


# STANDARD OPERATING PROCEDURE (SOP)

**TITLE: SOP/POLICIES CREATION, REVIEW, APPROVAL AND MAINTENANCE SYSTEM**



## **DO NOT USE THIS SOP WITHOUT FIRST CHECKING IT IS THE LATEST VERSION**

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<b>Applicable Clinique Research Site(s):</b>	All

<b>Approved By:</b>	Roseanne Onyia Founder/Director, Clinical Operations; Clinique Research
<b>Signature:</b>	
<b>Date:</b>	March 2020

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## **1. PURPOSE:**

The purpose of this SOP is to describe the procedure of SOP/Policies creation, review, approval and maintenance system 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:**

### **5.1 SOPs/Policies Creation**

SOP/Policies are created by Clinique Research's Clinical Operations Team to provide step-by-step instructions guide to help employees in performing operations smoothly and ensure uniform and quality output, while simultaneously reducing miscommunication and ambiguity.

### **5.2 Review**

The SOP/Policies are reviewed by the Clinical Operations Director; this process allows for amendment of the SOP/Policies after which it is sent to the Chief Executive Officer (CEO) for approval.

### **5.3 Approval**

The CEO makes the final decision on the SOP/Policies. Once approved by the CEO, implementation begins.

<b>SOP-CR021</b>	<b>Version: 1.0</b>		<b>Page 2 of 3</b>
<b>Please ensure you are working form the current version</b>			

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## 5.4 Maintenance

The Clinical Operations Director ensures compliance of the SOP/Policies by Clinique Research Team and periodically reviews the SOP/Policies to fit Clinique Research’s goals and values.

## 6. VERSION CONTROL:

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

## 7. APPENDIX: N/A