GVHealth	**TITLE:**	**Clinical Trial Standard Operating Procedure 13: Site Close Out and Archiving**	
Document Type:	Procedure	**Approved by:**	CMO & EDMS
Directorate:	CMO + Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

DO NOT USE THIS STANDARD OPERATING PROCEDURE IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION.

The definitive versions of all Goulburn Valley Health (GVH) Clinical Trial Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the GVH website or Prompt.

Document Details

Document Title:	Clinical Trial Standard Operating Procedure 13: Site Close Out and Archiving
Document ID:	GVH_CT-SOP-13
Version Number:	2.0
Effective Date:	16 June 2023
Review Date:	16 June 2025

Document Approval

Name:	Dr John Elcock
Position:	Executive Director of Medical Services and Chief Medical Officer
Date:	16 June 2023

Amendment History

Version	Effective Date	Review Date	Author(s)	Amendment Details
1.0	12 Nov 2020	16 June 2023	Dr Ainsley Robinson Research and Ethics	Reviewed and updated to v2.0 based on ICH GCP and The Commonwealth Department of Health: National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia SOP 13 (14 Feb 2023).

1. 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.

2. SCOPE:

This Standard Operating Procedure (SOP) applies to all Goulburn Valley Health (GVH) employees, visiting health professionals, contractors, any external researchers, consultants, and volunteers who propose to undertake, administrate, review and/or govern human research involving GVH patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. PROCEDURE:

3.1. Premature Termination or Suspension of Trial

3.1.1. If the trial is prematurely terminated or suspended for any reason, the Investigator must:

- Promptly inform the relevant parties of Sponsor, Human Research Ethics Committee (HREC), Research Governance Officer (RGO), Associate Investigator, any Satellite Site and the Therapeutic Goods Association (TGA) by providing a detailed written explanation of the premature termination or suspension Review all study related documentation and be familiar with the Investigational Product (IP) and Protocol.
- 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 IP and dose they were administered.
- Assure appropriate therapy and follow-up for the participant's continued care.

3.2. 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.

3.2.1. The Investigator must:

- Supervise 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 outcome to the HREC, RGO and any Satellite Site.
- File documentation and correspondence in the Study Master File (SMF).
- Arrange for archiving of SMF/SSSF (Satellite Site Study File).
- Ensure appropriate final disposition of any IP/and other trial related material. This may include return to the Sponsor or destruction of remaining materials.
- Where a Satellite Site is involved: ensure the Satellite Site Supervision Plan is followed regarding the disposition of Essential Documents during the study. Also, ensure that evidence of the manner and frequency of supervision to be undertaken by the Principal Investigator (PI) with the Satellite Site staff during the study (e.g. minutes of calls with Satellite Site

staff to review patients/participants and study progress) is filed in the Primary Site SMF.

- Ensure any Satellite Site retains documentation and correspondence in their SSSF with original or certified copy of pre-determined documents sent to the Primary Site.

See Appendix 1: Example Close Out Checklist as a reference guide.

3.3. Archiving

- Study documentation is to be archived as specified in the Australian Code for the Responsible Conduct of Research, 2018, Part A, section 2.1 and 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.

3.3.1. 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 Clinical Trial Research Agreement (CTRA) and/or the Satellite Site Sub-Contract.
- Identifiable information (e.g. Participant Identification Log and Participant Information Sheet and Consent Forms (PICF)) is to be archived separately from the main study documents, e.g. with the PI – in case identification of participants is required later. A reference to the type and location of these documents is to be filed with the SMF.

- Satellite Sites will archive the original participant identifiable information at the Satellite Site as per the above and send a certified copy to the Primary Site for archiving with the Primary Site participant identifiable information (or as outlined in the Supervision Plan).
- Where the study documentation will be filed by the Sponsor, the Identifiable information (e.g. Participant Identification Log and PICFs) site records are NOT TO BE filed with the Sponsor study records.

3.3.2. 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.

3.3.3. 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 SMF 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.

ABBREVIATIONS AND TERMS:

Please refer to GVH_CT-SOP-Abbreviations and Terms.

KEY ALIGNED DOCUMENTS:

Nil.

REFERENCES:

ICH GCP E6 (R2)

NMHRC Australian Code for the Responsible Conduct of Research, 2018

APPENDICES:

Appendix 1: Example Close Out Checklist

Contributors to the document

	Name	Position	Department
Document Owner:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Document Author:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Contributor:	Dr Md Rafiqul Islam	Director of Research	Research and Ethics
Committee:	Executive Committee – Safety, Quality & Performance		
	Dr John Elcock, Chief Medical Officer/ Executive Director, Medical Services		

Appendix 1: Example Close Out Checklist

Activity	Complete
Ensure all protocol required data has been collected.	
Finalise accountability and disposition of investigational product (medicine/device).	
Verify that all study files are complete.	
Discuss overall study conduct at the site.	
Collect final signatures for any delegation or training logs or reports.	
Discuss archiving of original data and documents.	
Dispose of or return any remaining trial specific supplies including biological samples	
Formally close the site.	
Notify the HREC and /or Governance Office that the study has been closed; submit the final report and study materials returned/destroyed/archived.	
Other (please specify).	
Other (please specify).	