STANDARD OPERATING PROCEDURE (SOP)

TITLE: CRA RECRUITMENT, TRAINING AND MANAGEMENT

CLINIQUE RESEARCH
Expertise on the ground... global experience

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

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Applicable Clinique Research Site(s):	All

Approved By:	Roseanne Onyia Founder/Director, Clinical Operations; Clinique Research
Signature:	
Date:	February 2020

1. PURPOSE:

The purpose of this SOP is to describe the procedure of Clinical Research Associate recruitment, training and management 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 Clinical Research Associate (CRA) Recruitment

- Confirm potential CRA's resume shows required expertise
- Recruit CRA's with adequate knowledge of Good Clinical Practice, CRA must have a certification to prove this.

5.2 Clinical Research Associate Training

- Newly recruited CRA undergo training upon joining the team.
- Clinique Research typically offers new CRAs administrative training, regulatory/procedural training, and project specific training.

❖ CRA Administrative Training

  - Information Technology (IT): Accessing the Computer, Intranet and Email Policy, Company Specific Websites or Applications, Using Microsoft Outlook/Lotus Notes, Setting up Voicemail and Email Signatures, Electronic Data Capture (EDC) System

- Human Resources (HR): Company Overview, Employee Benefits, Performance Review and Employee Development System, Ethics and Compliance, Insider Training, Conflicts of Interest, Privacy Policy, Dispute Resolution, Harassment/Sensitivity Training, Ergonomics, Workplace Safety

❖ Regulatory Procedural Training
- Regulatory: ICH/GCP; Good Documentation Practices; HIPAA/Confidentiality
- SOPs: Informed Consent Process, Investigator Site Selection, Pre-Study Selection Visit (PSV), Site Initiation Visit (SIV), Routine/Interim Monitoring Visit (MV), Close Out Visit (COV), Source Document Verification, Record Keeping and Retention, Electronic Signatures, Fraud and Misconduct, Protocol Deviations, Audits, Inspections by Regulatory Authorities

❖ Project Specific Training
- Writing a Monitoring Report
- Monitoring Plan
- Trial Master File Maintenance
- Completing Site Contact Records
- Case Report Form (CRF) Completion Instructions
- Integrated Voice Response System (IVRS)
- Using Diaries, PDAs, or other Patient Reported Outcomes (PRO) Instruments
- Protocol Training
- IRB & Regulatory Submissions
- Study Budget
- Investigational Product Handling and Accountability
- Randomization and Unblinding
- Study Supply Management
- Serious Adverse Event (SAE) Reporting

5.3 Clinical Research Associate Management

- CRAs undergo routine training to stay abreast of good clinical practices and newly included technology used in clinical practice.

6. VERSION CONTROL:

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

7. APPENDIX:

Associates Recruitment Interview Checklist
List of CRAs-consultants
CV Disclosure Authorization
Confidentiality Agreement Template
Senior CRA Job Description
CRA Job Description
Employee Training Record