STANDARD OPERATING PROCEDURE (SOP)

TITLE: MONITORING PLAN

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 routine monitoring 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. SITE MONITORING SCHEDULE

Ordinarily, a pre study, initiation, routine and close out monitoring are planned and conducted in the life span of a study. The site initiation visit will be conducted as soon as:

- All the necessary approvals have been obtained
- Staff recruited
- Investigational product has been delivered to site (is about to be delivered to site)
- CRF and source documents are ready
- Laboratory is ready to start storing study samples

The first routine monitoring visit will occur as soon as the first participant is recruited or within 2 weeks of the first participant being recruited. The table below provides an estimate of what will be

needed in terms of time on site for the monitor. This needs to be continually assessed by the study management team and the monitors. The monitoring frequency may need to increase if recruitment is faster than predicted, at times of data entry deadlines (such as interim analysis or if the DSMB request a safety report) then two or more people can attend the visit.

Site	Location	Number Predicted	Study Start	Frequency Of Monitoring

6. PROCEDURE:

Clinique Research is responsible for monitoring and managing clinical trials in accordance with ethical and regulatory standards. Clinique Research will appoint a Clinical Research Associate (Study Monitor) to monitor the trial. The monitor will be trained on the study protocol and will be familiar with all study procedures.

6.1 Monitoring Plan

For each site visit the study monitor will work according to an agreed schedule of tasks, including the following that will be given as specifics in the monitoring form and guidelines:

- Schedule a date with the study investigator/coordinator to discuss the monitoring procedure and provide them with a list of the study sections that will be monitored in the visit.
- Review the last monitoring procedure report.
- Review the site study file and ensure that it is updated appropriately.
- Verify written informed consents were given for every subject enrolled in the study and that they were obtained according to the ICH GCP regulatory requirements.
- Review status of the study's participant enrolment versus anticipated enrolment, losses to follow up, outstanding data issues, reported serious adverse events, outstanding laboratory issues.

- Review the study forms and database ensuring that the participants were eligible and note any safety issues and protocol violations or deviations.
- Review the handling, storage, and shipment of laboratory samples.
- Verify source data.

During the initial visits the monitors will review 100% of the fields of all the study forms. Subsequently the monitors will review 100% data contributing to the primary endpoint and 100% of fields for a randomly selected sample of study forms. All forms monitored during a visit will be detailed in the monitoring visit report. A data base check for accuracy of data entry will be performed at regular intervals. The data points to be checked will be end point data and safety data. After each monitoring visit the monitor will debrief the study team i.e., praise them where they are getting it right and highlight areas which need improvement. The monitor will then write up a monitoring report citing all findings and status of such findings (resolved or not) and forward a signed copy to the sponsor and/or sponsor appointed project manager. The monitoring report may be shared with the Principal Investigator (PI).

At close out visit(s) the monitor will ensure all queries are resolved, the study product is accounted for and returned or destroyed according to sponsor SOP, and study documents are properly archived. The comprehensive list of activities during this visit(s) will be detailed in a study close out SOP.

7. VERSION CONTROL:

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

8. APPENDIX:

Site initiation visit checklist
Routine Monitoring SOP
Routine Monitoring Report
Close out visit SOP