CLINICAL TRIAL SOP 9: Site Close Out and Archiving

Purpose

To describe the procedures related to close-out of a clinical trial at all sites and archiving of trial related documentation at the end of the clinical trial.

Scope

This SOP applies to all Investigators (Principal and Sub-Investigator), Study Coordinators, visiting medical officers (VMO), and other Research staff and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

Cabrini Health policies and regulatory requirements

This SOP should be read in conjunction with policies and other documents provided by the Cabrini Research Governance Office (CRGO) relevant to the conduct of clinical research at Cabrini Health including but not limited to:

- Aboriginal and Torres Strait Islander Health – asking for Aboriginal and Torres Strait Islander identity
- Monitoring of Research Policy
- Research Integrity and Misconduct Policy
- Safety Monitoring and Reporting in Research Policy
- Cabrini Research Data Management, Access and Sharing Policy
- Data Classification and Labelling Standard
- Cabrini Authorship and Publications for Research Policy
- Research Participants Complaints and Compliments Procedures Policy
- Cabrini Research Governance Handbook

Researchers at Cabrini must foster quality research and abide by the following directives:

- The National Clinical Trials Governance Framework (NCTGF)
- National Statement on Ethical Conduct in Human Research (2023)
- Catholic Health Australia Code of Ethical Standards
- Act in accordance with Cabrini Research policies in order to protect the rights, safety and welfare of research participants
- Support patient and family carer involvement in their own research participation through abidance with the Australian open disclosure policy, and Charter of healthcare rights.
- Agree to comply with all reasonable directions and policies by Cabrini Research for Cabrini to meet or exceed the requirements of the NCTGF. To the extent that the NCTGF applies to the position, compliance with the specified roles and functions of the workforce, as set out by the NCTGF.

Procedure

9.1 Site Close-Out

9.1.1. Premature Termination or Suspension of Trial

If the Trial is prematurely terminated or suspended for any reason, the Investigator must:

- In the instance the termination or suspension has been initiated by Cabrini, promptly inform the relevant parties of Sponsor, HREC, RGO, and Associate Investigator, by providing a detailed written explanation of the premature termination or suspension.
- In the instance the termination or suspension has been initiated by sponsor, promptly inform the relevant parties of HREC, RGO, Associate Investigator, and the TGA by providing a detailed written explanation of the premature termination or suspension.
- Promptly inform the trial participant and their primary care physician where the trial participant has consented, of the termination or suspension and, if applicable, of the Investigational Product and dose they were administered.
- Assure appropriate therapy and follow-up for the participant's continued care.

9.1.2 Site Close-Out

A final close out of a trial can only be done when the Sponsor has reviewed both Investigator/Institution and Sponsor files and confirmed that all necessary documents are in the appropriate files. The Sponsor notifies the Investigator close-out can occur.

The Primary Investigator must:

- Oversee all staff carrying out close-out activities to ensure they are undertaken in accordance with Sponsor requirements, the Delegation Log and the Supervision Plan.
- Provide a summary report of the trial's status and any outcomes to the HREC, CRGO.
- File documentation and correspondence in the ISF.
- Arrange for archiving of ISF.
- Ensure appropriate final disposition of any IP/and other trial related material. This may include return to the Sponsor or destruction of remaining materials.

9.2 Archiving

Study documentation is to be archived as specified in:

(i) the Australian Code for the Responsible Conduct of Research. Part A, section 2.1
(ii) ICH GCP E6 (R2) 4.9.5, 5 and 5.12

- Where the specified archiving period is conflicting, documentation is to be archived for whichever period is the longest.
- For legal reasons, sites may consider archiving for longer periods or indefinitely.
- Jurisdictional and Institutional requirements for clinical trial records where the participants are minors must be adhered to.
- Jurisdictional and Institutional requirements for clinical trial records where the participants are adults must be adhered to.
- Archived material should be enduring (e.g. fax thermal paper copied to standard paper to prevent fading) and protected from damage or destruction in a secure, environmentally controlled location (e.g. protection from fire, water damage, pest infestation, and theft).
- Access to archives should be restricted to authorised personnel. Any change in the ownership and location of the archived materials should be tracked. The PI should make the Sponsor aware of the storage arrangements for the Essential Documents and if at any

stage these arrangements can no longer be maintained, the Sponsor should be notified in writing so that alternative storage arrangements can be agreed.

9.2.1 For Paper Records

- Original documents or certified copies are to be retained.
- Evident identification (e.g. a document retention sticker) that the health and medical record forms part of a clinical trial is to be placed on all volumes of the participant's health and medical record in an appropriate position, without obscuring any information, as guided by the local health information management services practice.
- For commercially sponsored research, archiving arrangements are negotiated with the study Sponsor (and the site's health information management services) prior to study commencement. These details are to be noted in the study specific CTRA.
- Where the study documentation will be filed by the Sponsor, the Identifiable information (e.g. Participant Identification Log and Participant Information Sheet and Consent Forms) site records are **NOT TO BE** filed with the Sponsor study records.

9.2.2 For Electronic Records

- Where electronic documents and data are archived, they must be suitably protected from unauthorised changes.
- Electronic Medical Records may be archived indefinitely.

9.2.3 Transfer of Paper Records into an Electronic Format

When original records are transferred to other media for the purpose of archiving, the system of transfer should be validated to ensure that information will not be lost or altered. Filing systems should allow review (e.g. by an auditor) in an efficient manner, analogous to that possible with paper study files. Paper records must be scanned in a logical order (e.g. in accordance with the Investigator Site File (ISF) index) to ensure that trial reconstruction is possible. There should be a quality control process to certify that the scanned image has been captured without error and so is a suitable record of the original document.

Current Version

DOCUMENT ID:	CLINICAL TRIAL SOP 9: Site Close Out and Archiving
VERSION:	1.0
EFFECTIVE DATE:	01 October 2024
REVIEW DATE:	01 October 2026

Document Approval

NAME	POSITION	SIGNATURE	DATE
Professor Gary Richardson	Group Director, Cabrini Research		18 September 2024

Document History

VERSION NUMBER	EFFECTIVE DATE	DETAILS OF AMENDMENTS /EDITIONS