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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : DM-507 |
| **Title**  **DATA 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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1. **Introduction**

Appropriate record retention ensures that information from clinical research will remain secure and that it will still be available in the future for inspection by regulatory authorities. Archiving in the context of clinical research relates to the collection for long term storage of essential documents that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced. Section 8 of ICH GCP lists those documents which are considered to be essential documents that shall be stored

1. **Objectives**

This SOP describes the process for the archiving of essential documents and other study-related material at the appropriate time.

1. **Responsibility**

This SOP applies to the clinical personnel responsible for the archiving of research data and the ongoing retention of archived data.

1. **Definitions**

**Case Record Form (CRF)**: A printed, optical, or electronic document designed to record all of the protocol-required information on each research subject.

**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.

**Source Data**: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents (original records or certified copies).

**Source Documents**: Original documents, data and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, subject’s 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).

**Study Closure**: For the purposes of data retention, study closure refers to the date on which the last piece of source data is captured for a research study.

1. **Process overview**

A. Retaining paper source documents and essential study files

B. Retaining electronic source documents

C. Retaining case report forms (CRFs)

**6. Procedures**

**A. Retaining Paper Source Documents and Essential Study Files**

1. After study closure, all of the essential documents (including source documents) should be compiled and checked for completeness.
2. Complete a record of archived materials including the following information:
   1. The study name and number
   2. The name of the investigator
   3. The date of archival
   4. The period of retention required
   5. The location of the documents
   6. The number of containers
3. Take measures to prevent accidental or premature destruction of the essential documents.
   1. Clearly identify storage boxes
   2. Store in a locked area
4. Prepare to archive the files according to local policies and, if applicable, the sponsor agreement.
5. At the request of the sponsor, monitor, auditor, or regulatory authorities direct access to all study-related records must be made available.
6. Maintain all clinical study records for a minimum of 10 years from completion of the study or more if required by sponsor or regulatory authority

**B. Retaining Electronic Source Documents**

1. After study closeout, all of the electronic source documents should be compiled and checked for completeness.
2. Complete a record of archived materials including the following information:
   1. The study name and number
   2. The name of the investigator
   3. The date of archival
   4. The period of retention required
   5. The location of the documents (physical or on a network, as applicable)
   6. The date the data was written to the current storage device
   7. The storage format of the documents (type of storage device)
   8. The number of storage devices, if applicable
3. Electronic source documents associated with study must be maintained in a format that makes them accessible for the duration of the prescribed archival time.
4. Electronic storage methods are constantly evolving, and current methods of data storage do not maintain the integrity of the data over long periods of static storage. Therefore electronic data must be reviewed every 2 years during the retention period to maintain the integrity of the data and ensure its accessibility.
5. When reviewing the data, consider the following issues, and record the assessment in the record of archived material:
   1. When was the data recorded onto the storage device
   2. How long does the device reasonably maintain data integrity under current conditions
   3. Is the hardware and/or software required to access data on the device expected to be readily available until the next review
6. If, as a result of this assessment, the current data storage device is considered inadequate, copy the data to a new device and update the record of archived materials to reflect the changes made.
7. If the current data storage device is considered adequate until the next review, document this on the record of archived data.
8. Maintain all clinical study records for a minimum of 10 years from completion of the study or more if required by sponsor or regulatory authority
9. Take measures to ensure that the electronic data cannot be changed by making the files read only before storing, by storing on a read only device, or by restricting write access to the storage device to essential personnel.

**C. Retaining Case Report Forms**

a. The retention of Nigeria PreP Study case report forms is the responsibility of the study sponsor (NACA). Work with the study sponsor to archive the material and make a record of the process in the study files.

b. Best practices dictate that these files be retained for a minimum of 10 years from study closure or until analysis of study data is complete, whichever is longer or longer as dictated by sponsor or regulatory authority .

c. Back up electronic investigator CRFs on a regular basis using an automated system that allows for recovery of the data.

d. If data is lost or corrupted, take immediate steps to retrieve the data from the backup system. Assess the cause of the loss and take measures to prevent it happening again.

If a document contains identifiable information, the data must be stored securely.

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

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