# Florence eTMF and eBinders™ User Policy

## 1.0 Policy Summary & Applicability

This document explains the Florence eBinders™ User Policy (i.e. eTMF and eISF) and applies to all users of the Florence Platform, with respect to all Melbourne Children's Campus* employees, students, honorary research fellows and associates, who will utilise the Florence eBinders™ Platform.

*The Melbourne Children's Campus includes employees from the Murdoch Children's Research Institute (MCRI), the Royal Children's Hospital (RCH) & the University of Melbourne Department of Paediatrics.

## 2.0 Purpose

The purpose of this policy is to provide user guidance and instructions and to define standards, procedures, and restrictions for Melbourne Children's Campus employees in the use of the Florence eBinders™ Platform, who are engaged in the collection, creation, completion, maintenance, and management of essential documents for Clinical Trials.

## 3.0 Background

The Florence eBinders™ Platform is powerful cloud-based tool, developed by Florence Healthcare which facilitates the storage and maintenance of clinical trial related essential documents at both the Sponsor and Site level (i.e. eTMF and eISF).

Florence eBinders™ has a flexible and fine-grained authorisation matrix, allowing different members of the study team to have different levels of access (i.e. none, read-only or edit permissions) to various binders, folders or documents, as well as access to the various functions the platform offers, depending on their delegated role within the clinical trial.

Florence eBinders™ enforces authorisation granted to each user by providing and/or enabling certain functions and user rights according to granted privileges and pre-assigned permissions, including the ability to restrict access to folders and documents containing Personally Identifiable Information (PII)/Protected Health Information (PHI).

Florence eBinders™ includes a full audit trail, recording all operations performed within the platform, including viewing, annotating, signing, and downloading of documents. The audit log records operation, date and time, and the name of user performing the operation, permitting review of the audit trail by required personnel, as necessary.

The Florence eBinders™ platform is a fully validated 21 CFR Part 11 and GDPR compliant tool, ensuring data integrity protection by design.

## 4.0 Policy and Procedure

### *4.1 Organisational Administrator*

Melbourne Children's Florence eBinders™ is managed by a team of Organisational Administrators based within the Melbourne Children's Trial Centre (MCTC).

The role of the Organisational Administrator(s) is to:

- Manage the overall Melbourne Children's Campus team account settings
- Oversee and manage the entire Florence eBinders™ platform
- Create the Binder Administrator role(s) for individual clinical trials
- Create new Roles, Binders and Folders for individual clinical trials

- Assign and control access/permissions to newly created Binders and Folders
- Defines User Roles and maintains these Roles within the platform
- Responsible for the ongoing overall maintenance of the platform.

The Florence Organisational Administrators can be contacted by emailing: Florence@mcri.edu.au

### *4.2 Binder Administrator*

Each Binder within the Melbourne Children's Florence eBinders™ Team is managed by a Binder Administrator. The role of the Binder Administrator(s) is to:

- Manage the contents of the Trial Binder
- Manage the Roles which relate to the trial binder, including:
  - Assigning appropriate Roles to Users working on the study
  - Deactivating Roles when the User no longer requires access to the Binder
- Liaise with the Organisation Administrator to arrange new Roles and Site Files as required.
- Ensure all Users with access to the Trial Binder have completed all requirements detailed in 4.4 and 4.6 of this Policy

### *4.3 Use of Platform: Which Clinical Trials can utilise Florence?*

Clinical Trials which can utilise the Florence platform consist of studies with an effective start date on or after the Florence "Go Live Date" at Melbourne Children's, including:

- Commercially Sponsored Clinical Trials
- MCRI-Sponsored Investigator Initiated Clinical Trials*
- Other research studies e.g., Observational Research Studies

*Note: From January 2021, it will be mandatory for all International MCRI-Sponsored Investigator Initiated multi-site clinical trials to utilise the Florence eBinders™ Platform for managing essential documents.

### *4.4 User Training Requirement & Training Attestation*

Prospective Users must complete mandatory Florence Training prior to being granted access to Florence eBinders™:

- Prospective Binder Administrators may be trained by Florence Organisational Administrator(s) or delegates
- Prospective Users (both internal & external) must complete Florence training relevant to their role
- All prospective Users must provide evidence of completed training i.e. Florence Certificate of Completion.

Mandatory Florence training is not required for:

- Florence system product specialists
- Melbourne Children's Campus or non-MCRI personnel who require temporary read-only access, e.g. Regulatory Auditors or Inspectors, or RCH Research Ethics and Governance (REG) personnel
- Trial-specific personnel identified as requiring limited access to Florence eBinders™ e.g. read-only or sign-only access required only.

Limited task-specific training may be provided to these personnel by the Organisational Administrator or Binder Administrator.

#### *4.5.1 Establishing New Study Binders*

Requests for establishing new study eBinders™ (i.e., eTMFs/eISFs/eSIFs) within the Florence eBinders™ Platform can be submitted by any Melbourne Children's Campus employee/honorary.

- Employees must complete and submit a "Request for Florence eBinders™" form. Completed forms must be emailed to the Florence Organisational Administrator via: Florence@mcri.edu.au
- Requests for study eBinders™ will be reviewed by the MCRI Florence Team and the MCTC Business and Operations Manager (or delegate) for documentation, approval, and billing, prior to the creation of any new eBinder™

New eBinders™ will be created within a maximum of 7 business days upon approval of requests by the MCRI Florence Team.

### *4.6 Establishing New Individual User Accounts*

Access to Florence eBinders™ will be limited to approved users.

- Individual request for User Accounts will be directed to the Organisational Administrator(s), Binder Administrators(s) or delegates
- Only Organisational Email addresses should be provided by the User requesting access to the Platform – Florence accounts must not be generated using non-organisational email addresses such as Hotmail, Gmail, Outlook etc.
- Following completion of training, prospective users must complete and sign the following documentation prior to being granted access to the Florence Platform:
    - Wet-Ink Signature Page (internal Melbourne Children's Campus employees); or
    - Wet-Ink Signature Log (external Participating Site Staff, if applicable)

On confirmation of completion and receipt of the listed requirements above, the Organisational Administrator(s), Binder Administrators(s) or delegate will create a unique user account for the Prospective User. Login details, including passwords, must remain confidential and must not be shared between Florence users.

The Prospective Users permissions will be granted according to their role in the clinical trial. The user will then be granted access to the specific Binders and/or Folders they require access to.

User accounts will be created within a maximum of 7 business days of the receipt of appropriate documentation.

#### *4.6.1 Modifications to User Accounts*

Where a User wishes to make modifications to their user account details (e.g. modifications to an email address), users must contact the Organisational Administrators by emailing: Florence@mcri.edu.au, and include justification/explanation for the modification.

The Organisational Administrator or delegate will make any required modifications to the user account within 7 business days of the receipt of appropriate documentation. Where the Platform does not allow changes to an existing user's account details, the original user account should be deactivated, and a new user account created.

### *4.7 Assigning User Permissions and Roles*

It is the responsibility of the Organisational Administrator(s) or delegate to create and maintain Roles within the Florence Platform and assign the relevant permissions in accordance with the description of the Roles.

- Roles have been pre-determined
- Permissions assigned to pre-determined roles are also pre-defined
- Requests to amend/modify certain permissions to pre-determined roles must be made in writing (via email) to the Organisational Administrator(s) via: Florence@mcri.edu.au
    - Supporting documentation must be provided to justify the request for modifications to permissions

Refer to the Florence Roles & Permissions Reference Guide for further information.

### *4.8 Wet-Ink Signature Page/Log*

This section applies to all documents generated by Melbourne Children's Campus employees for clinical trials utilising Florence eBinders™ and where electronic signatures and handwritten signatures executed to electronic documents are intended to be equivalent to paper records and handwritten signatures.

- The purpose of the Wet-Ink Signature Page/Signature Log is to maintain a record of the handwriting sample of every individual involved in study-related activity who utilises the Florence eBinders™ platform to execute electronic signatures

*For Commercially-Sponsored Studies:*

- An individual Wet-Ink Signature Page will be obtained from every Melbourne Children's Campus personnel not directly involved within a clinical trial, but is providing ancillary support to the study, e.g. MCRI Chief Operating Officer, Legal Team Representatives, Supporting Department Representatives, etc
- An individual Wet-Ink Signature Page will be obtained from every Melbourne Children's Campus personnel directly involved with a clinical trial and any study-related activity
- Each completed Signature Page will be uploaded and stored within the study's eISF binder within Florence eBinders™
- Alternatively, Signature Logs may be provided by the commercial Sponsor for completion
- A copy of the original Wet-Ink Signature Page or Signature Log, whichever is completed, should be maintained at site.

*For MCRI-Sponsored IITs:*

- An individual Wet-Ink Signature Page will be obtained from every Melbourne Children's Campus personnel not directly involved within a clinical trial, but is providing ancillary support to the study, e.g., MCRI Chief Operating Officer, Legal Team Representatives, Supporting Department Representatives, etc
- An individual Wet-Ink Signature Page will be obtained from every Melbourne Children's Campus personnel directly involved with a clinical trial and any study-related activity
- A Wet-Ink Signature Log will be maintained by each external Participating Site
- Each completed Wet-Ink Signature Page obtained from both Melbourne Children's ancillary personnel and Melbourne Children's personnel directly involved within the study, will be uploaded, and stored within the Central Folder of the eTMF, within the Florence Platform
- Copies of the original Wet-Ink Signature Pages will be maintained by the Organisational Administrator and stored within the Melbourne Children's Trials Centre
- Each completed Wet-Ink Signature Log obtained from external Participating Sites, will be uploaded, and stored with each site's eISF and corresponding eSIF within Florence eBinders™
- A copy of the original Wet-Ink Signature Log should also be maintained at site.

Refer to the Florence eBinder™ Workflow and eSignature Reference Guide for further information.

### *4.9 Source Documents*

Source documents are documents which contain source data. Source data is defined as: "All information in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." [Section 1.51, Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments].

It is not mandatory to use the Florence eBinders™ platform to file and store source documents to enable remote monitoring for IITs. The decision to upload source documents into Florence eBinders™ is on a per trial basis.

The following general principles apply if source documents are maintained in the Florence eBinders™ platform for the purpose of remote monitoring:

- Ensure a nominated folder has been created within the eISF index to upload and file source documents
- Ensure all identifying participant information, including participant names, addresses, hospital numbers, clinician/provider information etc. have been completely removed/redacted; or if users do not wish to redact source documents, ensure the source document has been 'Marked as containing PHI'
- Ensure users have been adequately trained in the redacting and uploading of source documents into Florence eBinders™
- Ensure Users do not have access to view PHI unless it directly pertains to their Role within the Trial.

Contact MCTC [mctc@mcri.edu.au] for further information regarding the use of Florence eBinders™ for the filing off source documents and remote monitoring.

### *4.10 Documents in Draft/Development Format*

The Florence Platform does not allow for the generation and drafting of documents. These tasks require completion outside the platform and documents only uploaded and filed into Florence once they are finalised and/or approved.

- Storage and maintenance of trial-related documents in draft/development format should be stored on secure MCRI network drives or other MCRI supported cloud-based software applications i.e., OwnCloud, Share Point
- The filing index of folders appearing on the MCRI network drives should mirror the filing structure of the corresponding eTMF or eISF within the Florence eBinders™ Platform.

### *4.11 Periodic Review and Deactivation of User Accounts*

The Binder Administrator(s) or delegate must conduct periodic reviews of all Users within the Florence Platform to ensure that all Users have the correct permissions and are still active Users.

- Periodic reviews of all Users should occur every six (6) months
- Alternatively, ongoing User reviews can occur in real-time by reviewing specific roles against the trial's Signature and Delegation of Authority Log, removing Users as they cease their active participation within a study
- Documented evidence of periodic reviews must be maintained

Refer to the Florence Periodic Reviews Reference Guide for further details and instructions on undertaking periodic User reviews.

### *4.12 Quality Assurance (QA) Reviews of eISF for Commercially Sponsored Trials*

Commercial Sponsors will be responsible for conducting Quality Assurance (QA) reviews of the eISF for their trials.

### *4.13 Quality Assurance (QA) Reviews of eTMF and eISF for Investigator Initiated Trials*

An annual Quality Assurance (QA) review of the eTMFs and eSIF contents against the filing structure/index will be performed through Binder Administrator(s) or delegated Peer Reviewers. The review will assess consistency and timeliness of filed documents, currency of filed documents filed and ensure ICH-GCP essential documentation requirements are met.

The relevant Binder Administrator(s) or delegate will be advised of any inadequacies or omissions and a corrective and preventative action (CAPA) plan completed.

The Binder Administrator(s) or delegate should ensure that documentation in the eTMFs and eSIFs is consistent with the information provided to the site for the eISF, if applicable. Documents absent from the eTMF required from an investigator site should be noted and requested from the site. Similarly, the Site Investigator File (SIF) should be reviewed in parallel for completeness and omissions/inadequacies resolved.

If required, the Sponsor and the Research Ethics and Governance (REG) Office may undertake ad hoc reviews of any eBinders appearing in the Florence eBinders™ Platform.

### *4.14 Archiving*

The Florence eBinders™ platform can be utilised as an archiving solution. The Organisational Administrator(s) will maintain access to all Study Binders in order to meet any minimum retention periods of the data and be able to reinstate access to authorised Users upon request, should it be deemed required.

In the event that the Florence eBinders™ Platform and/or service agreement were to be replaced or discontinued, Florence will maintain storage of data for one hundred eighty (180) days so to allow for study eBinders™ to be exported/ downloaded by Users.

All Binder Administrators or delegates will be notified with ample time so that Users can export their study eBinders™. If eBinders™ are not exported/downloaded within the 180 day period, Florence will delete any data remaining on its platform and servers.

At the time of determining that data analysis is complete, and the trial is ready for archiving, the Organisational Administrator, Binder Administrator(s), or delegate will move the study into 'archive' mode within the Florence eBinders™ Platform.

This is completed by revoking/removing access to all Users who have access to the relevant study Binder and subsequent Folders.

Contact MCTC [mctc@mcri.edu.au] for further information regarding archiving requirements.

## 5.0 Failure to Comply

Failure to comply with this policy may result in the suspension of Florence User Accounts. Additional actions may include, but is not limited to, one or more of the following:

- Temporary or permanent revocation of access to the Florence Platform
- Disciplinary action according to applicable MCRI policies
- Undertake additional training/education on the use of the Florence eBinders™ Platform, applicable to their role.

## 6.0 Applicable Regulations and Guidelines

- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry - here
- General Data Protection Regulation - here
- US FDA 21 CFR Part 11 Electronic Records; Electronic Signatures - here
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff - here
- Part 11, Electronic Records; Electronic Signatures – Scope and Application - here
- Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions & Answers - here

- US FDA 21 CFR Part 312.62(c) – Investigational New Drugs – Drugs for Human Use - here
- US FDA 21 CFR Part 812 – Investigational Device Exemption - here
- US FDA Industry Guidelines and Information Sheets - here
- FDA Compliance Policy Guidance Programs - here
- Australian Code for the Responsible Conduct of Research - here
- EMA Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic); dated: 06 December 2018. EMA/INS/GCP/856758/2018 - here

## 7.0 Other Applicable Policies

- MCRI Data Protection Policy and Procedure
- MCRI Research Data Storage, Retention & Disposal

## 8.0 Other Applicable SOPs and Supporting Documents

- Florence Roles & Permissions Reference Guide
- MCTC101 SOP - Use of Florence eTMF for Commercially Sponsored Investigator Site File (ISF) Electronic Records and Electronic Signatures
- MCTC102 SOP - Use of Florence eTMF for MCRI-Sponsored Investigator-Initiated Clinical Trials (IITs) Trial Master File (TMF), Site Investigator File (SIF) and Investigator Site File (ISF) Electronic Records and Electronic Signatures
- MCTC103 Guidance - eISF/eBinders™ Workflows and eSignature Reference Guide for Commercially Sponsored Studies
- MCTC104 Guidance - eISF/eBinders™ Workflows and eSignature Reference Guide for Investigator-Initiated Studies
- MCTC105 Guidance - eTMF eISF/eBinders™ Workflows and eSignature Reference Guide for Investigator-Initiated Studies
- MCTC069 Guidance - eTMF Filing Guidance Document for Investigator-Initiated Studies
- MCTC070 Guidance - eSIF Filing Guidance Document for Investigator-Initiated Studies
- MCTC071 Guidance - eISF Filing Guidance Document for Investigator-Initiated Studies

For documents referenced within this SOP that are not currently available on the CRDO Launching Pad, please email CRDO.info@mcri.edu.au to obtain a status update.

## 9.0 Policy Review and Renewal Date

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| Policy Sponsor: | MCTC |
| Policy Owner: | MCTC |
| Policy Approved By: | MCTC Business & Operations Manager |
| Policy Approved Date: | 07/12/2020 v1.0 |
| Policy Approval Date: | 11/10/2021 v2.0 |
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