

REFERENCE DOCUMENT

Title: Florence eBinders™: User Roles and Permissions Overview

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Document History

Revision	Modified by	Effective Date [DD/MMM/YYYY]	Description of Change
14.0	Laura Galletta	26/05/2026	Updated assigned user permissions per role to align with current permissions.

INTRODUCTION

This document will define the customisable Florence Permissions and outline the standardised Roles which have been developed for MCRI staff. Each Florence Binder has its own set of Roles which are based off these standard Roles.

Please contact florence@mcri.edu.au if you would like to set up one of these Roles for your binder or customise a Role for your Binder.

KEY CONCEPTS

FLORENCE PERMISSIONS

Permissions are a specific interaction which can be assigned broadly to Binders, or to specific documents and folders. Permissions that are assigned at the higher level are inherited by the lower-level files within, as follows:

1. **Team** Inherited by Binders, Folders, and Documents within the MCRI Team
2. **Binder** Inherited by Folders and Documents within the Binder
3. **Folder** Inherited by Documents within the Folder
4. **Document** Only applies to that specific Document.

Consequentially, if you give a User access to a Binder, they will also receive the same abilities as Indirect Permission access to the Folders and Documents contained within that Binder.

FLORENCE ROLES

Most commonly Permissions will be granted to Users by Assigning them a 'Role'. A Role is a set of permissions that you can assign to one or more users. This means that rather than managing Permissions directly for each User, similar Users are instead grouped together and managed centrally. Updating the Role updates Permissions for ALL Users assigned to that Role.

DIRECT PERMISSIONS

Florence Organizational Administrators can assign Direct Permissions to a specific document or folder in Florence.

For example, you can ask the Florence team to give a User access to a specific Folder, which is a "Direct" Permission. Any items lower in hierarchy (Folders, Documents, and Placeholders inside that Folder) will receive the same "Indirect" or Inherited Permissions due to their inclusion in the Folder.

INDIRECT PERMISSIONS

Indirect Permission is the access inherited by a lower-level file when Permissions are assigned to an Object higher in the hierarchy (a parent item), as explained in '[Florence Permissions](#)' section above.

FLORENCE PERMISSIONS:

CODE	PERMISSION NAME	PERMISSION DESCRIPTION
D	Download Documents with PHI	The User may download Documents in their original pre-redacted versions or flagged as PHI to their local computer.
V	View Documents with PHI	The User may view Documents flagged as PHI, and in both their pre- and post-redaction versions.
R	Manage Long-term Archive	All items in location starting with R
R1	Downloading long-term archive	Allows you to download long-term archived documents (will include PHI documents).
R2	Schedule long-term archive	Allows you to schedule long-term archive.
M	Manage Monitor Reviews	All items in locations starting with M
M1	Approve Monitor Reviews	The User may approve documents (note: Users with Approve permissions can close any Open Queries at time of Document approval).
M2	Comment on Monitor Reviews	The User may comment on a Monitor Review on a Document.
M3	Create/Close Queries	The User may Open or Close Queries on the Document.
M4	Review Monitor Reviews	Mark Document as Reviewed.
M5	View Monitor Reviews	The User may view all Monitor Reviews on the Document.
A	Manage Team and Its Contents	All items in locations starting with A
A1	Create Binders	The User may generate new Binders for the team
A2	Create Tags	The User may generate new Tags for the Team.
A3	Delete Tags	The User may remove Tags for the Team.
A4	Download All Audit Trail Events for the Team	The User may download a report of all Team-level Audit Trail events to his/her local computer in either PDF or CSV format.
A5	Designate Objects for Job Title Signature Requirement	Each user's job title will be included in all signatures at the Binder or Folder level
A6	Invite Users to the Team	The User may add new members to the Florence Team via the "Manage Team Members" page under the Settings menu.
A7	Manage Labels	All items in locations starting with A7
A7.a	Assign Labels	The User may assign Labels to different Binders on their Team
A7.b	Create/Edit Labels	The user may create or edit Labels for their Team
A7.c	Delete Labels	The User may delete or remove Labels for their Team
A8	Manage Access and Permissions for the Team	All items in locations starting with A8
A8.a	Assign Roles (Off) for the Team	The User may Assign Roles and turn them on and off.
A8.b	Manage Access Dates for the Team	Manage Access Dates for the Team: The User can select start and end dates for assigned Roles.
A8.c	Manage Roles and Permissions for the Team	Manage Roles and Permissions for the Team: The User can create, assign, and manage Roles and Permissions for the Team.
A8.d	Run Role Manager for the Team**	Run Role Manager for the Team: [Premium feature] The User can run the Role Manager to create and assign Roles for the Team.
A8.e	View Users, Roles and Permissions for the Team	View Users, Roles and Permissions for the Team: The User can view all Users, Roles, and their Permissions for the Team.
A9	Manage Binder	All items in locations starting with A9
A9.a	Delete Binder	The User may remove a Binder and all of its contents from Florence
A9.b	Download All Audit Trail Events for the Binder	The User may download a report of all Binder-level Audit Trail events to his/her local computer in either PDF or CSV format.

CODE	PERMISSION NAME	PERMISSION DESCRIPTION
A9.c	Manage Folder	All items in locations starting with A9.c
A9.c1	Import/Upload Document	The User may upload a Document via email, drag and drop, or browsing from his/her local computer.
A9.c2	Create Folder	The User may make a new Folder within the Binder(s) where s/he is granted permissions.
A9.c3	Create Log	The user may make a log within the Binder(s) where s/he is granted permissions.
A9.c4	Delete Folder	The User may remove a Folder and all of its contents from a Binder on which s/he has this permission.
A9.c5	Download All Audit Trail Events for the Folder	The User may download a report of all Folder-level Audit Trail events to his/her local computer in either PDF or CSV format.
A9.c6	Duplicate Folder	The User may create a new copy of the Folder and all of its contents in a new location within Florence.
A9.c7	Import Folder Structure	Import Folder Structure: The User may upload a Folder template into a Binder (analogous to setting up tabs in a paper binder).
A9.c8	Manage Document	All items in locations starting with A9.c8
A9.c8.a	Annotate Document	All items in locations starting with A9.c8.a
A9.c8.a1	Add Text to Document	The User may add wording to the Document via a text box.
A9.c8.a2	Finalize Form	The User may finalize a form after making any annotations necessary or after signing a form. User MUST have this permission if you need them to sign a form.
A9.c8.a3	Highlight Document	The User may highlight parts of the Document.
A9.c8.a4	Redact Document	The User may censor part or all of the Document by drawing a black box over the information being redacted. Note that when a redaction is made on a document, Florence then recognizes the document as PHI. This impacts permissions that cannot view PHI.
A9.c8.a5	Request Signatures	The User may send notifications to other Florence Team members to ask for their electronic signature on the Document and select the reasoning that applies.
A9.c8.a6	Sign Document	The User may electronically sign the Document and select the reasoning that applies.
A9.c8.a7	Timestamp Document	The User may add a timestamp to the Document.
A9.c8.b	Assign Tags	The User may select Documents to include in a pre-determined category, or Tag, to help customize options in the Reports module.
A9.c8.c	Create Document Shortcut	The User may create a shortcut of a Document to other Folders or Binders within Florence. Other Users without permissions to certain Folders or Binders are able to view the shortcut if it's placed in their permissible Folders and Binders.
A9.c8.d	Delete Document	The User may remove the Document from Florence. Note that this action CANNOT be undone, but the audit trail will show when the document was deleted, and by whom.
A9.c8.e	Mark/Unmark PHI	The user may flag a document as containing PHI or remove the PHI flag from the document. Note that the PHI flag should only be removed if the document has been properly redacted.
A9.c8.f	Download All Audit Trail Events for the Document	The User may download a report of all Document-level Audit Trail events to his/her local computer in either PDF or CSV format.

CODE	PERMISSION NAME	PERMISSION DESCRIPTION
A9.c8.g	Download Documents without PHI	The User may only download Documents to his/her local computer that have not been redacted or in their post-redaction versions.
A9.c8.h	Duplicate Document	The User may create a new copy of the Document in a new location within Florence. Note that the User needs to have permission to the location they are duplicating the Document to.
A9.c8.i	Manage Locked Document	All items starting with A9.c8.i
A9.c8.i1	Lock Document	The ability to mark documents as Locked, which will restrict the majority of actions available on documents, except Downloading, Duplicating, and Viewing Audit Trails
A9.c8.i2	Move Locked Document	The Ability to move locked documents, or folders containing locked documents
A9.c8.i3	Unlock Document	The ability to unlock documents marked as locked which will remove the Locked Restrictions and allow normal document actions to be available
A9.c8.k	Manage Log	All items in locations starting with A9.c8.k
A9.c8.k1.a	Annotate Log Entries	All items in locations starting with A9.c8.k1.a
A9.c8.k1.a1	Create Log Entry	The user can create entries in the log.
A9.c8.k1.a2	Edit Log Entry	The user can edit entries that have already been input in the log.
A9.c8.k1.a3	Sign Log Entry	The user can add their signature to log entries. Note: please specify to users where their signature(s) should be placed.
A9.c8.k1.b	Update Log Details	User can update the log name, numbers, sponsor, etc.
A9.c8.l	Move Document	The User may transfer the Document into an alternate location within Florence. Note that the User needs to have permission to the location they are moving the Document to.
A9.c8.m	Rename a Document	The User may change the name of the Document. The original Document name will show in the audit trail.
A9.c8.n	Replace a Document or Fill a Placeholder	The User may upload a new version of a Document or upload a Document into the previously created Placeholder.
A9.c8.o	Update Document	All items in locations starting with A9.c8.o
A9.c8.o1	Manage Tasks on a Document	The User may create and modify Tasks for the Document on which this permission is granted, as well as assign Tasks to other Team members within Florence.
A9.c8.o2	Manage Document Due and Expiration Dates	The User may set or clear Due and Expiration Dates on Documents and Placeholders.
A9.c8.o3	View All Audit Trail Events for the Document	The User may view Audit Trail events for Documents on which this permission is granted.
A9.c8.o4	View Documents without PHI	The User may view only post-redaction versions of Documents and Documents that have not been edited with the redaction tool.
A9.c9	Move Folder	The User may transfer the Folder into an alternate location within Florence.
A9.c10	Rename Folder	The User may change the name of the Folder.
A9.c11	Update Folder	All items in locations starting with A9.c11
A9.c11.a	Manage Tasks on a Folder	The User may create and modify Tasks for the Documents contained within the Folder on which this permission is granted, as well as assign these Tasks to other Team members within Florence.

CODE	PERMISSION NAME	PERMISSION DESCRIPTION
A9.c12	View All Audit Trail Events for the Folder	The User may view Audit Trail events for Folders on which this permission is granted, including the Audit Trails for the Documents contained within those Folders for which the User also has permission to access.
A9.d	Rename Binder	User may change the name of the Binder.
A9.e	Update Binder	All items in locations starting with A9.c10
A9.e1	Manage Tasks on a Binder	The User may create and modify Tasks for the Documents contained within the Binder on which this permission is granted, as well as assign these Tasks to other Team members within Florence.
A9.f	View Binder	The User may view the Binder, in addition to any of its contents (Folders and Documents) for which the User also has permission to access.
A9.g	View All Audit Trail Events for the Binder	The User may view Audit Trail events for Binders on which this permission is granted, including the Audit Trails for the Folders and Documents within those Binders for which the User also has permission to access.
A10	Manage Form Field Placeholders	Edit and update text fields in the Signature Fields and Text fields (under the team profile tab) for the Team
A11	Manage Log Templates	All items in locations starting with A11
A11.a	Archive Log Templates	Archive log templates for the team
A11.b	Create log templates	Create Log templates for the team
A11.c	Duplicate log templates	Duplicate log templates for the team
A11.d	Edit log templates	Edit log templates for the team
A11.e	View log templates	View log templates for the team
A12	Manage Projects	All items in locations starting with A12
A12.a	Create Projects	The User may set up a new Dashboard Project via the “Manage Projects” page under the Settings menu.
A12.b	Delete Projects	The User may remove a Dashboard Project and all of its included Timelines from Florence.
A12.c	Duplicate Projects	The User may make a copy of an existing Dashboard Project.
A12.d	Import Project Structure	The user can import a structure template for new projects
A12.e	Manage Timelines	All items in locations starting with A12.e
A12.e1	Assign to Timelines	The User may add Documents and Placeholders to Dashboard Project Timelines.
A12.e2	Build Timelines	All items in locations starting with A12.e2
A12.e2.a	Create Timeline	The User may add a new Timeline to a Dashboard Project.
A12.e2.b	Update Timeline	The User may edit a Dashboard Project Timeline, including changing its name, completion status, and projected start and end dates, as well as duplicating or deleting it.
A12.e3	Delete Timelines	The User may remove a Dashboard Project Timeline from Florence.
A12.e4	Duplicate Timelines	The User may make a copy of an existing Dashboard Project Timeline.
A12.e5	View Dashboard	The User may access Dashboard Projects and Timelines via the “Dashboard” icon in the left-hand navigation panel.
A12.f	Update Projects	The User may edit a Dashboard Project, including changing its name, completion status, and included Timelines, as well as duplicating or deleting it.
A13	Manage SSO	Manage SSO setup and updates for the team

CODE	PERMISSION NAME	PERMISSION DESCRIPTION
A14	Manage Study Profiles	All items in locations starting with A14
A14.a	Create / Edit Study Profiles	Create and edit Study Profiles for the Team
A14.b	Manage Monitor Groups	Create and edit Monitor Groups on the Team
A14.c	View Study Profiles	View Study Profiles created for the Team
A15	Manage Structure Templates	All items in locations starting with A15
A15.a	Assign Structure Templates	Assign and view Structure Templates saved to the Team into a Binder or Folder, and add or associate update Labels associated
A15.b	Delete Structure Templates	Remove and view any Structure Templates saved to the Team
A15.c	Download Structure Templates	Download and view existing Structure Templates saved to the Team as an Excel file to your computer
A15.d	Import Structure Templates	Import and view Study Structure Templates to save and reuse when creating new studies
A16	Manage Tasks on a Team	The User may create and modify Tasks for the Documents contained within the Binders that belong to their Team, as well as assign those Tasks to other Team members within Florence.
A17	Rename Team	The User may change the name of the Florence Team.
A18	Send Announcement	The User can send Announcements in Florence.
A19	Manage SIP Configurations	Manage SIP configurations and connections for the Team

MCRI USER ROLES

BINDER ADMINISTRATOR	
Permission Name	Level <i>(Team/Binder/Folder)</i>
Assign Roles (Off) for the Team	Team
Manage Access Dates for the Team	Team
View Users, Roles and Permissions for the Team	Team
Send Announcement	Team
Invite Users to the Team	Team
Remove Users from the Team	Team
Assign Labels	Team
Create Tags	Team
Update Tags	Team
Manage Projects	Team
Download All Audit Trail Events for the Binder	Trial Binder
Manage Folder	Trial Binder
Manage Logs	Trial Binder
Rename Binder	Trial Binder
Update Binder	Trial Binder
View All Audit Trail Events for the Binder	Trial Binder
Manage Monitor Reviews	Trial Binder

SUPPORTING DEPARTMENT	
Permission Name	Level <i>(Team/Binder/Folder)</i>
Import/Upload Document	Folder
Manage Document Due and Expiration Dates	Folder
Update Document Status	Folder
Annotate Document	Folder
Download Documents without PHI	Folder
Manage Log	Folder
Manage Tasks on a Document	Folder
View Documents without PHI	Folder

CENTRAL FILES – GENERAL ACCESS

Permission Name	Level <i>(Team/Binder/Folder)</i>
Duplicate Folder	Folder – MC Staff Files
Redact Document	Folder – MC Staff Files
Request Signatures	Folder – MC Staff Files
Create Document Shortcut	Folder - All
Download Documents without PHI	Folder - All
Rename a Document	Folder – MC Staff Files
Replace a Document or Fill a Placeholder	Folder – MC Staff Files
Manage Document Tasks, Due Dates and Expiration Dates	Folder – MC Staff Files
View Documents without PHI	Folder - All
Import/Upload Document	Folder – MC Staff Files
View Binder	Central Files Binder

CENTRAL STAFF FILE

Permission Name	Level <i>(Team/Binder/Folder)</i>
Download documents with PHI	Staff Folder
View Documents with PHI	Staff Folder
Import/Upload Document	Staff Folder
Create Folder	Staff Folder
Download all Audit Trail Events for the Folder	Staff Folder
Annotate Document	Staff Folder
Create Document Shortcut	Staff Folder
Delete Document	Staff Folder
Mark/Unmark PHI	Staff Folder
Download all Audit Trail Events for the Document	Staff Folder
View and Download All Audit Trail Events for the Folder	Staff Folder
View and Download content without PHI	Staff Folder
Manage Locked Document	Staff Folder
Rename Documents and Folders	Staff Folder
Replace a Document or Fill Placeholder	Staff Folder
Update Document	Staff Folder
Finalize Form	Staff Folder
View Binder	Central Files Binder

TEMPORARY ROLES On a case-by-case basis, temporary roles may be created for specific purposes with predetermined set times. These temporary roles can be used for short term access needs, or expanded permissions during periods such as trial binder set up or close out. To request the set-up of a temporary role, contact MCRI Florence Organisational Administrator at florence@mcri.edu.au to discuss options.

MCRI INVESTIGATOR INITIATED TRIALS

CENTRAL TRIAL TEAM

BASIC FILING ACCESS	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder
Create Log Entry	Folder (TMF – 0.0)
Import/Upload Document	Folder (TMF – 0.0)
Manage Tasks on Document	Folder (TMF – 0.0)
Sign Document	Folder (TMF – 0.0)
Sign Log Entry	Folder (TMF – 0.0)
View Documents without PHI	Folder (TMF – 0.0)

SPONSOR INVESTIGATOR	
Permission Name	Level <i>(Team/Binder/Folder)</i>
Manage Timelines	Team
Send and View Announcements	Team
View Users, Roles and Permissions of Team	Trial Binder
View Log Templates	Team
View Binder	Trial Binder
Invite Users to the Team	Folder (TMF & SIF)
Import/Upload Document	Folder (TMF & SIF)
Create Folder	Folder (TMF & SIF)
Create Log	Folder (TMF & SIF)
Manage Log	Folder (TMF & SIF)
Download All Audit Trail Events for the Folder	Folder (TMF & SIF)
Duplicate Folder	Folder (TMF & SIF)
Import Folder Structure	Folder (TMF & SIF)
Manage Document	Folder (TMF & SIF)
Rename Folder	Folder (TMF & SIF)
Update Folder	Folder (TMF & SIF)
View All Audit Trail Events for the Folder	Folder (TMF & SIF)
Manage Monitor Reviews	Folder (TMF & SIF)

Download Documents with PHI	
View Documents with PHI	

TRIAL ASSISTANT	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Log Templates	Team
View Binder	Trial Binder
Manage Document Due and Expiration Dates	Folder (TMF & SIF)
Update Document Status	Folder (TMF & SIF)
Annotate Document	Folder (TMF & SIF)
Duplicate Document	Folder (TMF & SIF)
Mark/Unmark PHI	Folder (TMF & SIF)
Assign Tags	Folder (TMF & SIF)
Move Document	Folder (TMF & SIF)
Rename a Document	Folder (TMF & SIF)
Create Document Shortcut	Folder (TMF & SIF)
Replace a Document or Fill a Placeholder	Folder (TMF & SIF)
Create & Manage Log	Folder (TMF & SIF)
Manage Tasks on a Document	Folder (TMF & SIF)
View Documents without PHI	Folder (TMF & SIF)
View Documents with PHI	Folder (TMF & SIF)
Download Documents without PHI	Folder (TMF & SIF)
Import/Upload Documents	Folder (TMF & SIF)

CENTRAL TRIAL MANAGER	
Permission Name	Level <i>(Team/Binder/Folder)</i>
Assign Roles (Off) for the Team	Team
Create & Update Tags	Team
Invite Users to the Team	Team
Manage Access Dates for the Team	Team
Manage Projects	Team
Remove Users from the Team	Team
Send Announcements	Team
View Log Templates	Team
View Users, Roles and Permissions for the Team	Team
Comment on Monitor Reviews	Folder (TMF & SIF)
Create Folder	Folder (TMF & SIF)

Create Log	Folder (TMF & SIF)
Download All Audit Trail Events for the Folder	Folder (TMF & SIF)
Duplicate Folder	Folder (TMF & SIF)
Import Folder Structure	Folder (TMF & SIF)
Import/Upload Document	Folder (TMF & SIF)
Manage Document	Folder (TMF & SIF)
Move Folder	Folder (TMF & SIF)
Rename Folder	Folder (TMF & SIF)
Update Folder	Folder (TMF & SIF)
View All Audit Trail Events for the Folder	Folder (TMF & SIF)
View Documents with PHI	
View Monitor Reviews	Folder (TMF & SIF)

PHARMACIST	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Log Templates	Team
View Announcements	Team
View Binder	Trial Binder
Annotate Document	Folder (TMF & SIF)
Create Log	Folder (TMF & SIF)
Manage Log	Folder (TMF & SIF)
Download All Audit Trail Events for the Document	Folder (TMF & SIF)
Import/Upload Document	Folder (TMF & SIF)
Manage Monitor Reviews	Folder (TMF & SIF)
Manage Tasks on a Document	Folder (TMF & SIF)
Mark/Unmark PHI	Folder (TMF & SIF)
View All Audit Trail Events for the Folder	Folder (TMF & SIF)
View Documents with PHI	Folder (TMF & SIF)
View Documents without PHI	Folder (TMF & SIF)

PARTICIPATING SITE TRIAL TEAM

SITE BASIC ACCESS	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder
Download Documents without PHI	Folder (ISF – 0.0)
Import/Upload Document	Folder (ISF – 0.0)

Manage Tasks on a Document	Folder (ISF – 0.0)
Manage Document Due and Expiration Dates	Folder (ISF – 0.0)
Rename Document	Folder (ISF – 0.0)
Request Signatures	Folder (ISF – 0.0)
Sign Documents	Folder (ISF – 0.0)
View Documents without PHI	Folder (ISF – 0.0, 1.2 & 10.3)
View & Download Documents without PHI	Folder (ISF – 3.2, 4.2, 4.3, 8.0, 10.0, 12.1, 13.1, 13.2, 13.4, 14.2, 14.5 & 20.1)
Annotate Log Entries	Folder (ISF – 1.2 & 10.3)

SITE PRINCIPAL INVESTIGATOR	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Log Templates	Team
View Binder	Trial Binder
Import/Upload Document	Folder (ISF)
Create Folder	Folder (ISF)
Create Log	Folder (ISF)
Manage Log	Folder (ISF)
Download All Audit Trail Events for the Folder	Folder (ISF)
Duplicate Folder	Folder (ISF)
Import Folder Structure	Folder (ISF)
Import/Upload Document	Folder (ISF)
Manage Document	Folder (ISF)
Rename Folder	Folder (ISF)
Update Folder	Folder (ISF)
View All Audit Trail Events for the Folder	Folder (ISF)
View Monitor Reviews	Folder (ISF)
View Documents with PHI	Folder (ISF)

SITE COORDINATOR RESEARCH NURSE	
Permission Name	Level <i>(Team/Binder/Folder)</i>
Assign Roles (Off) for the Team	Team
Manage Access Dates for the Team	Team
View Users, Roles and Permissions for the Team	Team
View Log Templates	Team

View Binder	Trial Binder
Import/Upload Document	Folder (ISF)
Create Folder	Folder (ISF)
Create Log	Folder (ISF)
Manage Log	Folder (ISF)
Download All Audit Trail Events for the Folder	Folder (ISF)
Duplicate Folder	Folder (ISF)
Import Folder Structure	Folder (ISF)
Manage Document	Folder (ISF)
Rename Folder	Folder (ISF)
Update Folder	Folder (ISF)
View All Audit Trail Events for the Folder	Folder (ISF)
View & Comment on Monitor Reviews	Folder (ISF)
View and Download Documents without PHI	Folder (ISF)
View Documents with PHI	Folder (ISF)

SITE TRIAL ASSISTANT

Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder
Manage Document Due and Expiration Dates	Folder (ISF)
Import/Upload Document	Folder (ISF)
Annotate Document	Folder (ISF)
Duplicate Document	Folder (ISF)
Mark/Unmark PHI	Folder (ISF)
Assign Tags	Folder (ISF)
Move Document	Folder (ISF)
Rename a Document	Folder (ISF)
Create Document Shortcut	Folder (ISF)
Replace a Document or Fill a Placeholder	Folder (ISF)
Create & Manage Log	Folder (ISF)
Manage Tasks on a Document	Folder (ISF)
View Documents without PHI	Folder (ISF)
View Documents with PHI	Folder (ISF)
Download Documents without PHI	Folder (ISF)

STUDY MONITOR

Permission Name	Level <i>(Team/Binder/Folder)</i>
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View Binder	Trial Binder
Import/Upload Document	Folder (ISF)
Download All Audit Trail Events for the Folder	Folder (ISF)
Add Text to Document	Folder (ISF)
Finalize Form	Folder (ISF)
Request Signatures	Folder (ISF)
Sign Document	Folder (ISF)
Download All Audit Trail Events for the Document	Folder (ISF)
Download Documents without PHI	Folder (ISF)
Manage Document Due and Expiration Dates	Folder (ISF)
View All Audit Trail Events for the Document	Folder (ISF)
View & Download Documents without PHI	Folder (ISF)
View Documents with PHI	Folder (ISF)
Manage Monitor Reviews	Folder (ISF)
Annotate Log Entries	Folder (ISF)
Timestamp Document	Folder (ISF)

SITE PHARMACIST	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Log Templates	Team
View Binder	Trial Binder
Add Text to Document	Folder (ISF)
Create Log	Folder (ISF)
Download All Audit Trail Events for the Document	Folder (ISF)
Download Documents without PHI	Folder (ISF)
Finalize Form	Folder (ISF)
Import/Upload Document	Folder (ISF)
Manage Log	Folder (ISF)
Manage Monitor Reviews	Folder (ISF)
Sign Document	Folder (ISF)
View All Audit Trail Events for the Document	Folder (ISF)
View All Audit Trail Events for the Folder	Folder (ISF)
View Documents with PHI	Folder (ISF)
View Documents without PHI	Folder (ISF)

COMMERCIALLY SPONSORED TRIALS

BASIC ACCESS	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder
Import/Upload Document	Folder – 0.0
Manage Tasks on a Document	Folder – 0.0
Request Signatures	Folder – 0.0
Sign Document	Folder – 0.0
Sign Log Entry	Folder – 7.2 & 10.2
Create Log Entry	Folder – 7.2 & 10.2
View Documents without PHI	Folder – 0.0, 7.2 & 10.2
View and Download Documents without PHI	Folder – 9.1, 12.1 & 20.1

COORDINATING PRINCIPAL INVESTIGATOR	
Permission Name	Level <i>(Team/Binder/Folder)</i>
Manage Timelines	Team
Send Announcements	Team
View Log Templates	Team
View Users, Roles and Permissions for the Team	Team
Annotate Document	Trial Binder
Comment on & View Monitor Reviews	Trial Binder
Create Document Shortcut	Trial Binder
Create Folder	Trial Binder
Create Log	Trial Binder
Sign Log Entry	Trial Binder
Delete Document	Trial Binder
Delete Folder	Trial Binder
Download All Audit Trail Events for the Folder	Trial Binder
Download All Audit Trail Events for the Document	Trial Binder
Download All Audit Trail Events for the Binder	Trial Binder
Download Documents with PHI	Trial Binder
Download Documents without PHI	Trial Binder
Duplicate Folder	Trial Binder
Import Folder Structure	Trial Binder
Import/Upload Document	Trial Binder

Manage Log	Trial Binder
Manage Timelines	Trial Binder
Mark/Unmark PHI	Trial Binder
Move Document & Folder	Trial Binder
Replace a Document or Fill a Placeholder	Trial Binder
Rename Binder, Document & Folder	Trial Binder
Update Folder, Document & Binder	Trial Binder
View All Audit Trial Events for the Folder, Binder & Document	Trial Binder
View Documents with PHI	Trial Binder

RESEARCH NURSE / STUDY COORDINATOR	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder
Annotate Document	Trial Binder
Download Documents without PHI	Trial Binder
Import/Upload Document	Trial Binder
Create Log	Trial Binder
Manage Log	Trial Binder
Sign Log Entry	Trial Binder
View Documents without PHI	Trial Binder
View Documents with PHI	Trial Binder

TRIAL ASSISTANT	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Log Templates	Team
View Binder	Trial Binder & Central Files
Create Document Shortcut	Folders – All**
View & Download Documents without PHI	Folders – All**
Annotate Document	Trial Binder
Assign Tags	Trial Binder
Create Document Shortcut	Trial Binder & MC Staff Files
Create Folder	Trial Binder
Create Log	Trial Binder
Manage Log	Trial Binder
Sign Log Entry	Trial Binder
Delete Document	Trial Binder

Delete Folder	Trial Binder
Download Documents without PHI	Trial Binder
Duplicate Document	Trial Binder
Duplicate Folder	Trial Binder
Import/Upload Document	Trial Binder
Manage Document Due and Expiration Dates	Trial Binder & MC Staff Files
Manage Log	Trial Binder
Manage Tasks on a Document	Trial Binder & MC Staff Files
Mark/Unmark PHI	Trial Binder
Move Document	Trial Binder
Move Folder	Trial Binder
Rename Document	Trial Binder
Rename Folder	Trial Binder
Replace a Document or Fill a Placeholder	Trial Binder & MC Staff Files
View Documents without PHI	Trial Binder & MC Staff Files

*** Central Files folder access includes: 'RCH Lab Service', 'Policies, SOPs and Guidance', 'Templates'. Also have access to 'Melbourne Children Staff Files' although these permissions differ, as laid out above.*

STUDY MONITOR	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder & Central Files
Create Document Shortcut	All Central File Folders***
View Documents without PHI	Trial Binder & All Central File Folders***
Add Text to Document	Trial Binder
Annotate Log Entries	Trial Binder
Sign Log Entry	Trial Binder
Download All Audit Trail Events for the Document	Trial Binder
Download All Audit Trail Events for the Folder	Trial Binder
Download Documents without PHI	Trial Binder
Finalize Form	Trial Binder
Import/Upload Document	Trial Binder
Manage Monitor Reviews	Trial Binder
Move Document	Trial Binder
Sign Document	Trial Binder
View All Audit Trail Events for the Binder	Trial Binder
View All Audit Trail Events for the Document	Trial Binder

View All Audit Trail Events for the Folder	Trial Binder
View Documents with PHI	Trial Binder

** Central Files folder access includes: 'RCH Lab Services', 'Policies, SOPs and Guidance', 'Templates', 'RCH Medical Imaging', 'RCH Clinical Trial Pharmacy' and 'MCRU'

PHARMACIST	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder
Assign Tags	Folder – 0.0 & 13.0
Import/Upload Document	Folder – 0.0 & 13.0
Manage Tasks on a Document	Folder – 0.0
View Documents without PHI	Folder – 0.0, 13.0 & 20.0
View & Download Documents without PHI	Folder – 2.1
View & Download Documents without PHI	Folder – 5.3
Manage Log	Folder – 7.2
View Documents without PHI	Folder – 7.2
View & Download Documents without PHI	Folder – 9.1
Manage Log	Folder – 10.2
Sign Log Entry	Folder – 7.2
View Documents without PHI	Folder – 10.2
View & Download Documents without PHI	Folder – 12.1
Download Document without PHI	Folder – 13.0 & 20.0
Manage Log	Folder – 13
Rename Document	Folder – 13.0 & 20.0
Replace a Document or Fill a Placeholder	Folder – 13.0 & 20.0
Request Signatures	Folder – 13.0 & 20.0
Sign Document	Folder – 13.0 & 20.0

SUPPORTING DEPARTMENT	
Permission Name	Level <i>(Team/Binder/Folder)</i>
View Binder	Trial Binder
Import/Upload Document	Folder
Manage Document Due and Expiration Dates	Folder
Update Document Status	Folder
Annotate Document	Folder
Download Documents without PHI	Folder
View Documents without PHI	Folder

Manage Log	Folder
Sign Log Entry	Folder
Manage Tasks on a Document	Folder

GLOSSARY OF FLORENCE TERMINOLOGY

BINDER

Binders are the key organisational concept behind Florence eBinders™. The electronic Binder is meant to mirror a Trial's paper binder, and contains Folders, Documents, Logs, and/or Placeholders. One Binder will be assigned per Trial. You can manage all aspects of a clinical trial's documentation needs with Binders.

CENTRAL FILES

Central Files is a binder accessible in the MCRI team. It houses general documents such as SOPs, Policies and Guidance documents, administrative templates and forms, as well as legal and Insurance files accessible to all those in the MCRI team. Here external staff files and Central Staff Files are stored.

CENTRAL STAFF FILES

Central Staff Files – labelled Melbourne Children's Staff Files for the MCRI team – is the secure folder which stores each team members; CV, GCP Certificate, Florence training certificate and Wet Ink Signature page. Access to staff files is restricted to giving individuals full access to their own documents while providing additional safeguards such marking documents containing PHI, so to limit visibility and accessibility.

DASHBOARD

A Dashboard enables Users to create Timelines to track Document uploads for any given Project. For example, Dashboards can be used to site track start-up timelines and produce reports on outstanding Essential Records needed prior to site activation.

Each Project consists of at least one Timeline. There are no limits to the number of Timelines that can be created for each Project. Additionally, each Timeline has a Projected Start Date, Projected End Date, Timeline Status, and lists assigned Documents and Placeholders.

FOLDER

Folders in Florence eBinders are digital, organised containers within the electronic Trial Master File (TMF) and Investigator Site File (eISF) used to store, manage, and secure study-specific documents and logs. They serve as the electronic equivalent of paper binder dividers, providing a standardized structure for organizing regulatory documents, subject files, and study records for monitoring.

Folders can only exist within Binders and have the same purpose in Florence as elsewhere.

LABELS

Labels are organisational tools applied at the Binder or Folder **level** to classify, identify, and report on the purpose or status of studies. They help organise the electronic Trial Master File (TMF) and Investigator Site File (eISF) by allowing users to categorise study-specific information and identify workstreams.

LOGS

Florence eLogs are digital, customisable, and compliant logs within the Florence eBinders platform, used to track research activities, safety events, and site workflows in clinical trials. Synonyms for this functionality include electronic logs, digital logs, or eLogs within the eBinders system. They allow for electronic signatures, remote monitoring, and automated tracking, replacing paper forms to enhance efficiency and ensure compliance. Key usage examples of Florence eLogs are Delegation of Authority (DOA) Logs, Training Logs, Participant Screening/Enrollment Logs, Monitor Visit Logs, Participant Information and Informed Consent Forms (PICF) Trackers. Administrators can create log templates which standardise way of recording and storing the data. Users can create entries, edit entries, request signatures, and sign both

entries and the entire log within a Florence eLog. Suggested template eLogs have been available within the Florence platform for your convenience.

PHI

PHI stands for Protected Health Information and refers to sensitive, personally identifiable patient data. It acts as a security flag to restrict access, ensure HIPAA, GDPR and GCP compliance, and enables secure storage/redaction of documents like EMR records and informed consent forms. Users who do not have permission to view or download Documents with PHI will be blocked from viewing these documents.

PLACEHOLDER

A placeholder is a designated spot or "envelope" within the eBinders template structure that reserves a position for a specific, required document that has not yet been uploaded. Placeholders are used during the setup and management of study binders to indicate that a file is missing or required for compliance, but not currently available.

When developing a trial, you usually know from the outset, the certain 'key documents' that you will require in the future. Creating a Placeholder (also defined as a digital "sticky note") upfront, ensures that you hold a place for an expected Document, guaranteeing that you won't overlook them in the future. Some example Placeholders for specific key documents include CVs, GCP training certificates, Master PICFs, Ethics approval certificates, etc.

PERMISSIONS

Permissions are a specific action which can be turned 'on' or 'off' to change the capabilities of a Role. The Organisational Administrator is able to edit Permissions at the Team, Binder and Folder level for access to Binders, Folders, Documents, and Placeholders for each Role.

Permissions are most relevant to Roles when performing tasks such as defining the visibility of a Document and sharing Documents.

PROJECT

A Project is a Timeline or collection of Timelines which are saved and tracked on an ongoing basis. Projects can be found in the Dashboard. There are no limits to the number of Timelines

included in each Project.

REPORTS

The Reporting Tool allows permitted Users to Quickly see the status of critical Documents and Tasks across one or more Binders based on their assigned attributes, including Tags, Labels, Filing locations, et. al.

ROLE

A Role is a set of permissions that you can assign to one or more users. Common Roles are: Monitors, Investigator, Sub-Investigator, Coordinator or Team Admin.

Roles improve Permission management by allowing Teams to "group" similar Users together and select the appropriate Permissions for all Users in the group instead of having to manage Permissions directly for each User. Updating the Role updates Permissions for ALL Users assigned to that Role.

For example, you may create a Team Administrator Role that has Permissions to manage a Team and its contents, but that cannot download or view Documents with PII.

SSO

Single Sign On. MCRI uses SSO to allow staff access to Florence eBinders™.

TAG

A Tag is an organisational tool used to categorise, identify, and report on specific documents or placeholders based on their type, topic, or status. Tags are applied at the document level to enhance searchability and manage large amounts of data across multiple folders, study binders, or the entire electronic Trial Master File (TMF).

TASK

Tasks are a message attached to a specific Document, Folder, or Placeholder within Florence requesting an action. These are sent by email with a link directly to the document so the Task can be done right away. An information bar will also continue to remind Users of their pending tasks.

When viewing a Document, Folder or Placeholder the Tasks connected to that location will be listed in the side bar.

TEAM

Florence refers to the 'Team' as all Users and Files which form part of MCRI's Florence account.

MCRI maintains two Florence 'Teams': MCRI-EU Team and MCRI-AUS Team. Users can be granted access to both Teams, or only the EU or AUS Team, depending on where the Binder is located.

TIMELINE

A "Timeline" in Florence eBinders refers to a functional feature or capability within the electronic Investigator Site File (eISF) system designed to track, manage, and accelerate the chronological flow of clinical research study documents and milestones. It acts as a tool to streamline the regulatory workflow, often resulting in faster study start-up times

A Timeline can be used to track the expected progress of a set of Documents / Placeholders vs. the actual Filing dates. A Timeline comprises of a Projected Start Date, Projected End Date, Timeline Status, and any assigned Documents and Placeholders.

USER

A User is anyone who has a Florence account with access to the MCRI 'Team' and has been assigned with a specific Role. Everyone on a Team must register in Florence eBinders™ as a unique User. Team Administrators can assign Users one or more Roles based on their participation needs on the Team.

Current Electronic Signatures (v.3):

Signed electronically by: Kate Scarff (kate.scarff@mcri.edu.au)

Date: 26-May-2026 @ 09:06 AM AEST

Reason: *Approval*

Previous Electronic Signatures:

Version 2

Signed electronically by: Laura Galletta (laura.galletta@mcri.edu.au)

Date: 26-May-2026 @ 08:16 AM AEST

Reason: *Authorship*