

Standard Operating Procedure:

Archiving with Teletrials

**SOP Number: TT-SOP-12**

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| Author(s): | Hannah Cross  VCCC Program Manager |
| Approved by: | VCCC Teletrials Steering Committee |

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**Amendment History**

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Developed by the Victorian Comprehensive Cancer Centre (VCCC) in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU), based on the Clinical Oncology Society of Australia (COSA) Australasian Tele-trials Model.

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1. Introduction and Background

All essential documents relating to clinical trial conduct must be archived at the completion of the clinical trial. The archiving process must ensure the clinical trial has the ability to be reconstructed to demonstrate compliance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable local regulatory requirements.

1. Objective

To describe the procedure for archiving essential documents for clinical trials coordinated by SITE as required from the completion of the clinical trial, to the subsequent transfer of essential documents to the archiving facility.

1. Scope

This SOP applies to all clinical trials coordinated by SITE-SITE including Teletrials.

1. Ownership and Responsibility

It is the responsibility of the sponsor to inform the principal investigator when a clinical trial may be archived and provide the appropriate documents for completion.

It is the responsibility of the principal investigator to ensure that all essential documents are archived.

In a Teletrial, it is the responsibility of the principal investigator to inform the satellite site when all essential documents need be archived. Once informed the satellite site will send all essential documents to the primary site where they will be archived.

The study team will inform the sponsor of archiving arrangements or any changes made to these arrangements.

The SITE-SITE Named Archivist is responsible for the archiving process. In the absence of the SITE-SITE Named Archivist a Co-Named Archivist will be delegated responsibility.

The sponsor is responsible for any clinical trial abandoned prior to ethical and governance approval and must liaise with the study team in regards to the storage of essential documents. If the sponsor requests the essential documents be archived, an archiving fee will apply. Any requests should be forwarded to the SITE-SITE Named Archivist.

1. Glossary of Terms

Please refer to SITE TT-SOP-Glossary-of-Terms (see Related Documents) for full supporting glossary of terms.

1. Procedure
2. Clinical Trials of Investigational Drug Carried Out Under Therapeutic Goods Administration (TGA) Authorisation

Essential documents are required to be retained for a minimum of 15 years by the TGA If there is a market application, this will be considerably longer. Written approval from sponsors must be obtained before destroying any records.

1. Clinical Trials of Non-investigational Drug

* For clinical trials of non-investigational drug, the relevant documentation will be archived for a minimum of five years after the conclusion of the clinical trial unless the funding body stipulates otherwise.
* Documents can be retained for a longer period, however, if required by other applicable regulatory requirements or SITE-SITE i.e. if a research project is part of a student’s studies for a higher degree this may be longer.
* Extensions of archive retention periods will be agreed with the clinical trial sponsor. It is the responsibility of the sponsor to inform SITE-SITE as to when these documents no longer need to be retained.
* The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorised. The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.
* It is vital that all essential documents are maintained in a legible condition for the duration of the archival retention period. Clinical trials are only eligible for archiving upon approval by the SITE study team.
* A clinical trial participant’s medical documents are archived in accordance with applicable legislation and will be archived separately to the clinical trial essential documents.

1. Archival Preparation

* The sponsor will issue the principal investigator and SITE Named Archivist with notification of approval to archive the essential documents.
* The SITE Named Archivist/Co-Named Archivist will arrange for the delivery of the requisite number of storage boxes.
* The principal investigator will delegate the responsibility of preparation of essential documents for archiving to a member of the study team. The SITE Named Archivist/Co-Named Archivist will oversee the archival process, offering advice and assistance to ensure that the task is carried out in accordance with this SOP.
* All administrative aids used to maintain essential documents for the duration of the clinical trial are removed to ensure document integrity and longevity: plastic outer protective coverings (where applicable), adhesive tape, paperclips and staples are removed before placing in the archive box.
* The original delegation of duties log will be archived with the essential documents and a copy will be provided to the sponsor on request.
* Once the principal investigator is satisfied that all essential documents for the clinical trial have been boxed the SITE Named Archivist/Co-Named Archivist will arrange for the boxes to be collected.
* Archive labels will be attached to the top of each box, detailing the date the clinical trial should be retained until.
* The archive location is recorded electronically and will detail the number of boxes and the contents in each box to allow for easy recall.

1. Retrieval and Return of Archived Essential Documents

* Only the SITE Named Archivist/Co-Named Archivist can authorise and arrange the retrieval of essential documents from archive facility.
* A minimum period of two working days is required for the retrieval of archival boxes.
* The principal investigator or delegated study team member will advise in writing the SITE Named Archivist when the essential documents are ready to be re-archived.
* Essential documents will be made available during office working hours for inspection/audit by any appropriate sponsor/regulatory authority.

1. Destruction of Archived Essential Documents

* The Sponsor will notify the principal investigator and SITE Named Archivist in writing when the essential documents can be destroyed. In lieu of sponsor notification, the SITE Named Archivist will contact the sponsor on behalf of the principal investigator to confirm destruction date.
* The reasons for destruction of essential documents shall be documented and signed for by a person with appropriate authority. This record should be retained for a further five years from the date of destruction.

1. Disaster Recovery

In the event of fire, water damage or pest infestation the SITE Named Archivist will see if any essential documents can be recovered. In some cases essential documents may be recoverable with the assistance of a document restoration service. The SITE Named Archivist will arrange collection of all documents that may be recovered or restored. For all records that have been lost, a file note will be produced and forwarded to the sponsor and regulatory authority (if required) explaining the circumstances and which documents have been lost.

1. Closure of the Archive Facility

In the event of the closure of the used archive facility, it is the responsibility of the SITE Named Archivist to ensure that an alternative facility is found within sufficient time and all archived essential documents are safely transferred to the new facility.

1. Dissemination and Implementation.

Approved SOPs will be disseminated electronically by SITE. SOPs will be made available in hard copy format or electronically upon request. Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

1. Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of the SITE monitoring and audit process. Any queries concerning the effectiveness of this SOP identified during the SITE monitoring process or through use will be addressed and may result in the requirement to update the SOP.

1. Review and Updating

This SOP will be reviewed every three years, or when changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

1. Reference

N/A

1. Relevant Document(s)

SITE TT-SOP-Glossary-of-Terms

SITE TT-SOP-11: Essential Document Management