STANDARD OPERATING PROCEDURE (SOP)

TITLE: ARCHIVING COMPLETED STUDY DOCUMENTS

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:	
Date:	February 2020

1. PURPOSE:

The purpose of this SOP is to describe the procedure of archiving completed study documents 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. Clinique Research (the CRO) will appoint a Clinical Research Associate (Study Monitor) to monitor the trial. The monitor will be trained on the study protocol and will be familiar with all study procedures.

5.1 Archiving Completed Study Documents

After study completion the study monitor will work according to an agreed schedule of tasks in archiving the study documents, including the following that will be given as specifics in the study protocol:

- During the final closeout visit the study monitor along with the Principal Investigator (PI) and the study team must identify the study specific documents that require to be archived.

- Before archiving, it is important to note any records that are subject to rapid deterioration or need special requirements in order for them to be retained e.g. electronic media, photographs, sample packaging, plastic wallets.
- The identified documents must be inventoried, packed in archival boxes, and sealed. The boxes must be labeled appropriately to indicate the tenure of archival, the content of the box and the study reference number.
- The sealed archival boxes must be stored in an area with restricted access. The area (room or cupboard) must be secure with access only by authorized personnel.
- The documents should be archived in an appropriate room or locked cupboard (consider fire protection without water sprinkler systems, water protection, for humid conditions, pests etc.).
- For electronic data, the data may be held on a server or transposable media. It is recommended that more than one copy is retained (i.e., a backup server or back-up media stored in a separate location is used). Consideration should be given to storing the data in different formats on different types of media or even on the same media from different manufacturers.
- The documents must be stored in a way that preserves their integrity and readability.
- The PI should make available all requested trial-related records upon request by the sponsor, study monitor, auditor, IEC, or Regulatory Authority.
- The PI must record and retain the inventory record for future reference.
- A written request for retrieval must be sent to the archivist or delegate by the study site. Telephone requests will not be accepted. The required box(es) will be identified by the archivist or delegate and sent by courier to the required Investigational research department.
- The study documents must be archived for 15 years post the study close out or until the sponsor confirms that the records are no longer required; whichever is earlier. However; prior to destroying the records, a confirmation for destruction of records must be sought by the PI from sponsor in accordance with study protocol.
- In cases where there is not enough space for storage of the study records, the PI can place the study record in a secure off-site facility where they may be readily accessed in the event of an audit.

- If the PI leaves the organization, he/she will provide the Sponsor and CRO with written notice of the location of the study records and the name and phone number of an alternate contact in the event of an audit

6. VERSION CONTROL:

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

7. APPENDIX:

Data backup SOP
Data protection policy SOP
Study documentation filing SOP