STANDARD OPERATING PROCEDURE (SOP)

TITLE: STUDY DOCUMENTATION FILING

DO NOT USE THIS SOP WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

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Applicable Clinique Research Site(s):	All

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Signature:	
Date:	February 2020

1. PURPOSE:

The purpose of this SOP is to describe the procedure of study documentation filing undertaken at Clinique Research and to ensure:

- All relevant parties (sponsors and sites) are consulted and can support the project.
- The proposed trials are a strategic fit and aligns with Clinique Research's core values.
- Research projects have the best possible outcome in terms of recruitment, patient safety, budget, and time frames.

2. SCOPE:

All clinical trials to be monitored and managed at Clinique Research.

3. APPLICABILITY:

This applies to all Clinique Research employees, contract staff and to all relevant external persons or parties proposing to engage in the clinical trial services at Clinique Research.

4. GLOSSARY OF TERMS:

Please refer to Clinique Research SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

Clinique Research is responsible for monitoring and managing clinical trials in accordance with ethical and regulatory standards.

5.1 Study Documentation Filing

- The study monitor will create a Regulatory Master File (RMF) for documents created and used throughout the study.
- The study monitor will maintain and update the RMF as necessary, adding appropriate documents as they are generated or received.
- It is the responsibility of the study monitor to retain copies of original and revised study documents.
- The study monitor will ensure the current version is always used, save previous versions of documents in the archive section of each folder.

- The study monitor must ensure regulatory files are kept confidential and are stored in a secure, limited-access location.

- The study monitor will review with the site requirements for maintaining the integrity of study documents (including electronic data) for the period specified in applicable study agreement and regulations.

- Prior to site monitoring visits, the study monitor will review the RMF for completion, and ensure files are complete and organized after each visit.

- After the study closure, the study monitor will review the RMF for completion, and compare it with the ICH essential documents. He or she will ensure the inclusion of the following documents: Investigational product(s) accountability forms, documentation of investigational product destruction (if applicable), audit certificates and reports/NAFDAC inspection reports, final study closeout monitoring report(s), final study reports sent to the respective IRB(s), clinical study report.

- The study monitor will archive the RMF and ensure storage boxes are labelled clearly and completely.

- The study monitor must document inventory of storage boxes, and store documents in a secure location for the required period.

- The study monitor will review the site's regulatory files to ensure they are complete and contain the appropriate documents at site initiation, routine monitoring, and site closeout visits.

6. VERSION CONTROL:

Document History	
Version	**Summary of Changes**
1.0	N/A – First Issue

7. APPENDIX:

Archiving completed study documents SOP
Data backup SOP