STANDARD OPERATING PROCEDURE (SOP)

TITLE: ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

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 adverse events and serious adverse events reporting 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. Subjects should also be encouraged from the outset of any study to contact the research team at the time of any adverse event where possible.

5.1 Adverse Events (AEs)

- The study monitor will ensure the study site conducts continuous screening for AEs events on an ongoing basis using patient-reported histories, physical assessment/exam, laboratory reports, chart review, and any other available.
- Identified AEs must be documented including the appropriate toxicity grade from the study assigned toxicity grading scale on the study visit flow sheet or an AE log specific to that study participant. If the toxicity is not included in the toxicity table, grades 1,2,3,4 for mild, moderate, severe, and life threatening should be used.
- All AEs must be assessed by the Principal Investigator (PI) to determine causality and required course of action in accordance with the protocol and regulations.

- The study monitor must ensure all required course of action for an AE is followed to resolution by the study team.
- Clinical management of AEs should follow the toxicity guidelines outlined in the study protocol unless contraindicated.
- AEs ongoing at study completion should be followed up as per the requirements of the protocol and as clinically indicated.

5.2 Serious Adverse Events (SAEs)

- The study monitor will continuously screen for SAE events on an ongoing basis using patient or family-reported events, home-base care reports, in-patient census, obituaries, or any other available data.
- Once a site receives information of a SAE, the study monitor will ensure an initial report must be made to the Sponsor and Institutional Ethics Committee within 24 hours of notification.
- Once a SAE is identified, the study monitor must ensure the study team properly documents the SAE event, what makes this an SAE, study medication(s) and if ongoing, interrupted, or permanently discontinued, concomitant medication(s), and results of any procedures obtained. If the SAE is due to an unplanned hospitalization, the toxicity grading scale will be applied to any AE that may have prompted the unplanned hospitalization.
- The study monitor will ensure the study team reviews all SAE, assess causality, and required course of action followed to resolution in accordance with the protocol, and interim SAE reports sent to the Sponsor and Institutional Ethics Committee as events unfold.
- SAEs ongoing at study completion should be followed up as per the requirements of the protocol and as clinically indicated.

5.3 Unexpected Adverse Drug Events (UADEs)

- The study monitor will ensure the study team continuously screens for UADE on an ongoing basis using participant-reported histories, physical assessment/exam, laboratory reports, chart review, and any other available data compared to the package insert or investigational brochure.

- The Principal Investigator (PI) will review all UADE, confirm causality and unexpectedness of this event by the study product, and course of action in accordance with the protocol and regulations.
- All UADE must be reported to the study Sponsor and Institutional Ethics Committee and be followed to resolution.
- Clinical management of UADE should follow the toxicity guidelines outlined in the protocol unless contraindicated.

6. VERSION CONTROL:

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

7. APPENDIX:

Management of Project Escalation SOP