

1. **Objective**

This SOP applies to the activities involved in establishing and maintaining the regulatory records for Nigerian PreP Study.

1. **Responsibility:**

* This SOP applies to all Nigeria Prep study Staff.
* Nigeria PreP study core team, Principal Investigators and Co-investigators are responsible for ensuring that complete and precise data are collected, documented, and maintained throughout the course of this study.
* The monitor (internal and external) is responsible for verifying that the files are complete, accurate and securely maintained by the Principal Investigator and Co-investigators.
* The Sponsor (NACA) is responsible for terminating the participation of and discontinuing shipments of investigational product to any participating PI or co-investigator who has failed to maintain or make available required records or reports of the study.

1. **Definitions**

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

**Case Report Form (CRF):** A printed document designed to record all of the protocol-required information in this study.

**Compliance (in relation to study):** Adherence to all the study-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

**Confidentiality:** Prevention of disclosure, to other than authorized individuals, of a sponsor’s proprietary information or of a Participant’s identity and data.

**Contract:** A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

**Direct Access:** Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of the study. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of Participants’ identities and sponsor’s proprietary information.

**Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of the study, the factors affecting the study, and the actions taken.

**Essential Documents:** Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

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

**Investigator:** A person responsible for the conduct of the clinical study at a clinical study site. If a study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the principal investigator.

**Inspection:** The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical study and that may be located at the site of the study, at the sponsor’s , or at other establishments deemed appropriate by the regulatory authority(ies).

**Monitoring:** The act of overseeing the progress of a clinical study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirements.

**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 change(s) to or formal clarification of a protocol.

**Quality Assurance (QA):** All those planned and systematic actions that are established to ensure that the study is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

**Source Documents:** Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical study).

**Sponsor:** An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study.

1. **Process**

**Process overview**

* Collecting, filing and storing study-related documents and records
* Monitoring the site(s) regulatory files

1. Collecting, filing and storing study-related documents and records

For the study, create a Regulatory Master File (RMF) for documents created and used throughout the course of the study. The RMF may be a series of paper and/or electronic file folders and/or in a binder. See Attachment A- Essential Documents).

Maintain and update the RMF as necessary, adding appropriate documents as they are generated or received. Retain copies of all original and revised documents (e.g., protocol, investigator’s brochure, informed consent form). To ensure the current version is always used, save previous versions of documents in the archive section of each folder.

Ensure regulatory files are kept confidential and are stored in a secure, limited-access location.

Prior to site monitoring visits, review content of the RMF for completeness.

Ensure that files are organized and complete following the visit.

When the study is over, review the contents of the RMF for completeness by comparing with the adapted summary of the ICH Essential Documents and the RMF structure document. In addition to the documents maintained in the RMF during the course of the study, the following documents will be included after study closure or termination:

1. Investigational product(s) accountability forms
2. Documentation of investigational product destruction, if applicable
3. Audit certificates and reports/NAFDAC inspection reports
4. Final study closeout monitoring report(s)
5. Final study reports sent to the respective IRB(s)
6. Clinical study report

Archive the RMF.

Label storage boxes clearly and completely.

Document inventory of storage boxes.

Store in a secure location for the required period of time.

1. **Monitoring site regulatory files**

At the site initiation visit, routine monitoring visits, and site closeout visit, review the participating site’s regulatory file(s) to ensure they contain the appropriate documents, completed as applicable. (Attachment A, Adapted Summary of ICH Essential Documents)

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

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