STANDARD OPERATING PROCEDURE (SOP)

TITLE: FEASIBILITY AND TRIAL START UP

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

Document ID:	SOP-CR003
Version No:	1.0
Effective Date:	January 2020
Review Date:	N/A
Applicable Clinique Research Site(s):	All

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

1. PURPOSE:

The purpose of this SOP is to describe the procedure of feasibility and study start up 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 FEASIBILITY

Key Attributes of our Feasibility Assessments Include:

- The project scope: The first step is to define and outline all aspects of the project. Carefully analyze and take all of a study's relevant factors into account when proposing a site for a potential study.
- The current analysis: This form of analysis is used to evaluate the current method of implementation of a common and similar project/study in the potential trial site.
- The requirements: Feasibility assessment takes into account all of the criteria required including site's infrastructural requirements, personnel training and experience requirement, subject recruitment capacity and regulatory requirements.

- Evaluation: Feasibility Questionnaire is completed by the potential trial site. A trial site is thus recommended to meet sponsor and study requirements after meticulously considering various alternatives.
- Review: Ultimately, all the above elements will be put together into a feasibility report and forwarded to the sponsor. The review will be used to make a project decision.

5.2 PRE-SITE SELECTION VISIT/PRE-STUDY VISIT

- Once a clinical trial has been deemed feasible, a pre-study visit may be arranged to include the Sponsor or representative(s), assigned Study Monitor (Clinical Research Associate, CRA) of Clinique Research, Principal Investigator (PI) and Site Study Team. The purpose of this is to evaluate the site's ability to perform the clinical trial in accordance with the study design and protocol.
- A confirmation letter is then sent to the potential trial site.
- Attendees may include sponsor representative(s), PI, Site study team, assigned Study Monitor.
- The protocol synopsis is presented by the Study Monitor to the site study team
- The Sponsor's checklist and questionnaire is used to ask questions to the site in the course of the meeting.
- A facility tour is conducted during the pre-study visit to confirm required equipment, space and services are satisfactory to facilitate the clinical trial protocol and all storage of clinical trial supplies and materials are secure with limited access.
- The Sponsor/Study Monitor should provide copies of relevant clinical trial materials to attendees prior to the visit.
- Study Monitor must confirm that the study team has adequate qualification and GCP training to conduct the trial.
- Study Monitor will confirm the ability for the trial site to recruit the proposed number of participants within the protocol specified time frame.
- On request, the potential trial site will provide the Sponsor/Study Monitor with appropriate documentation to support site selection.
- A report on the visit is made by the Study Monitor to the Sponsor.
- A follow-up letter is sent to the potential trial site.
- The Sponsor with the report of the visit decides whether or not to select the site for the study.

5.3 SITE SELECTION

- Where the Sponsor confirms selection of a trial site, a site selection letter is immediately sent to the PI.
- The PI/study team is responsible for requesting supporting documentation from the Sponsor or Clinique Research including, but not limited to, the protocol, investigator's brochure, pharmacy manual, laboratory manual, imaging manual, and data completion guidelines.
- Clinique Research will liaise between the Sponsor and trial site to ensure relevant documentation is sent and received.
- Clinique Research may help the sponsor or trial site with budgeting and legal processes.
- Clinique Research will proceed with ethics and regulatory applications for the clinical study.

5.4 CLINICAL TRIAL START-UP

- Once feasibility and site selection are completed the clinical trial start-up process will commence.
- It is the responsibility of the PI/Study Monitor to ensure that appropriate governance approvals, and regulatory notifications/approvals are in place before recruitment commences.
- Study Monitor must schedule a startup visit to trial site to ensure site's readiness for clinical study.
- An Investigator Site File (ISF) must be established before recruitment begins. It is the responsibility of the PI/Study Monitor to ensure that all required documents are collected and filed in the ISF.

6. VERSION CONTROL:

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

7. APPENDIX:

Study Startup Checklist
Monitoring Visit Follow Up Table
Monitoring Visit Follow Up Letter and Table
Site Feasibility Questionnaire