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The Department of Research and Innovation, in collaboration with the Cancer Centre Clinical Trials Unit, has developed a series of standard operating procedures (SOPs) designed to facilitate good clinical trials practice and compliance with applicable regulatory requirements for clinical trial research at Bendigo Health. These SOPs are based on those developed by the Parkville Cancer Clinical Trials Unit (PCCTU) who have kindly granted permission for adaptation and use at Bendigo Health.

SOP-11 Archiving Clinical Trial Research Documents

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	Final revisions by:	Approved on behalf of the Interdisciplinary Research Steering Committee by Chair:
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Position Title	Clinical Trials Research Manager	Director of Research and Innovation
Signature		
Date	20-Dec-2021	20-Dec-2021

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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 Council for Harmonisation (ICH) of Good Clinical Practice (GCP) and applicable local regulatory requirements.

2. Objective

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

3. Scope

This standard operating procedure (SOP) applies to all clinical trials undertaken at Bendigo Health.

4. Ownership and Responsibility

It is the responsibility of the sponsor to inform the Principle Investigator (PI) when a clinical trial may be archived and provide the appropriate documents for completion.

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

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

The relevant department manager is responsible for the archiving process, however this process may be delegated as required.

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 relevant department manager.

5. Glossary of Terms

Please refer to Bendigo Health's *Clinical Trial Research Standard Operating Procedures Glossary of Terms* for a full supporting glossary.

6. Procedure

6.1 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.

6.2 Clinical Trial interventions other

For clinical trials of interventions that do not involve an investigational drug, the relevant documentation will be archived for a minimum of seven (7) 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 departments at Bendigo Health 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 the relevant department as to when these documents no longer need to be retained.

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 relevant department's 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.

6.3 Archival Preparation

The sponsor will issue the PI and manager of the relevant department with notification of approval to archive the essential documents.

The PI will delegate the responsibility of preparation of essential documents for archiving to a member of the study team. The relevant department manager or appropriate delegate will oversee the archival process, offering advice and assistance to ensure that the task is carried out in accordance with this SOP.

6.3.1 Paper Documents

The manager of the relevant department or delegate will arrange for the delivery of the requisite number of storage boxes.

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 and paperclips are removed before placing in the archive box.

The original *Site Signature and Delegation of Duties Log* will be archived with the essential documents and a copy will be provided to the sponsor on request.

Once the PI is satisfied that all essential documents for the clinical trial have been boxed the department manager of appropriate delegate 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.

The participant identification list will be kept at the site.

6.3.2 Electronic Documents

Essential study documents on SiteDocs portal are prepared for archival by the department manager or delegate

Relevant department documents in the Core Documents module of SiteDocs portal are imported to the electronic Investigator Site File (eISF) in the Collaboration module of the portal

The eISF folder will be locked to further changes and access will be restricted to department portal administrators.

The completed audit trail of the eISF will be imported as an excel spreadsheet. The workflow history of applicable documents is imported as a PDF document.

A complete download of the eISF will be performed and data will be transferred to an external storage device which will be placed in the archive box with paper documents

The eISF will be transferred into the Archived module of SiteDocs portal for long term storage.

6.4 Retrieval and Return of Archived Essential Documents

6.4.1 Paper Documents

Only the department manager or appropriate delegate 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 PI or delegated study team member will advise in writing the department's manager 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.

6.4.2 Electronic Documents

Upon authorisation by the department manager or appropriate delegate, a portal administrators

of SiteDocs portal can arrange for the retrieval of electronic essential documents on SiteDocs portal from the Archived/Deleted Documents Module to the Collaboration Module.

A minimum period of two working days is required to provide access to an archived eISF on SiteDocs portal.

A SiteDocs portal account is required to view archived electronic essential documents.

In the case of regulatory authority (TGA, EMA, FDA) inspection/audit, a SiteDocs portal account will be requested through TrialDocs and the account will not require the user to accept terms and conditions

Access to the e-ISF will be made available during office working hours for inspection/audit by any appropriate sponsor/regulatory authority.

6.5 Destruction of Archived Essential Documents

The Sponsor will notify the PI and department manager or appropriate delegate in writing when the essential documents can be destroyed. In lieu of sponsor notification, the department's manager or appropriate delegate will contact the sponsor on behalf of the PI 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.

6.6 Disaster Recovery

6.6.1 Paper Documents

In the event of fire, water damage or pest infestation the department manager or appropriate delegate 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 responsible department manager or appropriate delegate 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.

6.6.2 Electronic Documents

In the event of a data loss, the responsible department manager will see if any essential documents can be recovered. Documents may be recoverable via regular data back-ups of SiteDocs portal. In the event of an unrecoverable data loss, 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.

6.7 Closure of the Archive Facility

In the event of the closure of the used archive facility, it is the responsibility of the department

manager or appropriate delegate to ensure that an alternative facility is found within sufficient time and all archived essential documents are safely transferred to the new facility.

In the event of the closure of SiteDocs portal, it is the responsibility of the department manager to ensure that an appropriate alternative platform or media is found within sufficient time and all archived essential documents are safely transferred.

7. Dissemination and Implementation

The Department of Research and Innovation at Bendigo Health is responsible for the dissemination and implementation of the Bendigo Health SOPs related to clinical research. Any content updates will be tabled at the Clinical Trials Sub-Group and the Interdisciplinary Steering Committee meetings. Content updates will be accompanied by relevant promotions and training.

Approved SOPs will be published on the Bendigo Health intranet and available through the SiteDocs portal. SOPs will be made available in hard copy format upon request to: clinicaltriasresearchsupport@bendigohealth.org.au.

Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

8. Monitoring Compliance and Effectiveness

SOP compliance will be monitored as part of the Bendigo Health SOP monitoring and audit process, initiated by the Clinical Trial Sub-group.

Any queries concerning the effectiveness of the SOP identified during the Bendigo Health monitoring and audit process or through use will be escalated to the Interdisciplinary Research Steering Committee to advise.

9. Review and Updating

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

10. Reference(s)

N/A

11. Related Document(s)

SOP Glossary of Terms
SOP 10: Essential Document Management for Clinical Trial Research

12. Amendment History

Version	Date	Amended By	Details of Amendment
2	11-Nov-2021	Jasmine Gillingham Dr. Rani Watts	• Revisions made in line with amendments to those made by the Parkville Precinct Clinical Trial Unit; Minor administrative amendments