SOP 13 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 Standard Operating Procedure (SOP) applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants 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.

Procedure Site Close-Out

Premature Termination or Suspension of Trial

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

- Promptly inform the relevant parties of Sponsor, HREC, RGO, Associate Investigator, any Satellite Site 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.

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 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 SMF.

- Arrange for archiving of SMF/SSSF.
- 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 16 Close-Out Checklist Example as a reference guide*.

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.

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 and/or the Satellite Site Sub-Contract.
- Identifiable information (e.g. Participant Identification Log and Participant Information Sheet and Consent Forms) 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 Participant Information Sheet and Consent Forms) site records are **NOT TO BE** filed with the Sponsor study records.

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.

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 Study Master File 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.

Appendix 16

Close-Out Checklist Example

ACTIVITY	YES	NO	N/A	ACTIONS/COMMENTS
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 Logs or Training Logs or reports				
Discuss archiving of original data and documents				
Dispose of or return any remaining trials specific supplies including biological samples				
Formally close the site				
Notify the HREC and/or Research Governance Office that the study has been closed, and study materials:				
– Returned	☐	☐	☐	
– Destroyed	☐	☐	☐	
– Archived	☐	☐	☐	

Glossary

TERM	DESCRIPTION
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association

ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

○ Revision Chronology

Document History			
Version	**Effective Date**	**Summary of Changes**	**Author**
1.0	*13/11/2025*	Initial Version	Katie Ozdowska