

# STANDARD OPERATING PROCEDURE (SOP)

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## 1. PURPOSE

The purpose of this document is to describe the process and procedures when archiving clinical trial and observational research binders that are stored and maintained within the Florence eBinder™ platform, ensuring compliance with Good Clinical Practice (GCP), the Therapeutic Goods Administration (TGA), the Health Records Act 2001 (Vic), the National Standard Operating Procedures for Clinical Trials, including Teletrials, the Australian Code for the Responsible Conduct of Research, and any other applicable local or international regulatory requirement.

All clinical trial binders maintained in Florence eBinders™ must be archived in accordance with this Standard Operating Procedure (SOP).

### 1.1. Quality Improvement

Compliance with this SOP ensures the documents and the data they contain are preserved and remain legible for the duration of the retention period and are appropriately archived. This process has been designed to archive both Investigator Initiated and Externally Sponsored Trials in Florence eBinders™ and meet all digital archiving requirements.

### 1.2. Participant Safety

Adhering to this SOP safeguards participants' sensitive information by maintaining confidentiality and preventing any undocumented modifications to archived eBinders™ that could put the integrity or reliability of trial data at risk

## 2. BACKGROUND

This SOP has been developed to support [MCTC170 SOP | Archiving Clinical Trials Investigator Site Files](#) and to provide guidance on how to archive clinical trials in Florence eBinders™.

Further guidance on archiving in Florence eBinders™ is addressed in [MCTC100 Policy | Florence User Policy](#).

## 3. SCOPE

This SOP applies to the archiving of electronic Essential Records for clinical trials stored and maintained within Florence eBinders™ for externally sponsored or MCRI-sponsored investigator led clinical trials along with observational research projects conducted at the Melbourne Children's Campus.



This SOP outlines the procedures for:

- a) Managing archiving of Binders
- b) Access to digitally archived trial documents within Florence eBinders™, and
- c) Retrieval of archived Binders (i.e. requesting access to an archived Binder).

This SOP does not cover the process of managing paper essential documents and/or producing certified digital copies for electronic archiving, nor does it cover archiving of hard-copy paper documents. See [MCTC170 SOP Archiving Clinical Trial Investigator Site Files](#) for more information and procedures on archiving requirements of paper documents.

#### 4. RESPONSIBILITY

This SOP applies to all members of the Melbourne Children's Campus who are responsible for the archiving of clinical trial binders maintained within Florence eBinders™.

Site Principal Investigators (PIs) and Sponsor-Investigators, or qualified delegated personnel, are responsible for ensuring archiving of clinical trial binders in accordance with this SOP. The digital archiving of Florence eBinders™ will be facilitated and actioned by the MCTC Florence Organisational Administrators (contactable at [florence@mcri.edu.au](mailto:florence@mcri.edu.au)). Should there be a change in a nominated PI/Sponsor-Investigator or delegate responsible for managing the archiving of a study and its future access, a study team member must inform the MCTC Florence Organisational Administrator immediately.

The MCTC Florence Organisational Administrator is tasked with:

- Facilitating and actioning the archival process
- Managing any requests for binder or document retrieval
- Managing user access to archived binders following approval and notification from the responsible parties; and
- Maintaining an up-to-date record of all archived eBinders™ and user access requests.

For externally sponsored trials where RCH/MCRI is a site:

- The Site PI is responsible for ensuring archiving responsibilities between the RCH/MCRI site and the external Sponsor is documented in the Clinical Trial Research Agreement (CTRA). Once the site has been closed out by the Sponsor and the site ISF is ready to be archived it is the Site PI's (or delegate) responsibility to prepare the Investigator Site File (ISF) for archival and notify the MCTC Florence Organisational Administrator that the ISF is ready for archiving.



- It is recommended that an internal quality assurance (QA) review of the ISF is completed by the Site PI (or delegate) to ensure presence and currency of all required documents.

For MCRI-Sponsored trials:

- The Sponsor-Investigator, or delegate, should ensure that the archiving responsibilities for both the participating trial sites ISF (if applicable) and the Trial Master File (TMF) and Site Investigator Files (SIF) are clearly delineated in the MCRI Certificate of Sponsorship delegation of responsibilities document.
- The Sponsor-Investigator, or delegate, is responsible for providing a complete copy of the ISF (e.g., downloaded zipped copy, selecting 'All Versions') to each participating trial site Principal Investigator, should the participating sites be maintaining their ISF within Florence eBinders™. Alternatively, the Sponsor-Investigator, or delegate, should provide participating trial sites with detailed instructions on how to download a copy of their own ISF eBinder and store locally.

## 5. RELATED DOCUMENTS

[MCTC084 SOP Trial Master File Quality Assurance](#)

[MCTC100 Policy | Florence User Policy](#)

[MCTC170 SOP | Archiving Clinical Trials Investigator Site Files](#)

[MCTC084 SOP | Trial Master File \(TMF\) Quality Assurance](#)

[MCTC064 Form | TMF QA Review Planning Form](#)

[MCTC067 Form | Trial Master File \(TMF\) Quality Assurance \(QA\) Review Checklist](#)

[MCTC189 SOP Trial Close Out](#)

## 6. PROCEDURE

### 6.1. Preparing Florence eBinders™ for Archiving

#### 6.1.1. Preparing Investigator-Initiated Trials (IIT) Binders for Archiving

Once the Sponsor-Investigator has confirmed the completion of all study related and site related close-out activities (see [MCTC189 SOP Trial Close Out](#)), the trial TMF/SIF and participating site ISFs are ready for archiving. It is recommended that



study teams complete an internal TMF and SIF QA review prior to archiving to ensure completeness and currency of all essential documents. (See [MCTC084 SOP Trial Master File Quality Assurance](#)). After ensuring all documents are filed accurately, any documents in Florence eBinders™ which have been uploaded via the 'shortcut' method to documents outside of the study binder must be downloaded and re-uploaded to the location where the shortcut appears. This is because documents appearing in binders via the shortcut method do not lock correctly during the archiving process (i.e. the shortcut must be broken before archiving the binder if the documents are shortcut from single sources in other binders such as the 'Central Files' binder).

Once the documents are re-uploaded, existing shortcuts must then be deleted from folders. All documents downloaded should have selected 'Include' for Signature Addendum Pages and 'All Versions' for document version.

During this period, any participating trial sites who are using Florence eBinders™ must be provided with a copy of their ISF for long-term storage locally. The study team must inform and instruct participating trial sites in how to download a local copy of their ISF, or alternatively, the study team must provide trial sites with a copy of their ISF in transferrable form (e.g. zipped file). An audit trail of the individual ISF folder must also be downloaded and stored with the digital ISF. When downloading the ISF folder ensure 'All Versions' is selected so that stacked document versions are also downloaded.

After each participating trial site has downloaded, or is provided with a copy, of their ISF, the Sponsor-Investigator (or delegate) must revoke all access and permissions to the ISFs from assigned users based at participating trial sites. This is to also prevent unauthorised access of the binder during the archival period.

Once the study team has confirmed the TMF/SIF and ISFs are ready for archiving, an audit trail of the entire binder must be downloaded and uploaded into the binder as a PDF document. The study team will then notify the MCTC Florence Organisational Administrator via email that their binder is ready for archiving at: [florence@mcri.edu.au](mailto:florence@mcri.edu.au), in accordance with [Section 6.2](#) below.

#### 6.1.2. Preparing Externally Sponsored Trials (ISF) Binders for Archiving

Following the close out of RCH or MCRI as a site and prior to archiving, it is recommended that a site study team complete an internal ISF QA review, ensuring all documentation required has been accurately filed, is current and complete. This includes final site close out letters and reports, if applicable.



After ensuring all documents are filed accurately, any documents in Florence eBinders™ which have been uploaded via the 'shortcut' method to documents outside of the study binder must be downloaded and re-uploaded to the location where the shortcut appears. This is because documents appearing in binders via the shortcut method do not lock correctly during the archiving process (i.e. the shortcut must be broken before archiving the binder if the documents are shortcut from single sources in other binders such as the 'Central Files' binder).

Once the documents are re-uploaded, existing shortcuts must then be deleted from folders. All documents downloaded should have selected 'Include' for Signature Addendum Pages and 'All Versions' for document version.

Once the site PI (or delegate) has confirmed the ISF is complete and accurate, an audit trail of the entire binder must be downloaded and uploaded into the binder as a PDF document. A site study team member will then notify the MCTC Florence Organisational Administrator that their binder is ready for archiving at: [florence@mcri.edu.au](mailto:florence@mcri.edu.au), in accordance with [Section 6.2](#) below.

## 6.2. Notify MCTC Florence Organisational Administrator of archiving needs

At the point of archiving, the Principal Investigator or Sponsor-Investigator (or delegate) must notify the MCTC Florence Organisational Administrator via email that the trial binder is ready for archival, by emailing: [florence@mcri.edu.au](mailto:florence@mcri.edu.au).

The following details must be included in the body of the email:

- The Florence eBinder™ name
- HREC number
- Protocol number (if different from HREC number)
- The number of high-level sub-folders contained within the eBinder™ requiring archiving i.e. the total number of TMF, SIF and/or ISFs folders scheduled for archiving
- A study team contact name and email address for archiving (generally this would be the assigned [Domain Data Controller](#))
- Date of archiving and length of the archival period e.g. 25 years

### 6.2.1. Record Retention

See section 4.4 of [MCTC170 SOP Archiving Clinical Trials Investigator Site Files](#).



## 6.3. Archival steps within Florence

### 6.3.1. Archiving IITs in Florence eBinders™

Upon notice to archive, the Florence Organisational Administrator will rename the trial eBinder™ to include '- Pending Archive' at the end of its title to indicate the archive process initiating.

The MCTC Florence Organisational Administrator will then revoke study team access to the eBinder in preparation for final archiving. This is also to prevent unauthorised access of the binder during the archival period.

Once access has been revoked, the eBinder will be renamed to include '- Archived' at the end of the title, replacing 'Pending Archive'. Status of the trial binder tag will also be updated to 'Archived'.

After the archival process is complete, only the MCTC Florence Organisational Administrator, acting as the Florence Archive Manager, will be able to access the trial eBinder or action any further tasks related to the trial binder.

### 6.3.2. Archiving Externally Sponsored Trial ISFs in Florence eBinders™

Upon notice to archive, the trial eBinder will be renamed to include '- Pending Archive' at the end of its title to indicate the archive process initiating.

The MCTC Florence Organisational Administrator will then revoke PI and study team access to the eBinder in preparation for final archiving. This is also to prevent unauthorised access of the binder during the archival period.

Once access has been revoked, the eBinder will be renamed to include '- Archived' at the end of the title, replacing 'Pending Archive'. Status of the trial binder tag will also be updated to 'Archived'.

After the archival process is complete, only the MCTC Florence Organisational Administrator, acting as Florence Archive Manager, will be able to access the trial binder or action any further tasks related to the trial binder.

### 6.3.3. Archiving digital EDC data provided by External Sponsor who maintained hard-copy trial binders

In the event an external sponsor provides MCRI/RCH site teams with a digital electronic data capture (EDC) data file following trial closure, and the trial has not used Florence eBinders™ eISF, site teams can contact the Florence Archiving Manager at [florence@mcri.edu.au](mailto:florence@mcri.edu.au), to assist with long-term archiving of the dataset.



A trial-specific folder is created in the 'z.Archive' binder; the folder name consists of the HREC number, protocol number and trial name. Temporary permission is granted to the site team to upload any data provided digitally by the sponsor e.g. via portal download, USB or CD. After uploading to Florence eBinders™ trial team should check all files can be opened. Once all data files have been uploaded and checked, the site team will notify the MCTC Florence Archiving Manager who will then revoke all access and permissions to the folder.

Retention of digital records should then be tracked in a trial specific [Archiving Document Log](#) by the PI (or delegate), created and stored locally by site team as per Section 4.3.1 of [MCTC170 SOP | Archiving Clinical Trial ISFs](#).

It is the responsibility of the PI (or delegate) to inform the MCTC Florence Archiving Manager when such folder may be deleted following the required retention period.

#### 6.4. Archive status and management

Once permission has been revoked from study team personnel by the MCTC Florence Administrator and the eBinder is ready for archiving, all eBinder names will be renamed to start with 'z.' and end with '- Archived'.

E.g. "z.60303 – Trial Name - Archived"

Study team personnel will not be able to view, or access archived eBinders appearing at the bottom of the MCTC Organisational administrators' 'Binders' tab.

Following the completion of the archiving procedure in Florence eBinders™, the MCTC Florence Organisational Administrator will record the archiving of all Florence eBinders™ within the [Archived Trial Registry](#). This registry will maintain a record of the following:

- a) Location of Archived Binder; i.e. Florence 'EU Team' or 'AUS Team
- b) Trial name
- c) HREC number
- d) Date of archiving
- e) Archival retention period
- f) Primary contact name and email address (generally the nominated Domain Data Controller).

This registry will also record the trial folders for the archiving of digital EDC data and note it's formatting by checking the excel sheet with a 'X'. All correspondence regarding the request and confirmation of archiving of a Florence eBinder™ will be filed within a project folder in



the Florence SharePoint filing location; [Archiving](#) by the MCTC Florence Archiving Manager and/or Florence Organisational Administrator.

For studies that use both paper and electronic documents, the record of the Florence eBinder™ archival status and completion must also be logged in a trial specific [Archiving Document Log](#) by the PI/Sponsor-Investigator (or delegate). This log must be created, maintained and stored locally by site team. Refer to [MCTC170 SOP Archiving Clinical Trials Investigator Site Files](#) for more information.

## 6.5. Confirmation of Florence eBinder Archival Process Complete

The nominated Domain Data Controller/primary contact will be notified by the MCTC Florence Archiving Manager (via email) once the archival process has been completed and all relevant details provided and logged into the archiving registry.

## 7. RETRIEVAL PROCEDURE

### 7.1. Requesting access to an archived Florence eBinder™

In the event access is required to an archived Binder, requests to retrieve archived eBinders by the MCRI study teams, the sponsor, the local HREC/RGO or other regulatory bodies must be made in writing to the PI, Sponsor-Investigator and/or study team. The Domain Data Controller (or delegate) or authorised personnel are responsible for approving the request and notifying the MCTC Florence Archive Manager, via email to: [florence@mcri.eu.au](mailto:florence@mcri.eu.au), including the following:

- a) Name of the Binder in which you are requesting access E.g. "z.60303 – Trial Name - Archived".
- b) Name of the sub-folders where access is required, if access to the entire Binder is not needed
- c) Approval status of the requestor/request details
- d) Contact details of the party/ies requiring access to the eBinder
- e) Duration of access in which the party/parties will require access to the binder contents.

All correspondence regarding the requests to access archived binders will be filed within the project folder in the Florence SharePoint filing location; [Archiving](#). An audit trail of who has been granted access, the name of the eBinder and date of access will also be maintained in the [Archived Trial Registry](#), by the MCTC Florence Archive Manager.



## 7.2. Retrieving Archive Access

To retrieve an archived Florence eBinder™, and provide viewable access to an individual, the MCTC Florence Organisational Administrator will create a specific role, entitled '<HREC number>' – View Archive', with the following permissions associated:

- View Binder
- View Documents Without Personal Health Information (PHI)
- View Documents With Personal Health Information (PHI)
- View All Audit Trail Events for the Binder

This role is then assigned to the approved individual for the approved duration of access. E.g. for the time period requested in the email to the MCTC Florence Archive Manager as detailed in [section 7.1](#). The duration of access must be logged by the MCTC Florence Archive Manager in the [Archived Trial Registry](#). At the end of the assigned access, the MCTC Archive Manager will terminate the approved individual's access.

In the event that only sub-folders of an archived eBinder have been approved for release to an individual, the role created must be amended to stipulate only the approved sub-folders and not the entire Binder. Such distinction will be recorded in the [Archived Trial Registry](#) by the Florence Archive Manager.

## 7.3. Amending/Additions to Archived Binders

Following the archive date, should additional documents require archiving or amendments to existing documents, an 'Editing Archive' role may be created for additional documents or amendments to existing documents required following the archive date.

The PI/Sponsor-Investigator (or delegate) must approve of the editing requirements and request the editing role to be created, outlining the length of time needed for access.

The 'Editing Archive' role will be a duplication of the template 'Binder Administrator' permissions and entitled as '<HREC Number>' – Archive Editing'. This additional role allows central study team members or MCRI/RCH site team members temporary access to a previously archived Binder, in order to upload a missed document or amend an error found on existing documents.

This temporary access must be recorded in the [Archived Trial Registry](#) and will require that any changes made to the archived binder be captured in the eBinders audit trail. Users must re-download the entire eBinder audit trail and upload the current audit trail as a subsequent new version stacked on top of the previously filed audit trail.



## 8. CORRECTIVE ACTIONS

Failure to follow this SOP during archiving may jeopardize meeting regulatory requirements.

This SOP is instigated at the time a Florence eBinder™ is deemed ready for archiving. The date of archival will only begin upon the completion of the procedures outline in [Section 4](#) of this SOP.

## 9. GLOSSARY

Refer to [MCTC218 Glossary](#) for an updated list of glossary terms.

## 10. REFERENCES

- European Medicines Agency: GCP Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) available at [https://www.tga.gov.au/sites/default/files/2024-07/guideline\\_on\\_the\\_content\\_management\\_and\\_archiving\\_of\\_the\\_clinical\\_trial\\_master\\_file.pdf](https://www.tga.gov.au/sites/default/files/2024-07/guideline_on_the_content_management_and_archiving_of_the_clinical_trial_master_file.pdf)
- Public Records office of Victoria: Retention and Disposal Authority for Records of the Higher and Further Education Functions available at <https://prov.vic.gov.au/sites/default/files/files/documents/1607var1.pdf>
- [Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022](#)
- [NHMRC Australian Code for the Responsible Conduct of research \(2018\)](#)
- [NHMRC National Statement on Ethical Conduct in Human Research \(2025\)](#)
- TGA Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (2) 2016 – Annotated with TGA comments available at <https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>

## 11. COLLABORATORS

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