STANDARD OPERATING PROCEDURE (SOP)

TITLE: MANAGEMENT OF PROJECT ESCALATION

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Applicable Clinique Research Site(s):	All

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Signature:	
Date:	March 2020

1. PURPOSE:

The purpose of this SOP is to describe the procedure of management of project escalation 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 Management of Project Escalation – Suspension

- The study monitor will discuss any concerns and send a written request of resolution regarding audit findings, monitoring report findings or consistent communication problems by a study team with the Principal Investigator (PI) detailing the given deadline for expected resolution, clearly stating that the study will be suspended to new requirement if a satisfactory response is not received by the date stated.
- In the likelihood that the PI is unable to resolve the concerns before the stipulated time, the study will be suspended to new recruitment until the study monitor is satisfied the study is compliant with ICH GCP regulatory requirements.
- The suspension will be notified to the REC by completion of a substantial amendment form.

- Support departments such as pharmacy and any other participating sites will also be informed that the study is suspended to new recruitment until further notice.

Recruitments following suspension will constitute a serious breach of GCP.

5.2 Management of Project Escalation – Post Suspension

- When the PI states that the study audit or monitoring findings have been corrected, the study monitor will perform a visit to assess whether the corrections are in accordance with ICH GCP regulatory requirements.
- If the corrections are appropriate, the study monitor will authorize the PI to notify the REC that the study is reopened through submitting an amendment form.
- Support departments all participating sites will be informed that the study is re-opened to new participants.
- If closing the study would pose a risk or adversely affect the ongoing patient management then identifying an alternative PI should be considered. All responsibilities by the non-compliant team members should be revoked. The Delegation of Responsibilities log should be updated with end dates for those team members.
- A simple report of the reasons leading to escalation procedure – actions taken by whom, should be placed in the site file. The sponsor should be kept fully informed at each stage of the process.

6. VERSION CONTROL:

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

7. APPENDIX:

Protocol Deviations and Violations