STANDARD OPERATING PROCEDURE (SOP)

TITLE: SITE CLOSEOUT

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:	
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1. PURPOSE:

The purpose of this SOP is to describe the procedure of site closeout visit 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 Site Closeout Visit

The site closeout visit will be arranged to include the study monitor (Clinical Research Associate at Clinique Research), the principal investigator, and other key personnel responsible for closeout visits. The close out visit ensures all obligations required of the principal investigator and all study regulatory requirements have been fulfilled.

- It is the responsibility of the study monitor to schedule a closeout visit at the study trial site,
- It is the responsibility of the study monitor to schedule the closeout visit with the principal investigator prior to the visit,

- The study monitor will review informed consent of subjects since last monitoring visit, case report forms, regulatory documents, investigator's study file and ensure they are all current and complete.

- The study monitor must complete the Closeout Visit Checklist and Report to document the closeout visit.

- Serious Adverse Events may occur in some subjects; hence the study monitor must discuss the requirements for follow up after the formal closure of the site.

- The study monitor will ensure the accountability of investigational products and the records are current and accurate.

- A report must be sent to the institutional review board informing them of the formal closure of the site. It is the responsibility of the study monitor to remind the site to inform the local IRB of the closure of the study, and file the appropriate final report, if they have not already done so.

- 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.

- The study monitor must ensure appropriate disposition of unused investigational products and other related items by the time of the closeout visit. In cases where this is not possible, obtain documentation of appropriate disposition as soon as possible.

- The study monitor will inform and send a report to the central IRB of the study closure.

- After all queries have been resolved, the study monitor must ensure proper secure storage of current and complete study files.

- A final letter indicating all outstanding activities have been completed and the closure of the study at the study trial site must be sent by the study monitor to the principal investigator.

6. VERSION CONTROL:

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

7. APPENDIX:

Site Closeout Visit Checklist
Investigator Site File Tracker