HANDBOOK

Title: **Florence eBinders™ User Handbook**

Document ID: MCTC225

Version: 2.0

Applicability: All Florence eBinders™ Users

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The author is signing to confirm the technical content of this document.

Date: 28/07/2026

Institution/Department name: Melbourne Children's Trial Centre & Clinical Research Development Office

Revision	Modified by	Effective Date	Description of Change
1.0	Grace Whitehouse	4/06/2026	New Issue
2.0	Grace Whitehouse	11/08/2026	Update made to section 10 eLogs

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1. PURPOSE

This Handbook provides guidance for Florence eBinders™ users on the consistent and appropriate use of the Florence platform for clinical research studies conducted at the Melbourne Children's Campus. It consolidates practical guidance, tips, and best practice instructions into a single, accessible reference to support efficient and compliant document management.

The objectives of this Handbook are to:

a) Provide Florence eBinders™ users with clear instructions on how to navigate and use the Florence platform and serve as a central reference point for Florence-related guidance and troubleshooting.
b) Increase user confidence by ensuring users are aware of, and understand how to access and use, the full range of Florence features available to support study document management.
c) Support Florence users to effectively use the Florence interface for appropriate study document management within their research activities, thereby facilitating alignment with Good Clinical Practice (GCP) principles and relevant Melbourne Children's Campus policies and procedures.

2. Requesting a New Florence eBinder™

To request a new eBinder, please complete the following Form: **Florence Binder Request Form**

Once this form has been submitted, the Florence Organisational Administrators will be notified and will begin setting up your binder.

Every effort will be made to set up your binder as quickly as possible; however, please allow up to seven (7) business days for completion. You will receive confirmation from florence@mcri.edu.au once your binder is ready.

Current fees for Binder set-up are provided as follows:

Trial Type	Binders Included	Cost	Frequency
Commercially Sponsored	Investigator Site File (ISF)	$2880	Once-off
Investigator-Initiated Trials (IITs)	Investigator Site File (ISF) Site Information File (SIF) Trial Master File (TMF)	$1000	Once-off
Investigator-Initiated Adaptive Platform Trials	Trial Master File (TMF)	$1000	Once-off
	Investigator Site File (ISF) Site Information File (SIF)	$700	Per domain

3. New User Accounts

3.1. Requesting a Florence eBinder Account

In accordance with MCTC100 | Florence User Policy, all users must complete three steps prior to having a user account created and access to Florence assigned:

1. **Training:** Complete role-based training on how to use Florence eBinders. Refer to Section 3.2 below.
2. **Evidence of Wet Ink Signature:** Create and submit an original record of the user's wet ink signature and provide both a digital and hard copy to the MCRI Florence Organisational Administrator. Refer to Section 3.2 below.
3. **Role and Permissions:** Organise appropriate roles and permissions with the Florence Organisational Administrator or the trial's Binder Administrator.

   Refer to MCTC113 Guidance | Florence Roles and Permissions

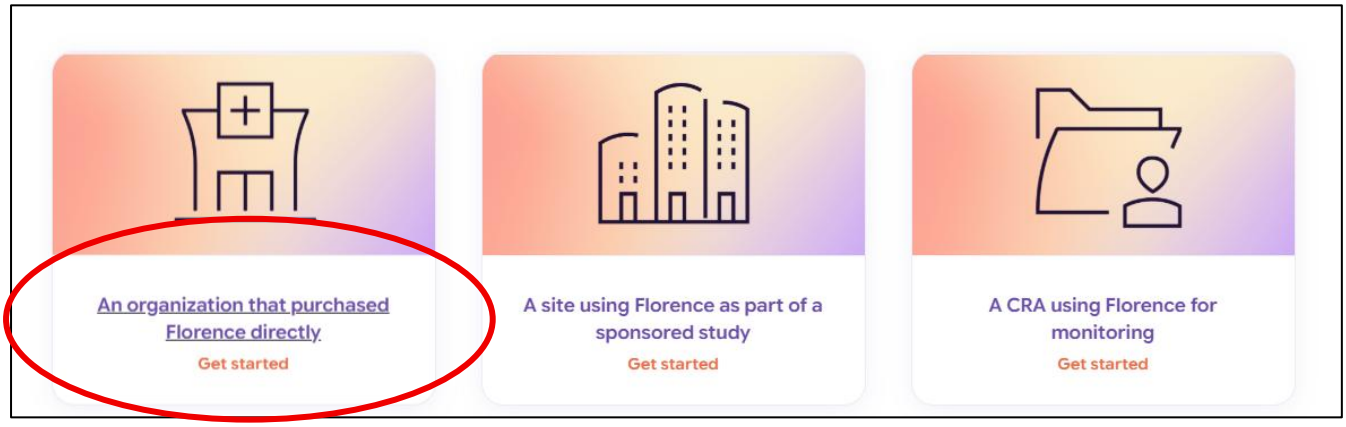
3.2.Florence Training and Wet-Ink Signatures

Prior to gaining access to Florence eBinders™, users are required to complete adequate Florence training. A series of training modules are available to users; training modules are role-based, and users should complete training modules which align to their role in a clinical trial.

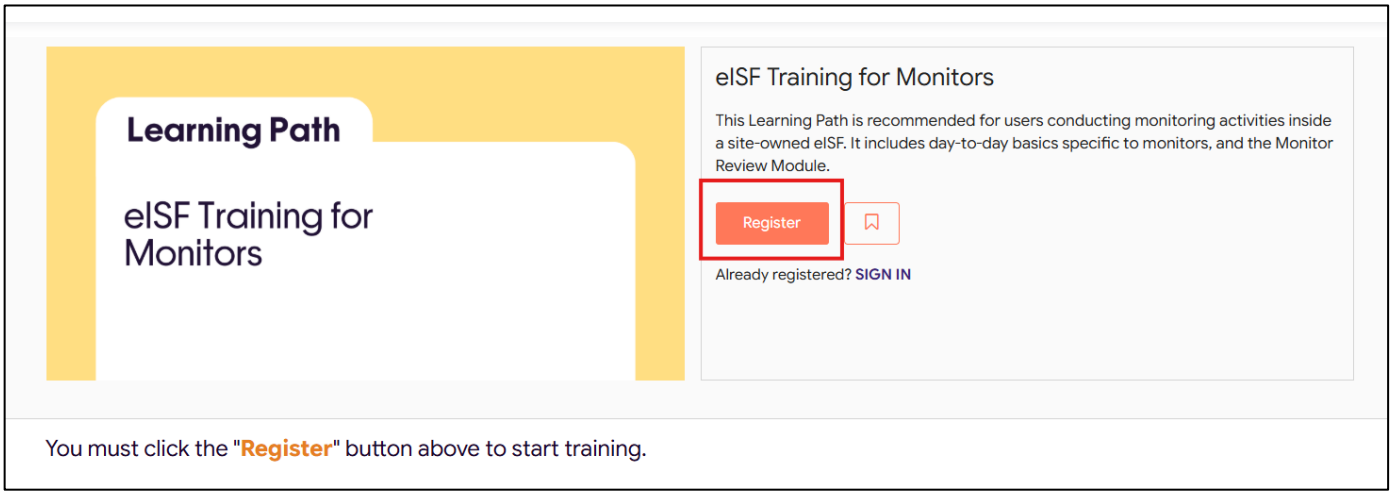
Refer to Appendix A "Florence Training Modules (via FloPro University)" for a full list of training modules available.

Follow these steps to complete training:

1. Click on the following link to access Florence training modules: university.florencehc.com
2. Navigate to the ***'How are you accessing Florence today'*** section and click ***'An organisation that purchased Florence directly'.***
3. Select the appropriate training module in accordance with the Training Guidance appearing in Appendix A, which outlines the required training based on your role and study type.



4. Once you have selected your course, select **'Register'**. You will be prompted to log in; please create a **guest account** using the same organisational email address that you will use to access Florence (e.g. name.surname@mcri.edu.au).



5. Complete all courses appearing within the selected training modules.

6. Upon completion of training, a Florence Training Certificate will be issued. Certificates will be sent to users via email or can be accessed via the **'My Profile'** tab (top right).

7. Prior to access being granted to Florence eBinders™:

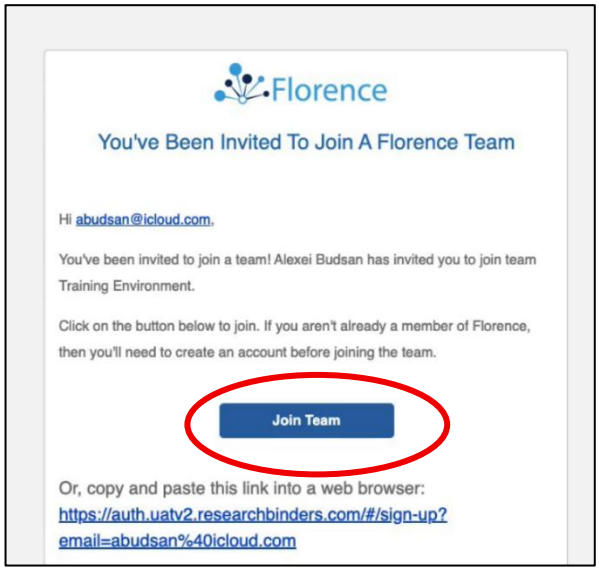
    a) **All MCRI/RCH staff** are required to sign and return an original wet-ink signature page. The hard copy should be returned to MCTC, South Building, Level 4.
    b) **Non-MCRI/RCH staff and site staff based at external sites** must sign a wet-ink signature log, which should be filed in the site's Site Information File (SIF) (for example, Royal Women's Hospital staff accessing Florence eBinders™).
    c) **Site Monitors** are required to complete a Monitor wet-ink signature page. Digital copies must be returned prior to the first monitoring visit at site, with hard copies returned during the visit.

8. Email a copy of both your Certificate of Training Completion and Wet-Ink Signature Page/Log to the trial coordinator and/or florence@mcri.edu.au

4. Activation of Florence eBinders Accounts

1. The MCRI Florence Organisational Administrator will invite you (via email) to a Florence team (AUS or EU Team) once the wet-ink signature page and training certificate have been received.

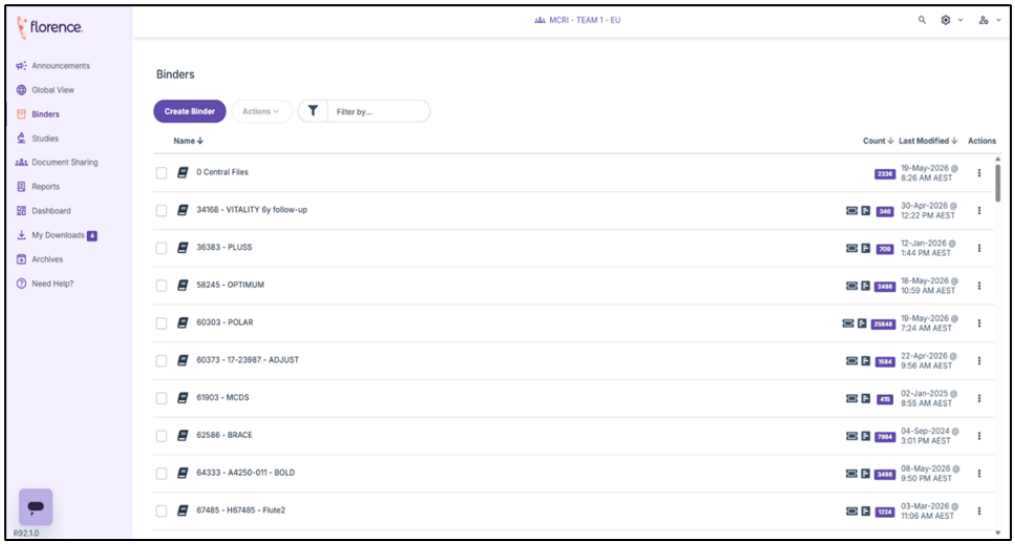
2. To activate your account, follow the steps in the invitation email and click 'Join Team'



5. Navigating Florence eBinders

When you sign in to Florence, you will be taken to the **Binder page**, which serves as the Florence homepage. This page displays all binders that you have permission to view.

As you navigate within a binder, **breadcrumbs** will appear at the top of the page. These show your current location within Florence and can be used as links to navigate back to previous levels.

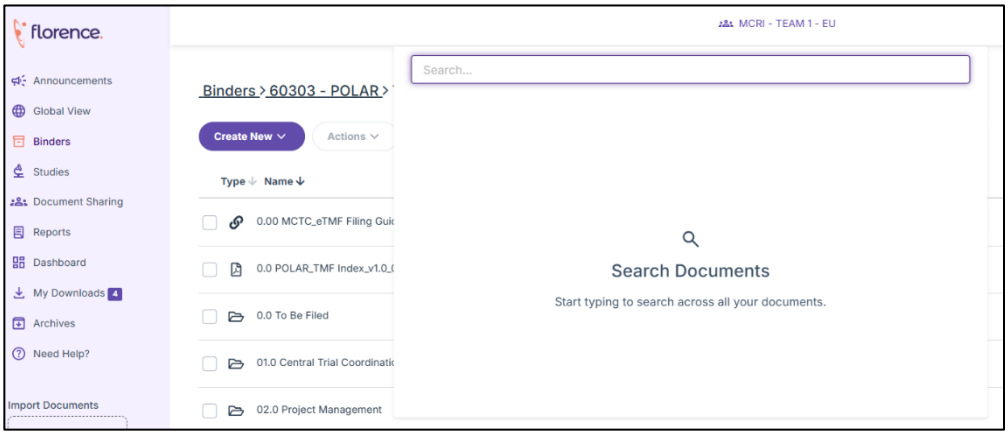


6. Florence eBinders Homepage

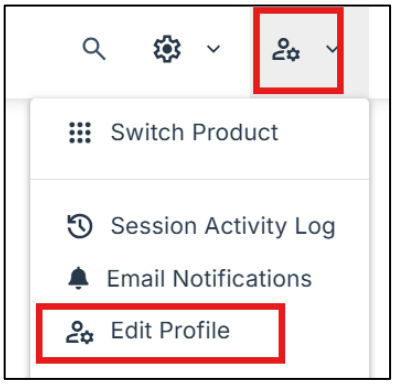
6.1. Search Function

The 'search' function allows users to search for document and/or placeholders that you have permission to view.

Search results show the item location, last modified date, and whether the item is a document, log or placeholder. Selecting a result will take you directly to that item.



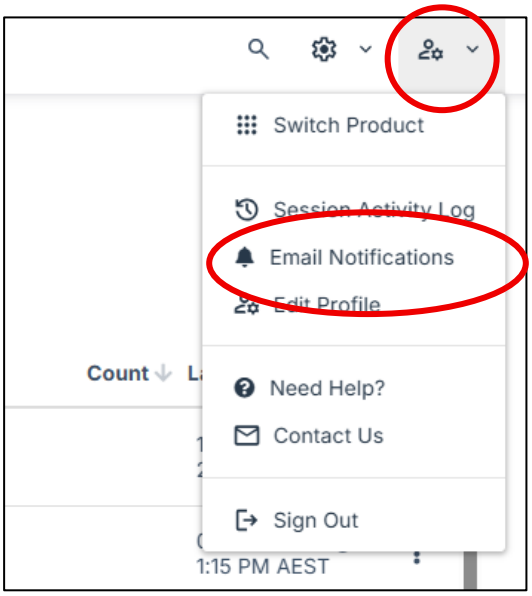
6.2.User Profile and Settings



Selecting the person icon opens the edit profile menu, where you can:

- Edit your personal details
- Update your password or signing PIN
- Manage privacy options selected during initial login

6.3.Email Notifications



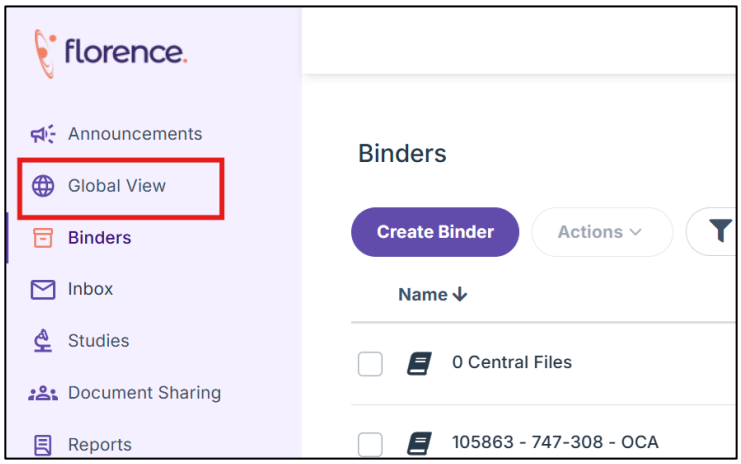
Email notifications help you stay on top of tasks in Florence eBinders™. Navigate to the person icon again and select **Email Notifications.**

- Select which notifications you'd like to sign up for.
- Once you turn on the notification, you can select how frequently you'd like to be notified by clicking on the option that appears and making your changes.
- Email notifications will then be received according to your preferences moving forward

6.4.Global View

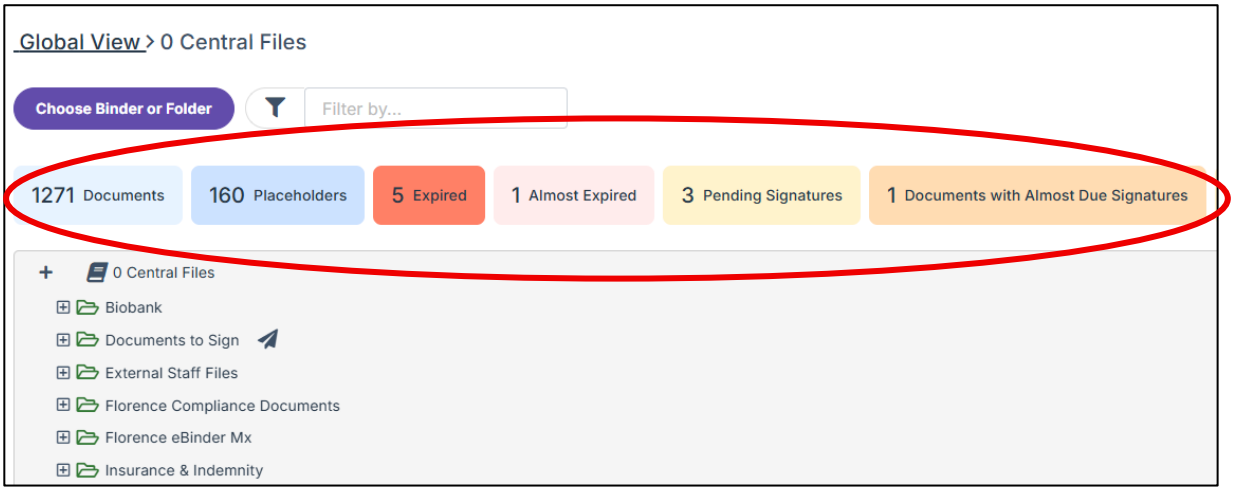
In Florence eBinders, the **Global View** is a high-level, centralised dashboard that provides a single source of truth for all your clinical trial documents, tasks, and tracking workflows.

Instead of clicking through individual physical binders, folders, or specific study files, Global View allows you to see the big picture across your clinical studies.



Navigate to **Global View** via the right-hand side panel and select the binder or folder you would like to view.

Here you'll see a bird's eye view of that binder or folder. Use the plus icon next to a folder to see what is contained within that location. Click it again to collapse that location. Key information will be shown at the top through clickable-coloured boxes.



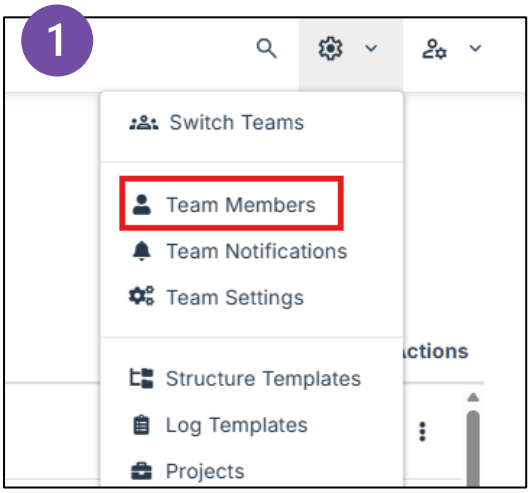
Once you click into a box, the display will show you only the locations that contain a document within that box's parameters. For example, click the Placeholder box to narrow the binder tree to only those folders that contain a placeholder.

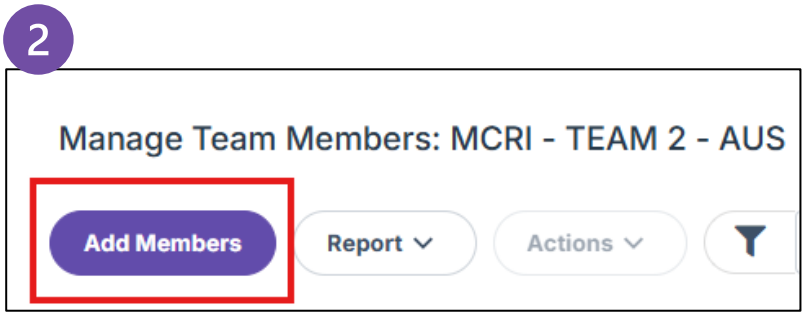
7. Access Management

7.1.Adding a new member to Florence

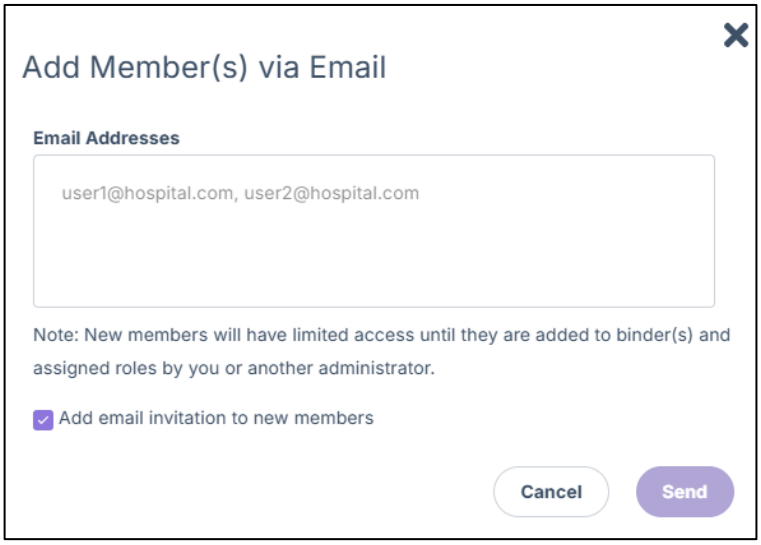
1. Ensure the new user has completed Florence Training and signed and returned an original hard copy of the wet ink signature page to the MCRI Florence Organisational Administrators at MCTC

2. To invite a new user, click **'Settings'**, select '**Team Members'** and select **'Add Members'**



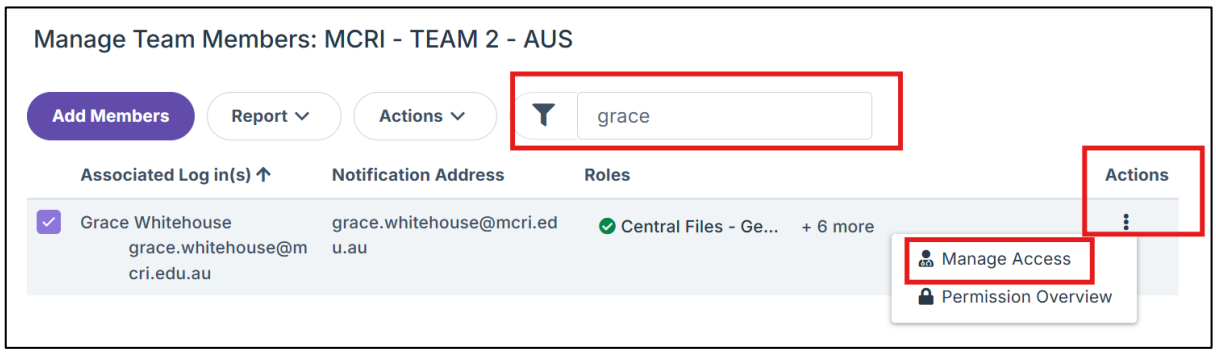


3. Enter the email address(es) of the user you would like to add to Florence. Select 'Add email invitation to new members' and select 'Send'.



7.2.Managing member access

1. To assign a role to a new user in Florence, locate the user via the **Team Members** function, then click the three dots under **'Actions'** and select **'Manage Access'.**



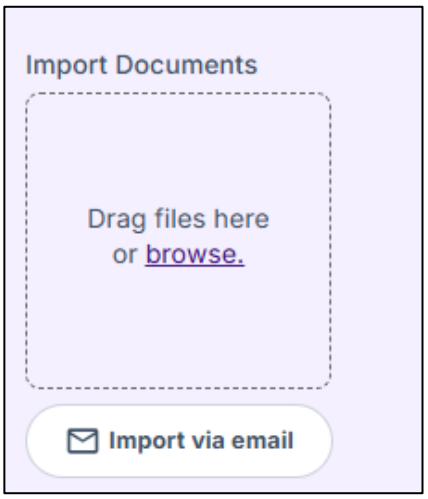
2. Begin typing the Trial name or Role name in the text box, all roles containing that phrase will appear.

3. Select the corresponding Role you wish to assign to the User. Ensure you turn the Role 'On'. Enter a scheduled start/end date if required for the Role. The Start date is immediate if nothing is entered. Click 'Save'.

   Please note: You can contact the MCRI Florence support team at florence@mcri.edu.au if you cannot find the role that you require.

8. Document Management

8.1. Uploading Documents



1. Navigate to the document where the folder should be located.
2. Locate the **"Import Documents"** box appearing on the left side of the page.
3. Drag and drop a document from your computer or taskbar into the dotted box or select **"Browse"** to find the document on your computer.
4. Documents uploaded will appear in alphabetical order in the folder location where it was imported.

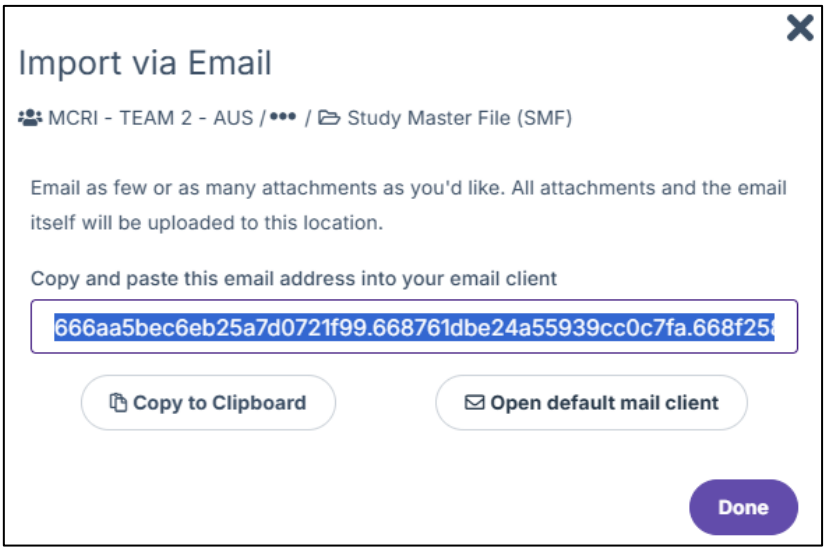
8.2. Importing correspondence via Email

Importing documents into Florence eBinders via email involves generating a unique target address and sending or forwarding your files directly to the specific folder or binder.

To import an email (either correspondence, or correspondence and email attachments) you need to 'send' it to the folder location you want the document to be.

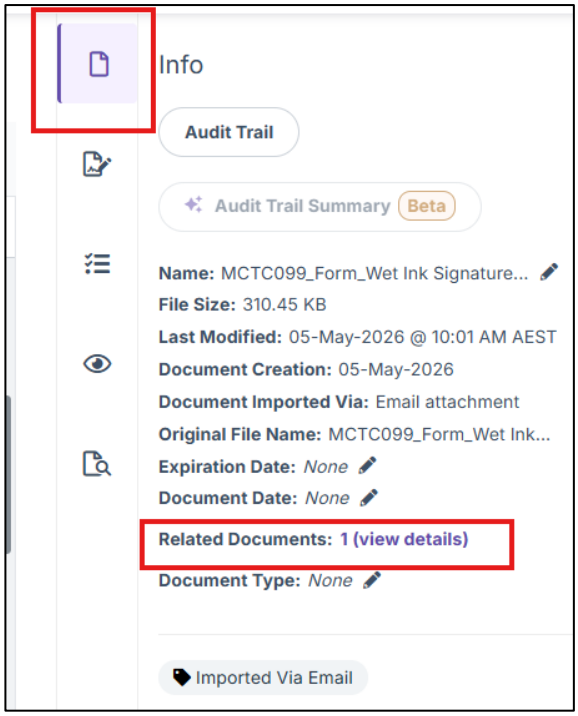
NOTE: emails themselves cannot be drag dropped into Florence, they will not import correctly.

1. **Navigate to the Binder:** Log into Florence eBinders and open the specific study binder or folder where you want to file the documents.
2. **Find the Email Address**: On the left-hand side of the page, click the Import via Email button.
3. **Copy the Address:** A pop-up box will appear containing a unique, system-generated email address. Click the Copy to Clipboard button
4. **Send/Forward the Email:** Paste this address into your email client. Attach the required documents, or forward an existing email thread.
5. **Rename the Subject (Optional):** The subject line of your email will become the name of the imported document or file in Florence



You can send, CC or forward an email. Anything imported by CCing, sending or forwarding will be automatically tagged as 'Imported via Email'.

Any emails sent with multiple attachments will be linked to each other, these can be found by selecting the paper icon in the top right corner which will display the document information and clicking 'Related Documents'.

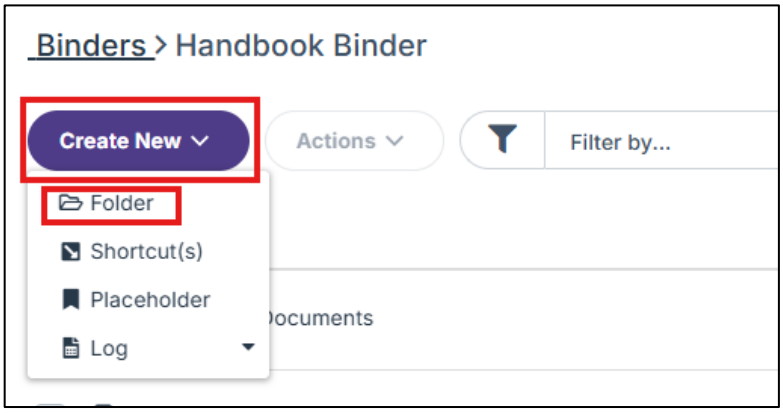


8.3.Filing multiple email threads on the same theme/subject

If you anticipate filing many emails on the same theme/subject, it is best to create a sub-folder for these emails in the corresponding folder.

New sub-folders can be created at any time following these steps:

1. Select **'Create New'** button and select **'Folder'.**

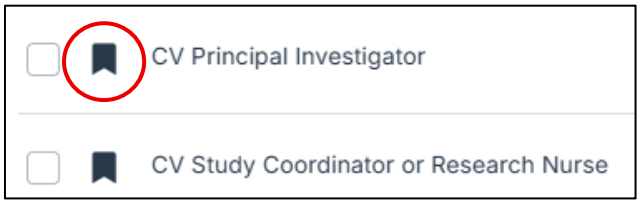


2. Assign an appropriate Folder name e.g. 'Patient questions', 'Log entry requests' etc.

3. All future emails pertaining to the specific theme/subject, can now be forwarded directly into the newly created folder.

8.4.Placeholders

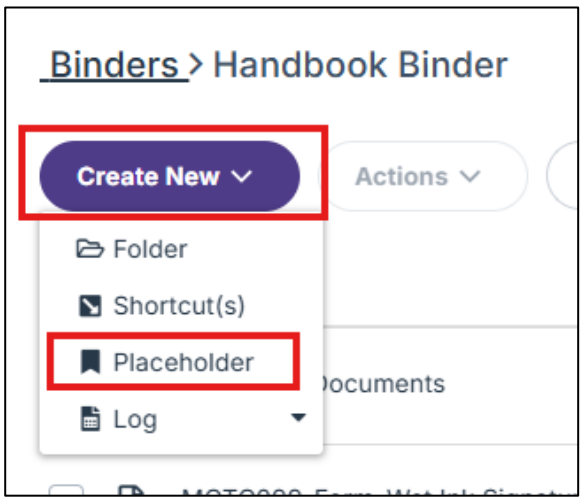
Placeholders are a useful way to track documents you know will be required during your study, even if they haven't been uploaded yet.



For example, if you are waiting for a team member's GCP certificate, you can create a placeholder titled "*[Name] GCP Certificate*" so it's clear that this document is expected. Placeholders appear as an upside-down flag icon:

1. To create a placeholder, navigate to where the placeholder should live and select **"Placeholder"** from the **"Create New"** dropdown toward the top left of the page.

2. Give your placeholder a name and click "Create".



8.5.Shortcuts

A shortcut is a reference to a document that allows the same file to appear in multiple locations, while being maintained in one central location. If the original document is updated, all shortcuts automatically reflect the update. This makes it easier to organise regulatory files that belong to more than one category or timeline without cluttering your system with duplicate files.

Example: When a shortcut might be useful

For multicentre studies, a single ethics approval (e.g. RCH ethics approval) may apply to multiple sites.

Instead of uploading the same ethics approval letter into each Site Investigator File (SIF):

- Store the ethics approval documents in the **Trial Master File (TMF)** as the original
- Create **shortcuts** to that document in each relevant **Site Investigator File (SIF)**

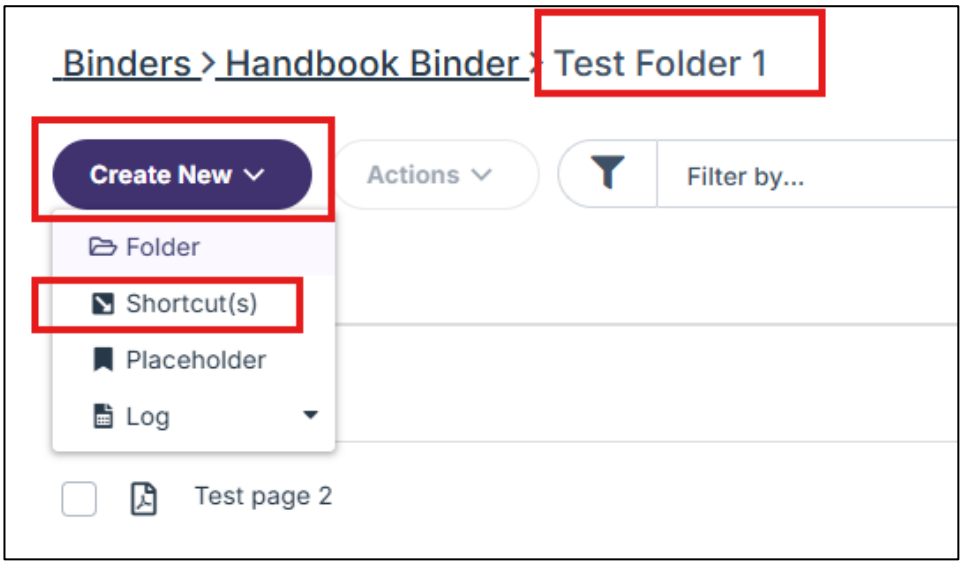
This ensures:

- The document is maintained in one central location (TMF)
- Any updates made to the ethics document are automatically reflected across all sites

There are **two ways** a shortcut can be created in Florence:

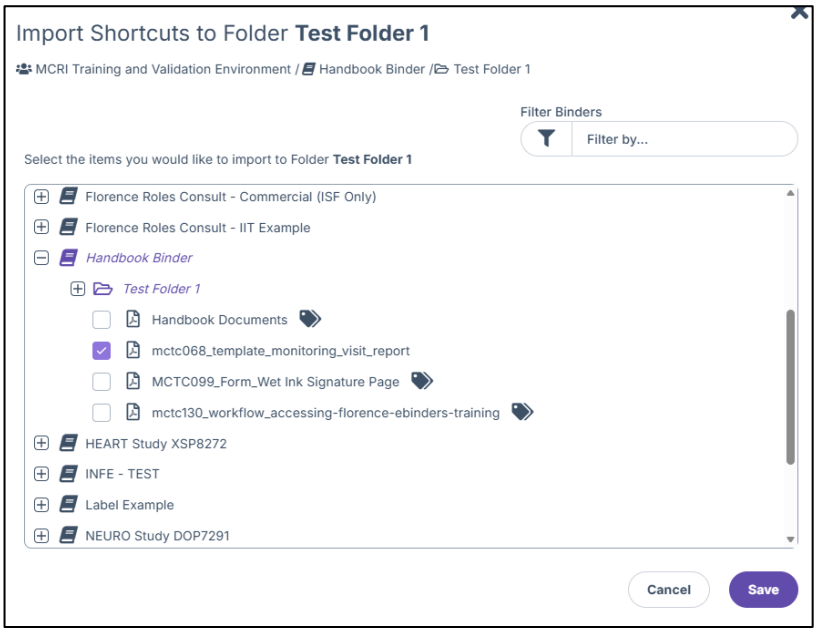
<u>Option 1: Import a short cut to the desired location</u>

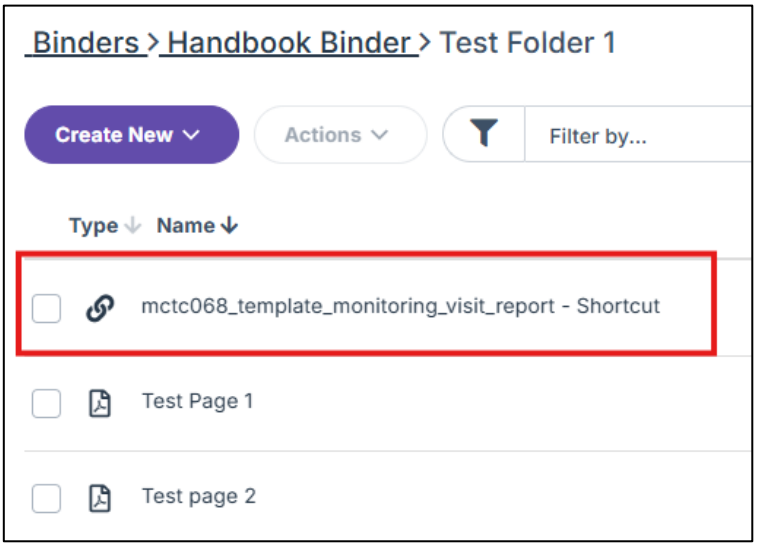
1. Navigate to the folder where you want the shortcut to appear
2. Select **'Create New'**
3. Choose **'Shortcut(s)'**



4. Select the document you would like to by navigating through the filing tree and locating the document you would like to shortcut

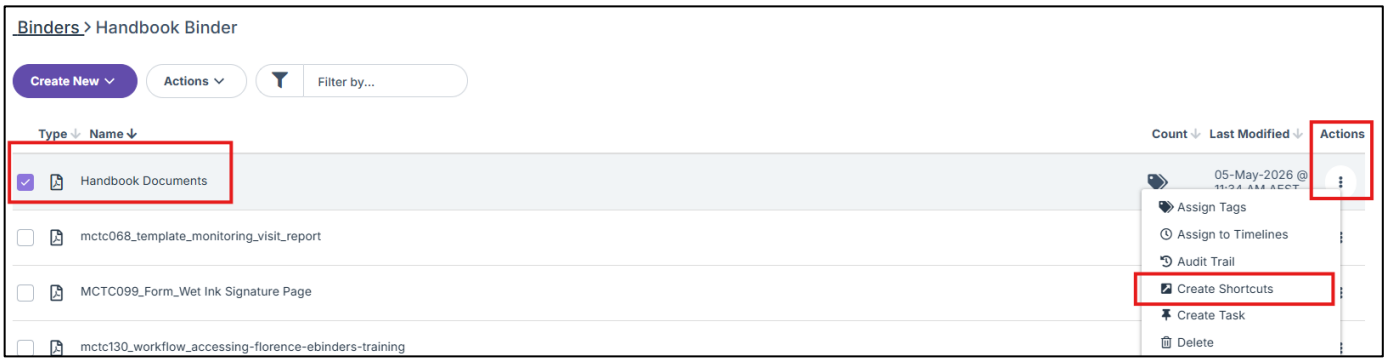
5. Select 'Save' and the original document will appear as a shortcut in the desired folder.





Option 2: Create a shortcut from the document

1. Navigate to the original document you wish to create a shortcut of
2. Click the three dots appearing next to the selected document
3. Select **'Create Shortcuts'**
4. Select the location where you would like to shortcut the document, by navigating through the filing tree Select 'Save'

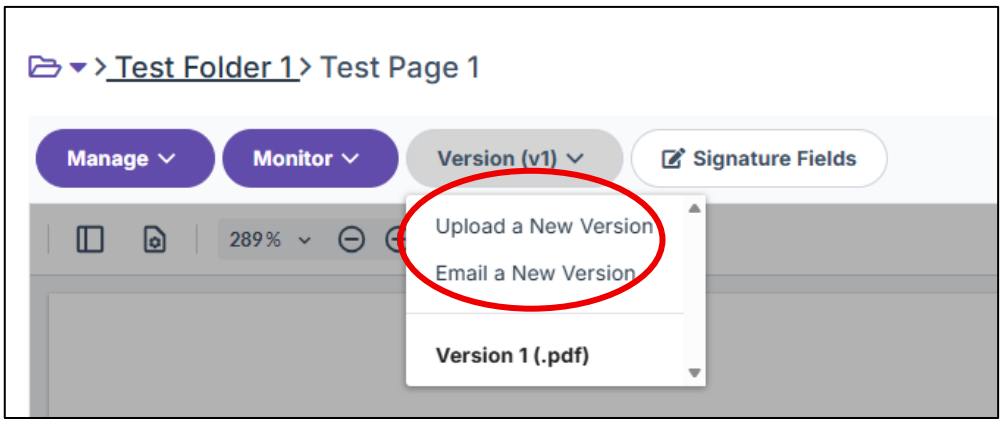


8.6 Version Control

Version control in Florence eBinders refer to the automated tracking of changes made to essential documents. It replaces manual draft numbering and paper versions by systematically logging every update while keeping older, superseded copies securely accessible. To upload a new version, follow these steps:

1. Navigate to document you wish to update and open the document

2. Select **"Version",** then **"Upload a New Version"**



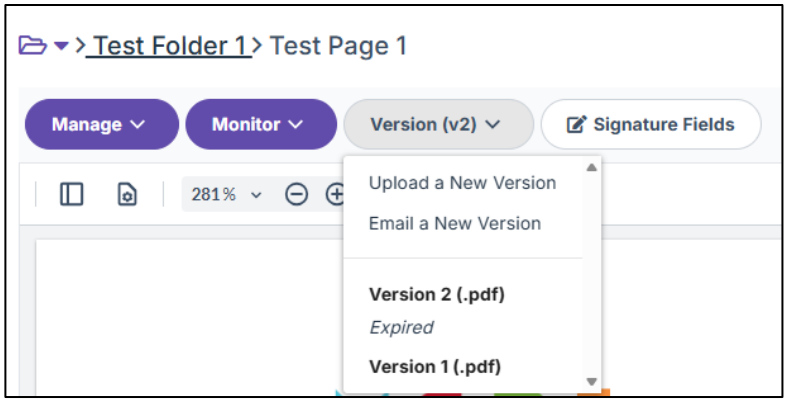
3. Select method of upload:
   - **'Upload a New Version',** or
   - '**Email a New Version via'** the email import process.

4. Provide your reason for uploading a new version, such as "Document Updated" or "Previous version expired" and change the document name if needed.

5. Clear and/or update any expiration dates associated with the document. Consider renaming any shortcuts that may relate to this document.

6. Click **'Save'.** A new electronic version of the document will be stacked on top of the previous version/s.

7. To access previous versions of any stacked documents, select the **'Version'** tab and navigate to the superseded version required.

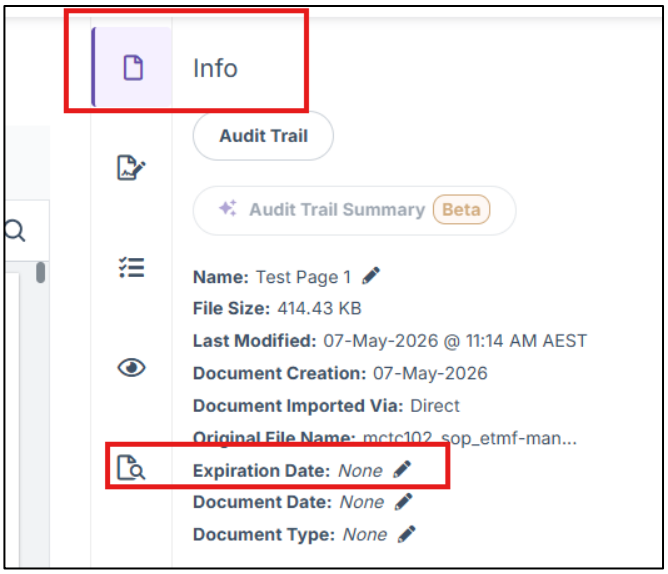


8.7 Expiration Dates

Expiration dates are a useful way to manage documents directly within Florence eBinders. Expiration dates refer to the time limits applied to specific research documents, staff credentials, or participant tasks. They help research sites maintain regulatory compliance (such as FDA 21 CFR Part 11 and HIPAA) by preventing the use of outdated materials.

For documents that require regular updates, such as CVs that expire every two years, setting an expiration date helps ensure they are reviewed and replaced on time.

1. Navigate to the document you wish to add an expiration date to.
2. Click on the **'Info'** panel
3. Select Expiration Date
4. Set the date
5. Click **"Save"**

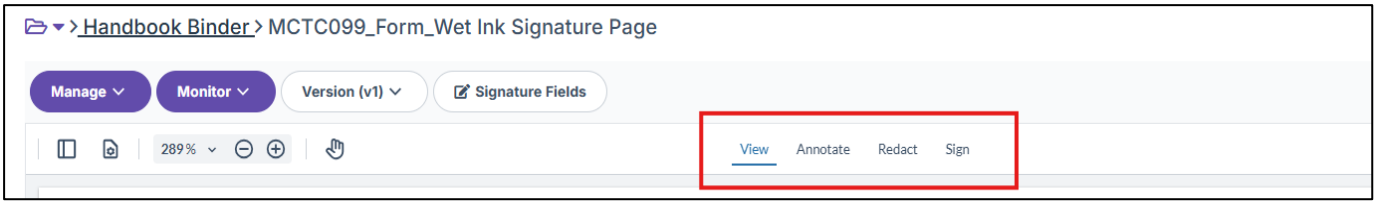


When an expiration date is approaching, an email notification is sent to users where their Florence notification settings are enabled to receive this notification. Expired documents appear in orange or red within the Global View function of Florence.

9. Annotations, Redactions and Signing

Documents can be edited in Florence eBinders using a range of in-system tools.

Click into the document, the bar at the top of the document displays four options **'View', 'Annotate', 'Redact'** and **'Sign'**.



Using these editing tools will physically change the document itself and therefore, will create a new electronic version of the document inside Florence eBinders.

9.6 Annotate Documents

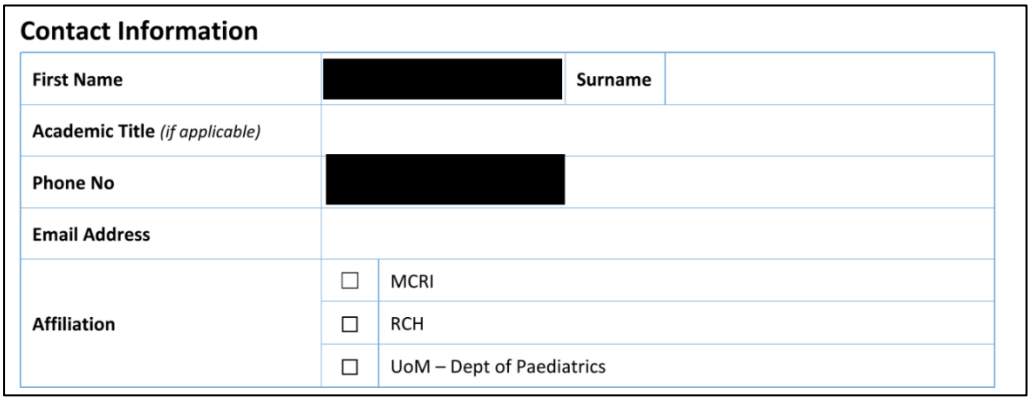
Annotating functions include:

- Highlight text
- Strikeout text
- Adding free-hand text

- Adding text to a document
- Eraser function
- Adding a date and timestamp to a document

9.7 Redacting Document

Redacting Protected Health Information (PHI) within Florence eBinders is built directly into the platform to allow Users to securely process source documents before remote monitoring by sponsors or CROs. If a document is uploaded into Florence eBinders and contains PHI, you have the option of redacting the document so that that only certain users are able to view the protected information. Only users with "View PHI" permission will be able to view previous, unredacted versions of the document.



Contact Information

First Name	[redacted]	**Surname**	
Academic Title *(if applicable)*			
Phone No	[redacted]		
Email Address			
Affiliation	☐	MCRI	
	☐	RCH	
	☐	UoM – Dept of Paediatrics	

9.8 Signing Documents in Florence

Florence offers three methods for requesting or applying a signature to a document:

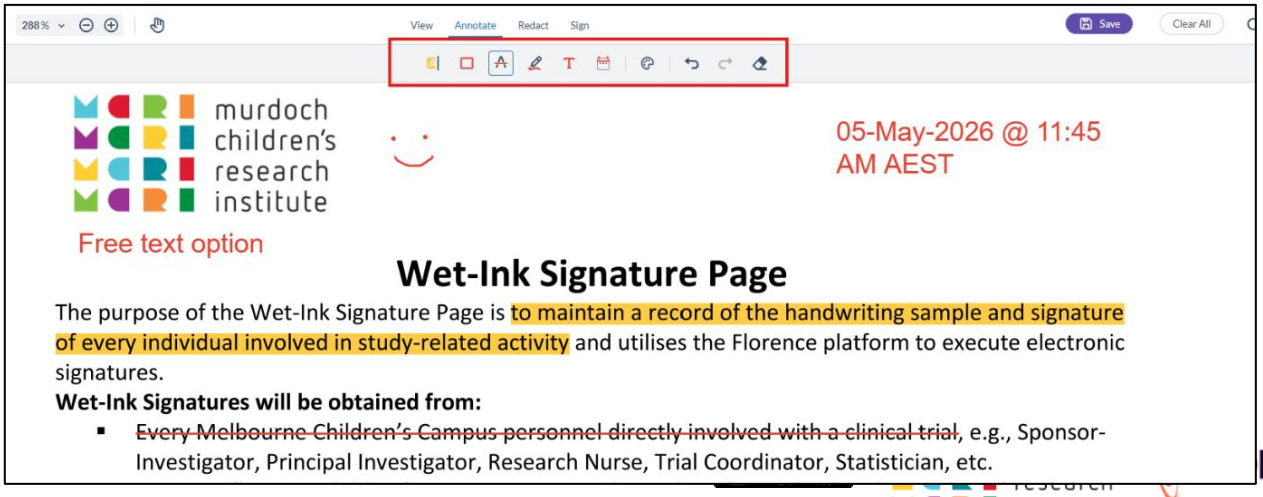
- Addendum signatures
- Stamp signatures, and
- Form or eLog signatures.

Addendum Signature

Use this option when the signature does not need to be visible on the document.

To request an addendum signature:

1. Select 'Manage' → 'Request Signature'



2. Select the Document
3. Set Signature Type to Addendum
4. Enter the Signature Reason
5. Select the 'Signers' tab
6. Search the signer's name
7. (Optional):
    - Set a Sign by Date
    - Alert to be notified once signed
    - Email the signer (recommended)
    - Add comments for the signer if required
8. Click Save

Stamp Signature

Use this option when a visible signature is required on non-form documents (e.g. CVs).

Follow the same steps as per the addendum signature but select 'stamp' as the signature type.

Form or eLog Signature

This is a visible signature on the document or within an eLog, where the specific location of a signature is predetermined with a yellow signature box.

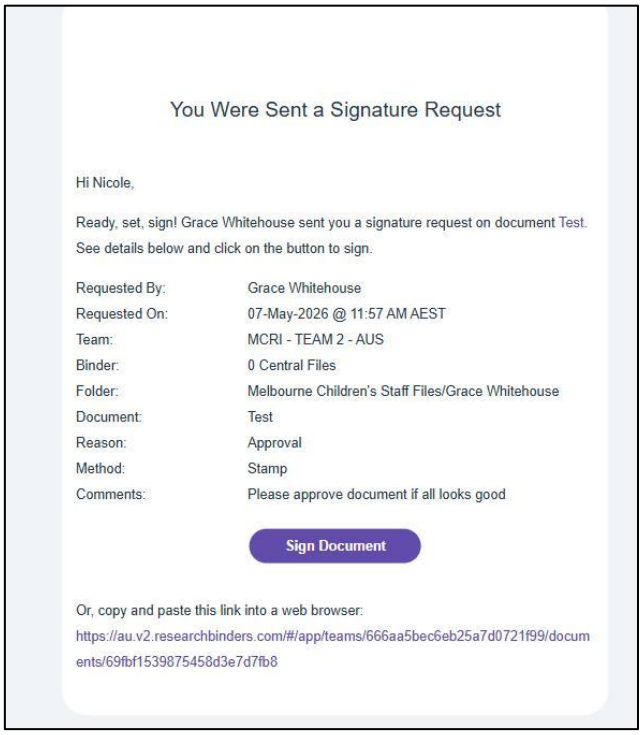
1. Open the document in Adobe Acrobat Pro and use Prepare a Form to add fillable fields and a yellow signature box.
2. Review and save the form, ensuring all required fields work correctly and the signature box remains yellow (do not flatten the PDF).
3. Upload the completed fillable PDF into Florence, where it can be used for completion and eSignature.
4. Select **Manage**, then select **'Request Signature'**
5. Select **Signers, signature type, reason for signature**, and enter a **"Sign By Date"** if desired. Check "Alert" to be notified upon signing and "Email" to send email notification to requested signer (Recommended).
6. Add clear instructions in comments and click "SAVE"

* When a user signs a Form, they MUST finalise the form upon completion of signature. This step is NOT required if users are signing an eLog.

Florence Digital Signatures are compliant with regulatory requirements, including ICH-GCP E6(R3) and FDA **21 CFR Part 11**, by using a secure authentication process. When a signature is requested, the signer must confirm their action and authenticate

using their Florence password or signing PIN, providing an additional layer of verification.

- If email notifications are enabled, users will receive an email when a signature is requested.
- Pending signatures are also highlighted within Florence via a blue notification bar at the top of the screen.
- Users can access their signature queue from this banner or by navigating to the **Global View** or **Report** section, where all signatures awaiting completion are listed.



To learn more about eSignatures and Digital Signatures please view the Appendix B eSignatures and Digital Signatures Fact Sheet.

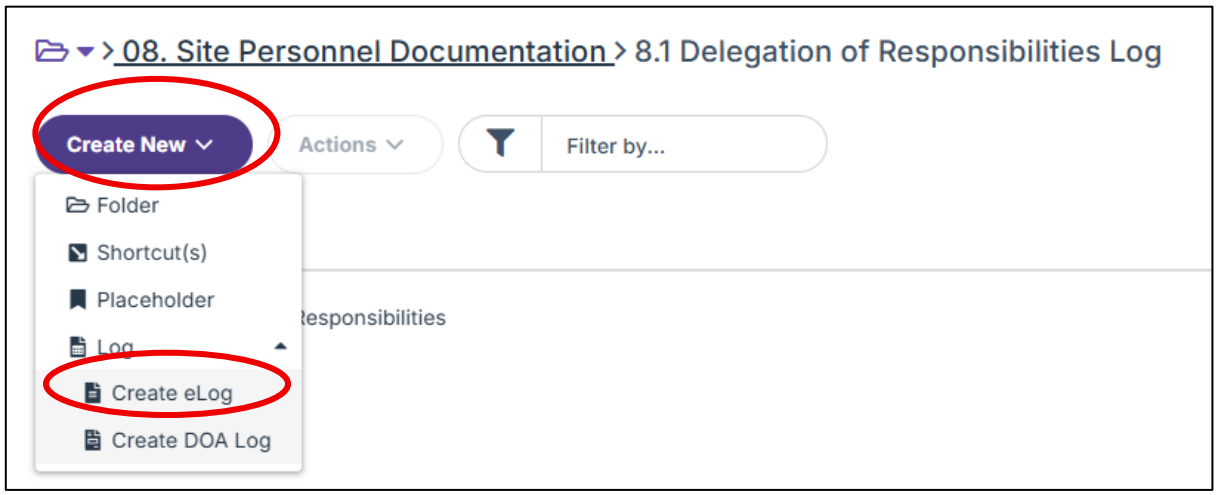
10. eLogs

Florence eLogs are digital versions of traditional paper logs used to track and standardise research activities. They replace messy, paper-based tracking with compliant, template-driven, and remote-accessible digital forms.

10.1 Creating eLogs

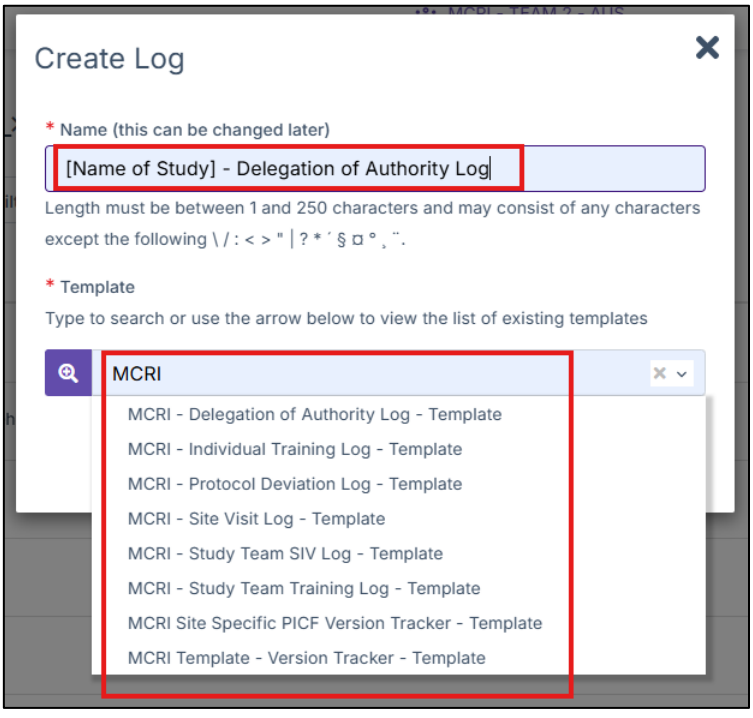
1. To create an eLog, first navigate to the folder level where you want the log to be stored. eLogs should always be created at the appropriate folder level so they are easy to locate and access by the study team.
2. Select **Create New**, then choose "**Create eLog"**.

Note: When creating Signature and Delegation Logs, it is important to select the "Create eLog" option rather than Create DOA Log, as eLogs are easier to update, and better suited for ongoing data entry.



3. Give your eLog a title/name. The recommended naming convention is: *Study name – type of log (for example, ABC123 – Delegation Log).*

4. Select a template eLog from the options available. It is strongly recommended that you use one of the **pre-existing MCRI eLog Templates** (refer to Appendix C for a list of available eLog templates). MCRI eLog Templates commence with "MCRI" as the leading word. Simply type 'MCRI' and the suite of MCRI eLog templates will appear. These templates are designed to meet regulatory and organisational requirements and promote consistency across studies.



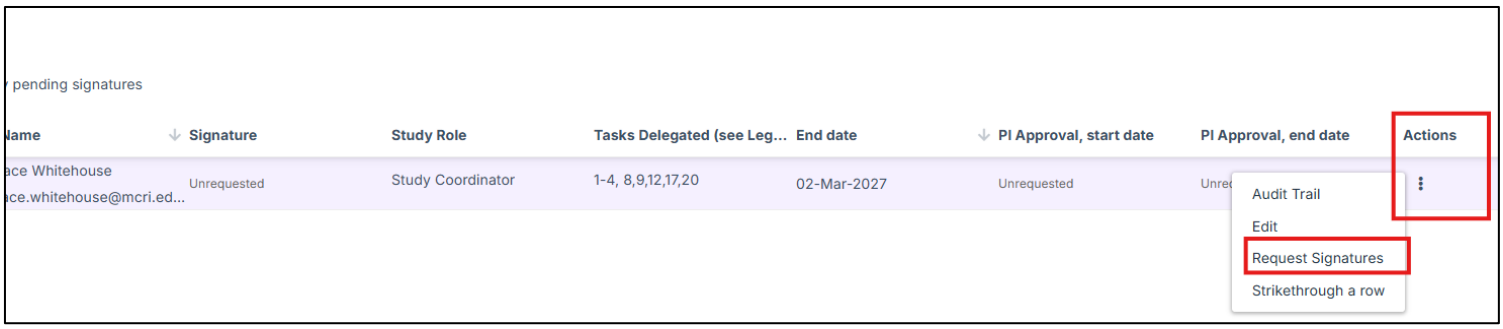
5. Once the eLog has been created, you will be prompted to edit the log details. This step ensures the template is tailored to your specific study. After eLog details are entered, a legend and log information section will appear, providing guidance on the purpose of the log and how it should be used.

10.2 Adding an entry to an eLog

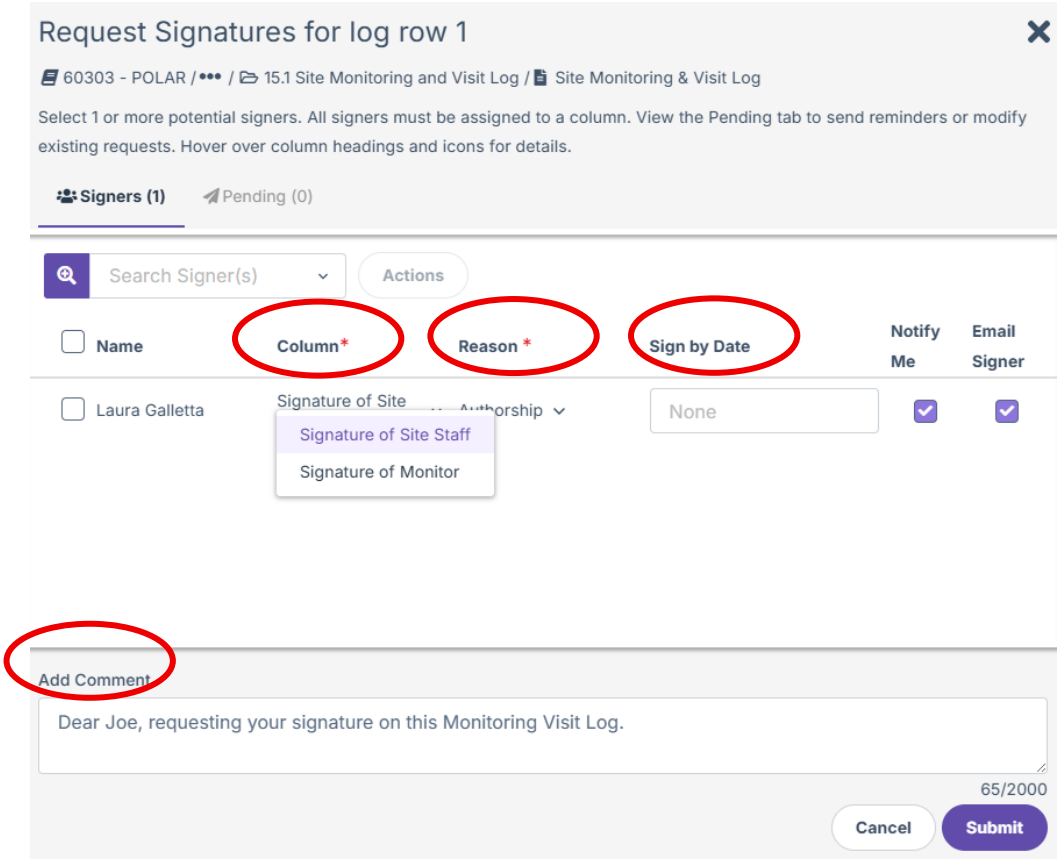
1. To populate an eLog, simply scroll down and hit 'Add Entry'
2. Complete data entry in all required fields
3. Select **'Save'** to save you log entry

10.3 Requesting Signatures on an eLog

1. eLog entries must be complete and saved before you can request a signature.
2. To request a signature, click the three **'Action'** dots appearing at the end of the log entry and select **'Request Signatures'**

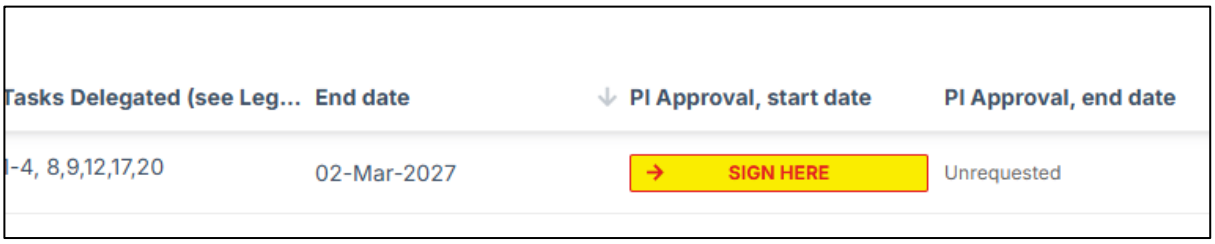


3. Select the **"Name"** of the signer, "**Column"** in which the signer must sign, **"Reason"** for the signature, and **"Sign by Date"** (if applicable),
4. Add a comment/instruction for the signer
5. Select **"Submit"**



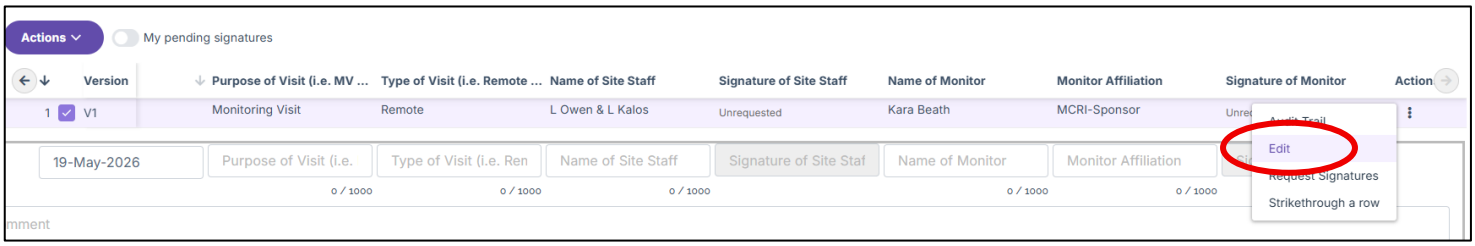
6. Users with pending signature requests on an eLog will need to scroll to the bottom of the page to locate their signature request block. The signature request box will be visible in yellow.

7. Click on the yellow button to sign the eLog. Signers will be prompted to enter their signing PIN. This will sign the log entry and complete the signature process.



10.4 Amending a Log Entry

1. To amend a log entry, navigate to the log entry (row) in which you wish to amend and scroll across until the **'Actions'** column appears.
2. Select the three dots appearing next to the log entry and select **'Edit'.**



3. All log/row details (except for any signature) can be edited here. Make necessary edits as required.
4. Once editing is complete, select "Save".
5. All edits to eLogs will require documentation of the reason for the change. You will prompted to provide a reason for the edit (ensure this is detailed).
6. Select 'Save'.

Note: After an edit is made, you will need to re-request the signature.

If you experience any issues with eLog management, please contact **Florence@mcri.edu.au** for support. Alternatively, refer to **Appendix D** which provides guidance on correcting errors and managing incorrectly submitted logs, to determine whether your issue can be resolved using these methods.

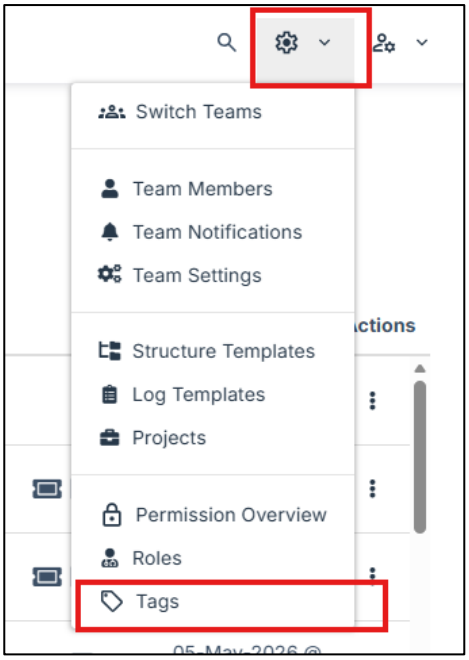
11 Reporting Tools

11.1 Tags

Tags are customisable, keyword-based identifiers applied directly to individual documents or placeholders. They serve as an organisational tool to help research teams categorise, filter, and track specific types of files. Tags are a useful tool in Florence as they are a way of linking items from all over the team into one location.

For example; if you want to keep track of all documents that pertain to Ethics and Governance (HREC) submissions, you have the option of tagging each document with the “Ethics Submission” tag. In turn, this enables reporting of all HREC submission documents within your Binder.

1. To get started, review the list of existing tags under the “Settings” dropdown in the top right corner of Florence in the Tags option.
2. Create a new tag if it does not appear in the list of existing Tags by selecting ‘Create Tag’.
3. Assign your Tag by navigating to your document, selecting the three ‘Action’ dots and click ‘Assign Tags’



11.2 Tasks

Tasks are actionable project management items that act as reminders or assignments used to keep clinical trials moving. They act as trackable, built-in "to-dos" designed to eliminate redundant workflows and keep study documentation organised.

Tasks are a useful tool that help you manage actions required on a document or placeholder. From there, you can track progress and report on pending tasks. To add a Task to an existing document, follow these steps:

1. Navigate to the document or placeholder

2. Select **‘Manage’** and then **‘Create Task’**

3. Give the task a ‘Task Title’. You can add more details in the message box to help the assignee understand what’s expected.

4. Determine and select your email notification preferences for this task. You can also decide if you want to be notified when the task is set to “closed”.

5. Select the user or users that are responsible for this task.

6. Click “Save”

Users who complete as assigned Task, the status of the Task changes to “Complete”. Completed tasks are then assigned back to the user who first created the Task, allowing you to review the completed work before marking the Task stage as “Closed”.

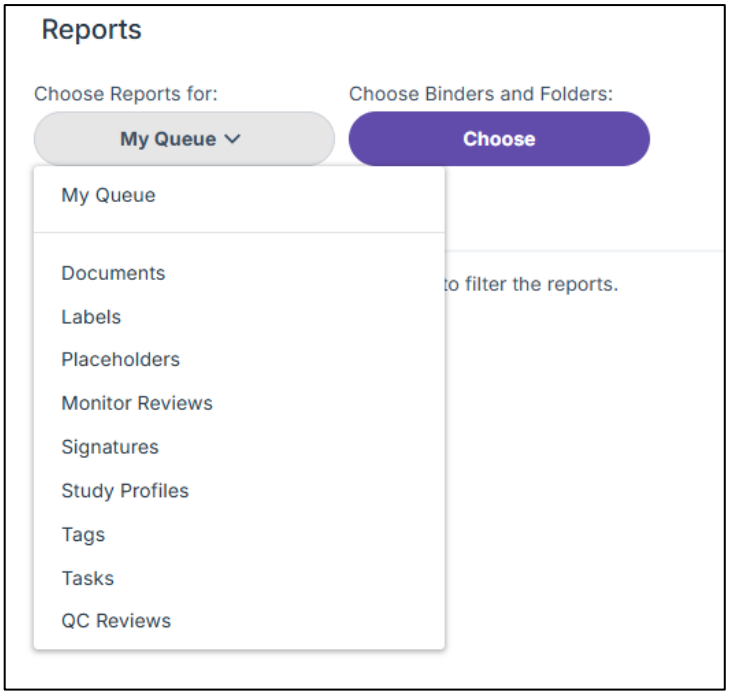
If email notifications are enabled, users will receive an email when a there has been a status change to a Task or a task has been updated to completed.

11.3 Reports

In Florence eBinders, reports are automated analytics tools and dashboards that provide real-time visibility into your clinical trial operations, regulatory compliance, and study binder completeness. They eliminate the need for manual tracking by offering a bird's-eye view of your site's document management.

Florence eBinders can generate the following types of reports to assist with document management:

- My Queue
- Documents
- Labels
- Placeholders
- Monitor reviews
- Signatures
- Study Profiles
- Tags
- Tasks
- QC Reviews



Reports can only be generated on Binders you have access to.

Example Reports to consider include:

- **Document Health & Completeness:** Provides metrics on ISF (Investigator Site File) completeness, tracking existing vs. missing documents.
- **Action Items & Approvals:** Summarises pending Tasks, documents requiring electronic signatures, and outstanding Monitor/QC reviews.
- **Deadlines & Expirations:** Highlights documents or team credentials (like medical licenses or CVs) that are approaching expiration or require immediate renewal.
- **User Activity & Audit Logs:** Tracks system usage and document access. These are frequently pulled to verify that external monitors or team members are actively reviewing files and to manage account provisioning.
- **Study Milestones:** Custom dashboards that allow users to aggregate document attributes and track operational goals across multiple binders or sites.

If you require any assistance with Florence Reports, please contact the MCRI Florence Organisational Administrators at: Florence@mcri.edu.au

12 Additional Florence Support

For assistance with accessing team-specific training, or enquiries regarding access and permissions, please contact the MCRI Florence Organisational Administrators at: **florence@mcri.edu.au**.

For support relating to the Florence system, please use one of the following resources:

- Florence Help Desk
- Customer Hub

DOCUMENT END

Appendix A: Florence Training Modules (via FloPro University)

Training Link: https://university.florencehc.com/page/courses-for-organizations-that-purchased-florence

Role in Study	Name of Florence Training Module to be Completed	Applicability	Listed Training Modules	Training Link
Participating Trial Sites Roles				
Site Principal Investigator (PI)	PI Training for eTMF and eISF (4 courses)	This is recommended for Principal Investigators simply needing to know how to register, find and view documents, and sign them. Both MCRI/RCH and non-MCRI users.	- Registration & Navigation - Documents & Signatures - eLogs & Forms - Finish	https://university.florencehc.com/path/pi-training-for-etmf-and-eisf
Study Coordinator | Research Nurse	eISF Training for Study Staff (11 courses)	This is recommended for site staff members who are using Florence eBinders at their institution. Both MCRI/RCH and non-MCRI users.	- Registration & Navigation - Documents & Signatures - Shortcuts, Due Dates & Placeholders - eLogs & Forms - Structure - Access Management - Admin Tasks - Reporting Tools (Tags, Labels, tasks) - MRM & Study Profile Management - ePrinter - Quiz	https://university.florencehc.com/path/eisf-training-for-study-staff
Clinical Trial Assistant/s	eISF Training for Study Staff (11 courses) OR Florence Basics for Remote Site Access (7 courses)	This is recommended for site staff members who are using Florence eBinders at their institution. Both MCRI/RCH and non-MCRI users.	As above. - Registration & Navigation - Documents & Signatures - Due Dates & Placeholders - eLogs & Forms	https://university.florencehc.com/path/eisf-training-for-study-staff OR https://university.florencehc.com/path/florence-basics-for-remote-site-access

Role in Study	Name of Florence Training Module to be Completed	Applicability	Listed Training Modules	Training Link
			- Reporting Tools (Tags, Labels, tasks) - Monitor Review Module - Quiz	
Pharmacist/s	Florence Basics for Remote Site Access (7 courses)	This is recommended for site staff members who are being given access to a Binder. Both MCRI/RCH and non-MCRI users.	- Registration & Navigation - Documents & Signatures - Due Dates & Placeholders - eLogs & Forms - Reporting Tools (Tags, Labels, tasks) - Monitor Review Module - Quiz	https://university.florencehc.com/path/florence-basics-for-remote-site-access
Supporting Department Role/s	Florence Basics for Remote Site Access (7 courses)	This is recommended for site staff members who are being given access to a Binder.	- Registration & Navigation - Documents & Signatures - Due Dates & Placeholders - eLogs & Forms - Reporting Tools (Tags, Labels, tasks) - Monitor Review Module - Quiz	https://university.florencehc.com/path/florence-basics-for-remote-site-access
Auditors	View-Only Training for Ancillary Roles (3 courses)	This is recommended for users with ancillary roles or anyone needing to register and view documents and audit trails.	- Registration & Navigation - Documents & Audit Trail - Finish	https://university.florencehc.com/path/view-only-training-for-ancillary-roles

Role in Study	Name of Florence Training Module to be Completed	Applicability	Listed Training Modules	Training Link
Ancillary Roles	View-Only Training for Ancillary Roles (3 courses)	. This is recommended for users with ancillary roles or anyone needing to register and view documents and audit trails.	- Registration & Navigation - Documents & Audit Trail - Finish	https://university.florencehc.com/path/view-only-training-for-ancillary-roles
Sponsor | Trial Coordinating Centre Roles				
MCRI Sponsor Investigator	PI Training for eTMF and eISF (4 courses)	This is recommended for Principal Investigators simply needing to know how to register, find and view documents, and sign them.	- Registration & Navigation - Documents & Signatures - eLogs & Forms - Finish	https://university.florencehc.com/path/pi-training-for-etmf-and-eisf
Clinical Trial Managers | Study Coordinators (Binder Administrators)	eTMF Training for Internal Users (11 courses)	This is recommended for day-to-day user (Sponsor-level).	- Registration & Navigation - Documents & Signatures - Shortcuts, Due Dates & Placeholders - eLogs & Forms - Structure - Access Management - Admin Tasks (Team set-up etc) - Reporting Tools (Tags, Labels, Tasks) - MRM & Study Profile Management - ePrinter - Quiz	https://university.florencehc.com/path/etmf-training-for-internal-users
	Team Admin Training for eTMF and eISF (8 Courses)	This is recommended for users responsible for user and role management within a Binder.	- Registration & Navigation - Documents & Signatures - eLogs & Forms - Access Management - Admin Tasks (Team set-up etc) - Reporting Tools (Tags, Tasks) - MRM & Study Profile Management - Quiz	https://university.florencehc.com/path/team-admin-training-for-etmf-and-eisf

Role in Study	Name of Florence Training Module to be Completed	Applicability	Listed Training Modules	Training Link
Clinical Trial Assistant, Data Managers, Statisticians etc	Florence Basics for Remote Site Access (7 courses)	This is recommended for site staff members who are being given access to a Binder.	- Registration & Navigation - Documents & Signatures - Due Dates & Placeholders - eLogs & Forms - Reporting Tools (Tags, Tasks) - Monitor Review Module - Quiz	https://university.florencehc.com/path/florence-basics-for-remote-site-access
Monitors	eTMF Training for Monitors (5 courses)	This Learning Path is recommended for eTMF Monitors. It includes an overview of basic eTMF functionality.	- Registration & Navigation - Documents & Signatures - eLogs - Reporting Tools - Quiz	eTMF Training for Monitors
	eISF Training for Monitors (6 courses)	This Learning Path is recommended for users conducting monitoring activities inside a site-owned eISF. It includes day-to-day basics specific to monitors, and the Monitor Review Module.	- Registration & Navigation - Documents & Signatures - eLogs - Reporting Tools (Tags, Labels, tasks) - Monitor Review Module & Remote Monitoring - Quiz	https://university.florencehc.com/path/eisf-training-for-monitors
Auditors	View-Only Training for Ancillary Roles (3 courses)	This is recommended for users with ancillary roles or anyone needing to register and view documents and audit trails.	- Registration & Navigation - Documents & Audit Trail - Quiz	https://university.florencehc.com/path/view-only-training-for-ancillary-roles
All Roles Requiring Remote Access	Florence Basics for Remote Site Access (7 courses)	This is recommended for site staff members who are being given access to a team.	- Registration & Navigation - Documents & Signatures - Due Dates & Placeholders - eLogs & Forms - Reporting Tools (Tags, Tasks) - Monitor Review Module	https://university.florencehc.com/path/florence-basics-for-remote-site-access

Role in Study	Name of Florence Training Module to be Completed	Applicability	Listed Training Modules	Training Link
			- Quiz	
MCRI Florence System Administrators				
MCRI Florence Organisational Administrators	eTMF Training for Implementation Team (11 courses)	This is recommended for users responsible for both admin tasks and day-to-day tasks and that may also be utilizing the Monitor Review Module feature. This is Florence's most comprehensive training. MCRI Florence Organisational Administrators only.	- Registration & Navigation - Structure - Access Management - Documents & Signatures - Shortcuts, Due Dates & Placeholders - MRM & Study Profile Management - Admin Tasks - eLogs & Forms - Reporting Tools (Tags, Labels, tasks) - ePrinter - Quiz	https://university.florencehc.com/path/etmf-training-for-implementation-team
	Team Admin Training for eTMF and eISF (8 courses)	This is recommended for admin users responsible for user and role management. MCRI Florence Organisational Administrators only.	- Registration & Navigation - Documents & Signatures - eLogs & Forms - Access Management - Admin Tasks - Reporting Tools (Tags, Tasks) - MRM & Study Profile Management - Quiz	https://university.florencehc.com/path/team-admin-training-for-etmf-and-eisf

Appendix B: eSignatures and Digital Signatures Fact Sheet

What is the difference between eSignature and Digital signatures?

A digital signature and eSignature are not the same. Digital signatures are a secure type of electronic signing.

eSignatures:

Equivalent of a handwritten signature online.

A signature that may be scanned, copied, or pasted.

Digital Signatures:

The most secure and valid version of an eSignature.

A type of signature that validates the signature is being done by the person signing e.g. includes a two-step authentication process/pre-set pin is required.

Time and date stamped with contact information link to signature and/or system account for systems where the system owner knows the identity of all signatories.

Other key requirements for digital signatures:

Digital signatures do not require a handwritten signature, or a photo uploaded when used electronically. Digital signatures do have to have to be able to authenticate the signer's identity, uniquely link the signatory, link the signature to the document and ensure that any changes following a signature are detectable (Refer to EFGCP).

There are a few different systems/software's available at the MCRI for executing eSignatures and digital signatures.

These platforms are:

- Florence HC
- Adobe Sign (supported by MCRI IT)
- DocuSign
- REDCap
- OpenClinica EDC

Digital Signatures in Clinical Trials?

Digital signatures are required by clinical trial regulations **GCP ICH section 5.5.3**, **FDA 21 CFR Part 11** and **Regulation EU No 536/2014**.

For clinical trials, digital signatures must be used for all trial-related documents signed electronically.

Digital signatures must authenticate the signatory, ensure non-repudiation, ensure an unbreakable link between signature and the document signed as well as provide timestamps.

To meet these requirements, completed copies of signed documents must be made available to signees and the software used to sign must invalidate any signatures on documents edited or altered after the time of signing.

When to use eSignatures?

eSignatures are appropriate for non-trial documents such as administrative documents e.g., timesheets, and legal documents such as contracts and indemnities. They cannot be used for other trial documents such as Participant Information & Consent Forms (PICFs) or Delegation and Training logs.

System/ Software	Signature Type Available	Compliance with FDA 21 CFR 11
Florence eBinders	Digital signature (with two step-authentication) can be stamped or provided as signature page to any document type e.g. logs, protocols etc.	System is compliant.
Adobe Sign	Digital signatures available with a paid account/corporate license to Adobe Sign ($500 p.a.).	Must have an account set up for validated digital signatures, but not compliant.
DocuSign	Sign envelope for a document available.	Only compliant if purchased license is used. Recommended for use in contracts only.
REDCap	Signature via ticked box acknowledgment.	Not compliant.
OpenClinica EDC	Digital signature	System is compliant.

Appendix C: eLog templates available in Florence

eLog Template Name	Trial Type Uses	Folder Use
MCRI – Delegation of Authority Log – Template	CSTs IITs	ISF TMF
MCRI – Individual Training Log – Template	CSTs IITs	Central File
MCRI – CST Protocol Deviation Log – Template	CSTs	ISF
MCRI - IIT Protocol Deviation Log – Template	IITs	ISF SIF TMF
MCRI – IIT SIF Site Monitoring and Visit Log – Template	IITs	SIF
MCRI – IIT ISF Site Monitoring and Visit Log – Template	IITs	ISF
MCRI – CST Site Monitoring and Visit Log – Template	CSTs IITs	ISF SIF TMF
MCRI - Site PICF Version Tracker - Template	IITs	ISFs SIFs
MCRI – Study Team Training Log – Template	CSTs IITs	ISF SIF TMF

MCRI – IB Version Tracker	CSTs IITs	ISF TMF
MCRI - ISF protocol version tracker	CSTs	ISF
MCRI IIT TMF Protocol Approval Log	IITs	TMFs
MCRI IIT TMF PICF Approval Log	IITs	TMFs
MCRI IIT TMF PICF Version Tracker	IITs	TMFs

Appendix D: Florence eLog Management – Correcting Errors

Mistaken/Incorrect Signature Request

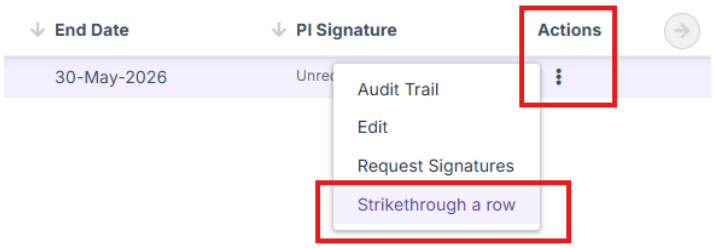
If you have accidently requested a signature from the wrong person.

- Scroll across to 'Actions' column, press the three buttons and re-select 'Request Signature'
- In 'Pending' tab select the incorrectly chosen person and press 'Action' button that appears top right of pop up.
- Select 'Mark Cancelled' to cancel their signature request and press 'Submit'. This will cancel the signature request and allow you to choose another name in 'Signers' tab.

Log Entry Created in Error

If a log entry has been created by accident or is no longer needed there is no way to delete a single entry. Instead:

- Click the three 'Action' dots and click 'Strikethrough a row'.
- You will then need to provide a reason for the change.
- Add a new entry with the correct information and ensure you re-request the signature.



Any time a log detail is edited (whether that be study role, delegated task number, date etc.) every signature will be removed from the current version of the row. *Audit track will still show previous signatures and reason for edits which reset them.

Correcting accidental signing: in the case someone has signed a column they shouldn't have

- Scroll bottom bar across to 'Actions' column, click on three dots, select 'Edit'.
- Edit any column that has text E.g. if Delegation log, tasks delegated are 2-4, 7. Delete the 7 and save – giving reason "Accidentally signed, will submit change details in separate entry".
- Submit a second entry with any deleted details of initial log entry, if required.