STANDARD OPERATING PROCEDURE (SOP)

TITLE: VENDOR MANAGEMENT

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Applicable Clinique Research Site(s):	All

Approved By:	Roseanne Onyia Founder/Director, Clinical Operations; Clinique Research
Signature:	
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1. PURPOSE:

The purpose of this SOP is to describe the procedure of vendor 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:

Clinique Research is responsible for monitoring and managing clinical trials in accordance with ethical and regulatory standards. Site Initiation is a visit is scheduled after the study sponsor has already selected the site to participate in a clinical trial.

5.1 Vendor Selection

The vendor selection process may begin prior to submission ethical or regulatory application. However, it is anticipated that all vendors will be identified and discussed during the pre-study visit if known.

- The Project Lead is responsible for ensuring that an appropriate contract is put in place with each vendor. In some cases, a Master Service Agreement may already be in place for a vendor.
- A risk-based approach will be taken when assessing vendor suitability based on the level of risk associated with the trial and prior experience of the vendor. Documentation to support the vendor selection will be filed in the TMF.

Examples of how to assess the suitability of a vendor include;

- ✓ Assessment questionnaires e.g. GCP Compliance Sample Questions document
- ✓ Review of vendor SOPs and quality systems
- ✓ On-site audits carried out by a suitably qualified person
- ✓ Cost
- ✓ Level of Insurance cover

5.2 Contracts and Agreements

There will be a fully executed contract in place with a vendor prior to any work being undertaken by a vendor.

Contracts will include statements regarding compliance with the protocol (including amendments) and regulations, sub-contracting, delegation of duties between each party, process for the escalation of issues or disputes, and mechanisms for reporting urgent safety measures and serious breaches of GCP to the sponsor. It is also important to consider whether any performance targets should be met and monitored.

5.3 Maintaining Oversight of Vendors

There will be a fully executed contract in place with a vendor prior to any work being undertaken by a vendor.

All external providers may be visited to ensure compliance with GCP, the study protocol and applicable regulations. Project Lead and Clinique Research's CRA will ensure oversight of vendors by conducting an initiation visit and regular monitoring visits to review SOPs and TMF documentation. The number of visits and level of information reviewed during monitoring visits will be assessed using a risk-based approach and this will be documented in the trial specific risk assessment and monitoring plan. The CRA will review minutes of Trial Management Group/Trial Steering Committee/Data Monitoring Committee meetings to ensure that any external vendor issues identified have been escalated as per section 5.4. If trial essential documents are amended during the course of a trial, the impact of the amendment on the contract with the vendor will be assessed by the Project Manager. If applicable, the CRA will ensure that the contract is amended and fully executed. The CRA will ensure that applicable amended documents are provided to the vendor throughout the trial. If a vendor is unable to produce evidence of compliance with GCP, the study protocol and applicable regulations a suitably trained individual may be requested to conduct a vendor audit on behalf of the sponsor organization(s).

5.4 Escalation of Issues

There will be clear instructions within the vendor contract detailing the process to be followed in the event of instances of non-compliance or poor performance. Non-compliance issues identified by the CRA. Upon receipt of an issue with a vendor the CRA will discuss the issue with the Project Lead/Sponsor. If the issue is considered a serious breach of GCP, SOP-CR021 "Protocol Deviations and CAPA" will be followed.

6. VERSION CONTROL:

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

7. APPENDIX:

Confidentiality Agreement Template