STANDARD OPERATING PROCEDURE (SOP)

TITLE: ROUTINE MONITORING

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:	January 2020

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. PROCEDURE:

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

5.1 Interim Monitoring Visit

- After the site initiation visit and before the study closeout visit, routine monitoring is carried out one or more times by the study monitor (Clinical Research Associate at Clinique Research) at the study trial site. The purpose of this visit is to ensure protection of rights and safety of study participants, confirm data integrity and quality, compliance with study protocol and regulatory requirements.

- The study monitor will estimate the frequency of monitoring visits based on the sponsor's SOP, enrollment rate, performance of the site, investigator team's experience, subject enrollment rate, complexity of the protocol, and the disease being evaluated.

- The study monitor will review previous monitoring reports (where applicable) and protocol to confirm adherence.
- The study monitor must have a routine monitoring checklist to be completed during the visit.
- The study monitor must document a routine monitoring visit by signing the site visit log at the study trial site.
- The study monitor will schedule routine exit visits with the Principal Investigator.
- The study monitor will review information about serious adverse event(s) and ensure it is reported to the sponsor or appropriate representative(s) of the sponsor in a timely manner.
- The study monitor will assess subject enrollment rate in the study trial site.
- The study monitor must review the informed consent form for new subjects enrolled since the last visit.
- The study monitor will review inclusion and exclusion criteria to confirm the eligibility of subjects.
- The study monitor will review trial site randomization and drug dispensing strategies.
- The study monitor will review laboratory samples and investigational product accountability in study trial site.
- The study monitor will review subject visit schedule and window.
- The study monitor must review the case report form (CRF) and source documents.
- The study monitor must have an error query/correction form to note potential errors.
- The study monitor will verify all the required study documents are complete, current, and accurate.
- If study supplies need to be ordered, the study monitor must ensure ordering be done before leaving the study trial site.
- The study monitor must schedule the next monitoring visit before leaving the study trial site.
- The Study Monitor must complete a Monitoring Report during and after the routine monitoring visit to be sent to the sponsor.

- A follow-up letter recapping important information should be sent after the visit to study trial site.

6. VERSION CONTROL:

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

7. APPENDIX:

Monitoring Visit Follow Up Letter and Table
Routing Monitoring Checklist
Temperature Monitoring Log