Clinical Research Facility archiving of clinical trial documents

PURPOSE

This work instruction outlines processes for archiving and retrieval of archived clinical trial documents by Clinical Research Facility (CRF) staff.

OUTCOME

The work instruction outlines the responsibilities of facilities, departments, clinicians, and researchers when archiving clinical trial documents in the CRF as part of their research.

This work instruction outlines processes described in MSH procedure PR2024-453 Clinical Research Facility (CRF) and upholds principles outlined within the Clinical Research Facility Handbook.

SCOPE

This work instruction applies to all CRF staff responsible for archiving of clinical trial documents and CRF users who access CRF archived records.

WORK INSTRUCTION

1. STEP 1: ARCHIVING CLINICAL TRIAL DOCUMENTS

- The CRF can provide on-site archiving for clinical trial documents and assist with external archiving arrangements for clinical trials conducted in the CRF upon request from the Principal Investigator/lead researcher.
- Archiving arrangements must be confirmed during study set-up and any requests to access CRF archiving facilities agreed in the CRF Application.

1.1 On-site archiving

- Archiving on-site in the CRF can be accommodated for a maximum of 2 years, following which the Principal Investigator is responsible for the ongoing storage of documents at an alternative site.
- CRF fees for archiving on-site will be charged as agreed in the approved CRF quote or at the applicable document storage fee rate in place at the time of the request.

1.2 Off-site/external archiving: Grace Records Management

- The Principal Investigator/lead researcher may contact Grace Records Management to confirm intention to store records with the service; detailed instructions relating to the preparation and collection of site documents for archiving will be provided by Grace Records Management.
- Contact Details Phone: 13 14 42, or website: www.grace.com.au/information

1.3 Archiving arrangements

- Archiving arrangements must be agreed between the sponsor and Principal Investigator/lead researcher and provisions outlined in the Clinical Trial Research Agreement (CTRA).
- Archive records must contain essential documentation, defined as ‘documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced’ (ICH GCP: Integrated Addendum to ICH E6:R2).
- A complete list of essential documents is listed in ICH GCP: Integrated Addendum to ICH E6:R2 (as updated from time to time).
- Relevant Patient Identifiable Data can be archived with clinical trial documents when stored securely in the CRF, with the PAH Health Information Management Service (HIMS) or externally with Grace Records Management (while a valid agreement remains in place; Standing Offer Arrangement HSQ97042 or updated agreement if applicable).
- Clinical Trial records are to be archived in accordance with relevant regulations and guidelines (as updated from time to time) including:
    - International Conference on Harmonisation (ICH): Guideline for Good Clinical Practice (GCP) E6 (R2)
    - National Health and Medical Research Council (NHMRC): Australian Code for the Responsible Conduct of Research
    - Queensland State Archives: Health Sector (Clinical Records) Retention and Disposal Schedule

2. STEP 2: ARCHIVING RETENTION

- The Health Sector (Clinical Records) Retention and Disposal Schedule (in line with ICH-GCP and NHMRC guidelines) requires clinical research records to be retained for:
    - 15 years from completion of clinical research/trial or after date of publication or termination of the study and 10 years after last patient/client service provision or legal action (whichever is later).
    - 15 years from completion of clinical research/trial or after date of publication or termination of the study; until patient/client attains 18 years of age; and 10 years after last patient/client service provision or legal action (whichever is later).
    - There may be longer (or indefinite) retention periods for certain trials which would be confirmed by the trial sponsor (e.g. gene therapy research data must be retained permanently in the form of patient records).

3. STEP 3: ARCHIVING PREPARATION

- To prepare documents for archiving, the Principal Investigator/lead researcher must:
- Ensure that sponsor approval for archiving has been documented and all required actions completed prior to archiving as per Attachment 1: CRF Archiving checklist.

- Order the required number of archiving boxes and USB storage device via the CRF Administration Officer.
    - Note: Archiving boxes can be ordered from Winc or from Grace Records Management if applicable.
- Archiving documents should be removed from the outer folders before placing in the archive box. It is recommended to use paper covering or elastic bands to ensure file integrity. Patient records and scan images performed at PAH are stored indefinitely in their electronic medical record and therefore do not need to be archived with trial documents.
- Each archive box must only contain documents from one trial (archiving documents from multiple trials in the same box is not permitted).
- Each box weight must not exceed 10kg. Please use the CRF scales to check weight.
- The Principal Investigator/lead researcher must:
    - Ensure that all electronic files relating to the clinical trial are transferred to a USB storage device and placed in archiving box 1.
    - Label each archive box using Attachment 2: CRF Archiving box label. The label is to be completed in full and attached on the front and top of the archive box using adhesive tape to allow easy identification.
    - Note: Identify archiving boxes as per Grace Records Management instructions if applicable.
- Ensure Attachment 1: CRF Archiving Checklist is completed with copies filed in archive box 1 and in the electronic CRF archiving folder.
- Once archiving boxes are prepared, complete the CRF Archiving Record Excel spreadsheet in the electronic CRF archiving folder.
    - Please continue to follow the relevant instructions below depending on the archiving location (CRF or external: Grace records management)

3.1 Archiving in the CRF

- Archiving boxes must be stored in sequential order on the compactus shelf location listed in the CRF Archiving Record excel spreadsheet with the Attachment 2: CRF Archiving Box label clearly visible on each box.

4. STEP 4: ARCHIVING PRIOR TO END OF TRIAL

- Clinical trial documents can be placed in the CRF archive room prior to receipt of the final clinical study report or sponsor approval if required with archiving prepared as per Section 1: Archive Preparation
- The CRF archiving record and archiving checklist should indicate the trial has been archived prior to end of trial, and the retention date is to be noted as pending until trial close-out has been completed.

5. STEP 5: RETRIEVAL OF ARCHIVING

- Staff members and/or external bodies can request archived records with relevant approvals. Please contact the Principal Investigator/lead researcher and/or sponsor for approval if the request is made to retrieve a trial archive by an external person where the authority to review the files is in doubt.

- CRF Archive Records stored in the CRF can be accessed on request with approval from the CRF Manager.
- Archive records stored with Grace Records Management can be requested from Grace Records Management.
    - Note a charge will be incurred for retrieval of documents from Grace Records Management

- Researchers must ensure all documents and box contents are returned to the archive in the same order as retrieved; contents are not to be removed from the archive boxes.
- Archiving is to be returned to the appropriate storage location as outlined above.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
CRF Manager	• Responsible for the day-to-day operations of the CRF including CRF Archiving procedures.	N/A
Principal Investigators (PIs)/lead researchers	• Retains overall responsibility for the conduct of their research at the CRF in accordance with the principles of Good Clinical Practice (GCP). • It is the responsibility of the PI/lead researcher to ensure compliance with requirements of appropriate legal, regulatory, ethical and guidance documents applicable to the research project.	N/A
Researchers/CRF users	• Share responsibility and accountability for research being conducted according to appropriate regulatory, ethical and scientific standards. • Comply with applicable TRI, Metro South Health and PAH policies and procedures.	N/A

CRF Administration Officer	• Assist with archiving processes and maintenance of records.	N/A

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Hospital and Health Boards Act 2011 (Qld)* • *Human Rights Act 2019 (Qld)* • *Information Privacy Act 2009 (Qld)* • *Public Health Act 2005 (Qld)* • *Therapeutic Goods Act 1989 (Cth)* **Regulations** • Gene Technology Regulations 2001 (Cth) • Therapeutic Good (Medical Devices) Regulations 2002 (Cth) • Therapeutic Goods Regulations 1990 (Cth) **Other authority** • Australian Code for the Responsible Conduct of Research • National Statement on Ethical Conduct in Human Research 2023 • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) • Queensland State Archives: Health Sector (Clinical Records) Retention and Disposal Schedule • National Health and Medical Research Council: Management of Data and Information in Research • Therapeutic Goods Association: Australian clinical trial handbook

Standards	• National Clinical Trials Governance Framework
	• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.
	  ○ Standard 1 – Clinical Governance
	  ○ Standard 2 – Partnering with Consumers

Supporting documents	**Procedures** • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **Work instructions** • WI2024-335 CRF application and use

	• WI2024-336 CRF participant admission, supervision and clinical management • WI2024-337 CRF investigational product management and administration • WI2024-338 CRF adverse event and clinical incident reporting • WI2024-339 CRF laboratory alarm response **Attachments** • Attachment 1: CRF Archiving Checklist • Attachment 2: CRF Archiving box label

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

WORK INSTRUCTION DETAILS

Work Instruction Name	Clinical Research Facility archiving of clinical trial documents
Work Instruction Number	WI2024-340
Current Version	1.0
Keywords	CRF, archiving, clinical trial documents, storage
Primary MSH or Directorate Procedure Reference	PR2024-453 Clinical Research Facility (CRF)
Executive Sponsor	Executive Director, Metro South Research
Document Author	CRF Manager, Metro South Research
Next Review Date	June 2027

REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
V1.0	28/06/2024	3/07/2024	Executive Director, Metro South Research	• New MSH work instruction.