

# Workflow: Adding a new User to Florence

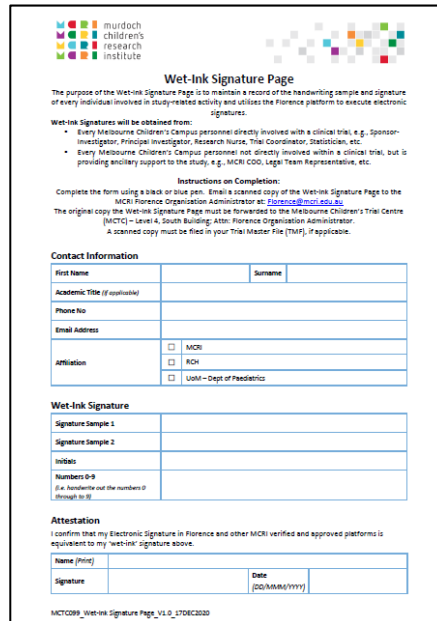
The only standardised MCRI Roles which can add new Users to Florence are:

- Central Trial Manager
- Binder Administrator

Please get in touch if you would like to add this permission for other roles eg. PI, Site Coordinator, etc.

<p><b>Step 1 - Training</b></p>	<p>Send new Users the EdApp link to Training  <a href="https://web.edapp.com/#sign-up">https://web.edapp.com/#sign-up</a>          Invite code: FLORENCE</p> <p>Template email wording for <b>MCRI staff</b> in <a href="#">Appendix A</a>          Template email wording for <b>external site staff</b> in <a href="#">Appendix B</a></p>																																																
<p><b>Step 2 – Documentation</b></p>	<p>I. New User returns a Florence Training Certificate to verify their training</p> <div data-bbox="491 871 919 1487" data-label="Image"> </div> <p>II. Collect original wet ink signatures</p> <p>a. <b>External site staff</b> sign the original hard copy of the <a href="#">wet ink signature log</a>, which is to be kept by the Site Coordinator</p> <div data-bbox="539 1659 1190 2110" data-label="Form"> <table border="1"> <thead> <tr> <th>Print Name</th> <th>Study Role (e.g. Principal Investigator, Study Coordinator, Pharmacist)</th> <th>Numbers 0 - 9</th> <th>Initials</th> <th>Signature</th> <th>Date (DD/MM/YYYY)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> </div>	Print Name	Study Role (e.g. Principal Investigator, Study Coordinator, Pharmacist)	Numbers 0 - 9	Initials	Signature	Date (DD/MM/YYYY)																																										
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b. **MCRI / RCH Staff** must sign and return an original hard copy of the [wet ink signature page](#).



**Wet-Ink Signature Page**

The purpose of the Wet-Ink Signature Page is to maintain a record of the handwriting sample and signature of every individual involved in study-related activity and utilize the Florence platform to execute electronic signatures.

Wet-Ink Signatories will be obtained from:

- Every Melbourne Children's Campus personnel directly involved with a clinical trial, e.g., Sponsor-Investigator, Principal Investigator, Research Nurse, Trial Coordinator, Statistician, etc.
- Every Melbourne Children's Campus personnel not directly involved within a clinical trial, but is providing ancillary support to the study, e.g., MCRI COO, Legal Team Representative, etc.

**Instructions on Completion:**  
Complete the form using a black or blue pen. Email a scanned copy of the Wet-Ink Signature Page to the MCRI Florence Organization Administrator at: [Florence@mcri.edu.au](mailto:Florence@mcri.edu.au).  
The original copy the Wet-Ink Signature Page must be forwarded to the Melbourne Children's Trial Centre (MCTC) - Level 4, South Building, Attn: Florence Organization Administrator.  
A scanned copy must be filed in your Trial Master File (TMF), if applicable.

**Contact Information**

First Name		Surname	
Academic Title (if applicable)			
Phone No			
Email Address			
Affiliation	<input type="checkbox"/> MCR		
	<input type="checkbox"/> RCH		
	<input type="checkbox"/> UoM - Dept of Paediatrics		

**Wet-Ink Signature**

Signature Sample 1	
Signature Sample 2	
Initials	
Numbers 0-9 (i.e. Numbered and the numbers 0 through to 9)	

**Attestation**  
I confirm that my Electronic Signature in Florence and other MCRI verified and approved platforms is equivalent to my "wet-ink" signature above.

Name (Print)		Date	(DD/MM/YY)
Signature			

MCTC089\_Wet-Ink Signature Page\_V1.0\_17DEC2020

### Step 3 - Filing

#### MCRI / RCH Staff

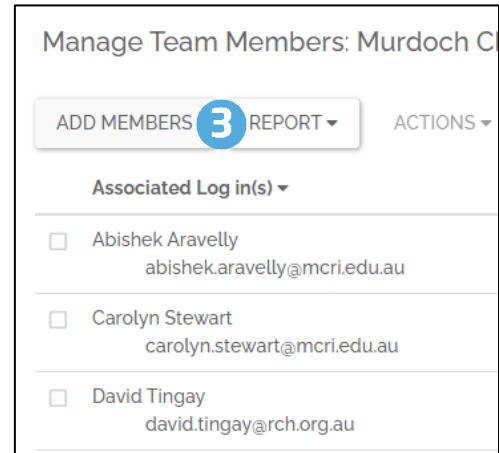
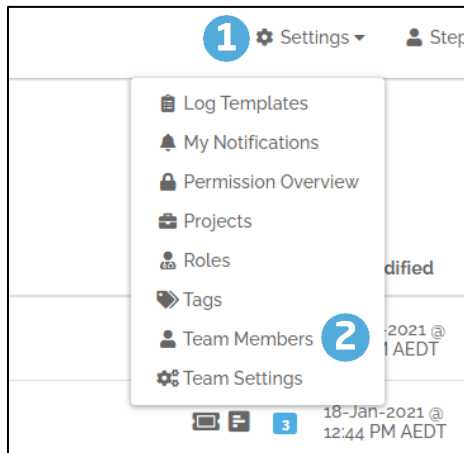
- I. File a digital copy of the Wet ink signature page and Training Certificate in [Florence Central Staff Files](#)
- II. [Shortcut](#) from your trial binder as required to the Central staff files.
- III. Return an original copy of the Wet Ink Signature Page to one of the MCTC Florence Administrators (South Level 4)

#### External Site Staff

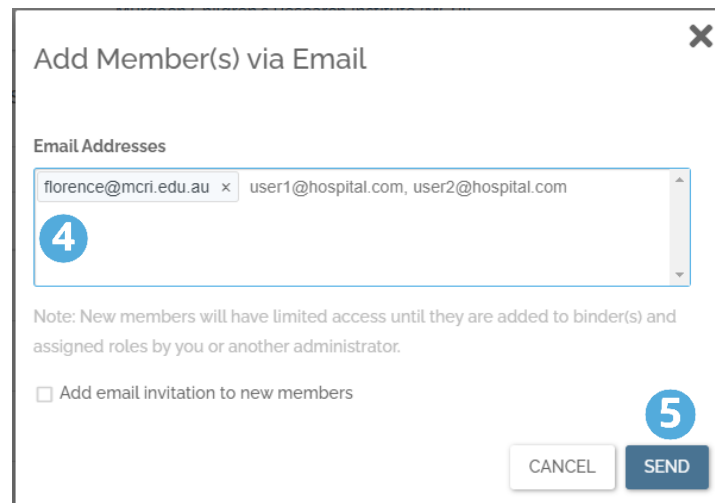
- I. File a digital copy of the Florence Training Certificate in your trial binder as per the Florence Filing Guidance documents
- II. A scanned copy of the wet ink signature eLog must be scanned and filed in both the Site Information File and the Investigator Site File.

## Step 4 – Invite User

- 1 Click 'Settings' in the top left corner.
- 2 Select 'Team Members'
- 3 Select 'Add Team Members'



- 4 Type in the email address(es) of the users you would like to add to Florence.
- 5 Click out of the email text box. The 'Send' button will change from grey to blue. Click 'Send'



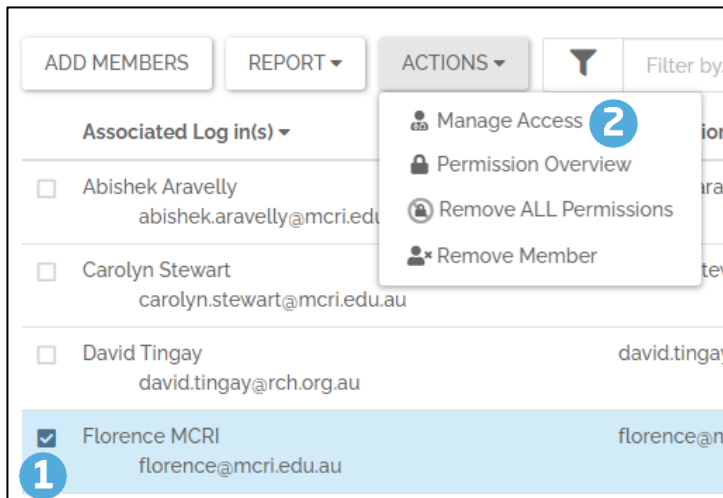
Please note: **MCRI Users** must access Florence via the MCRI Single Sign on (SSO) <https://okta.mcri.edu.au/>. DO NOT tick 'Add email invitation to new members' for MCRI staff, as the link will not work.

You can send an email invitation for **External Site users**.

**Step 5 – Assign the new User a Role**

**1** Select a User who you wish to assign a Role

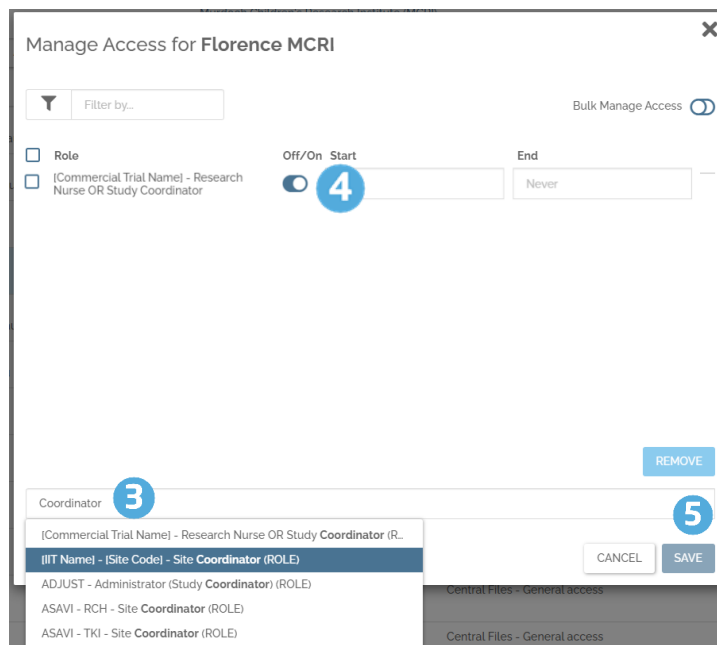
**2** Select 'Manage Access'



**3** Begin typing the Trial or Role name in the text box at the base of the pop-up. All roles containing that phrase will appear. Select the Role you need.

**4** 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

**5** Click 'Save'



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

## Appendix A

Prior to gaining access to Florence e Binders, you will need to:

- a) Complete Florence online training. You can access training at your convenience via the following link: <https://web.edapp.com/#login> You can also use the phone app if desired.  
  
Florence training takes ~1 hour to complete. The **attached document** outlines step-by step instructions on how to create your training account and access the training module.  
  
Once you have finished your training you can download the Certificate of Completion at the top of the EdApp Course Page.
- b) Print and complete a hard copy of the [wet ink signature page](#)
- c) return both the Training Certificate and the wet ink signature page to me via email. A digital copy of both will be kept in the Florence Central Files to allow for use across all trials within Florence.

In addition, please return the original hard copy of the Wet Ink Signature Page to the Florence Support team on South Level 4, as we need to keep the original hard copies of the wet ink signatures on file.

After you have returned these, you can log in to Florence via MCRI's single-sign on, [Okta](#), and clicking on the Florence Icon:



Florence PROD

When you first log in you should:

- a) Ensure that your Florence Training Certificate and Wet-Ink Signature Page have been filed in the 'Central Files > Melbourne Children's Staff Files' Binder. Please move them into the appropriate placeholder if this has not yet been done.
- b) Set your signing PIN in your "User Profile".
- c) Set your notification settings under "Settings".

If you cannot recall how to complete these tasks, you can review these tasks at the EdApp videos, or review the [Florence Help Article](#). MCRI staff can access additional information at the [CRDO intranet page](#).

Please note that it may take up to 48 hours for you to get access to the Trial Binder after you have returned your documentation. Please get in touch if you don't have access after 48 hours.

## Appendix B

MCRI is an international leader in paediatric and clinical research. As part of the Melbourne Children's Trial Centres (MCTC) mission and values, we strive to deliver excellence and quality while emphasizing the creation and implementation of new knowledge and cutting-edge technologies.

As such, we have implemented electronic regulatory binders for our clinical trials program.

Florence eBinders advances clinical research through Part 11-compliant purpose-built software. Florence is a validated FDA 21 CFR Part 11, HIPAA, ICH-GCP and GDPR compliant service that manages both regulatory and source documents. The system has audit trails, is backed up 3 times a day, and is a validated and compliance tested program.

The implementation of eBinders provides a streamlined approach to documentation for clinical trials. Roles and permissions allow for remote monitoring and improved oversight of documents. The electronic format allows for forwarding correspondence directly into eBinders via email, collaborating within the tool for eSignatures, training, redacting/de-identifying and annotating source documents and setting expiration dates on documents to improve efficiency and reduce duplication. The eBinder contains the full format of paper regulatory binders/ISFs and will be accessible to monitors for review during monitoring visits, either remotely or on site.

To gain access to your <<TRIAL NAME>> electronic study binder, some prior training must be completed. Full training is provided to all site investigators and site staff on the Florence eBinders™ platform by way of an online webinar. The online training webinar consists of one training session targeted to all Research Team members. All site staff identified as requiring access to Florence must complete this mandatory training prior to access being provided.

Florence training can be accessed via the following link: <https://web.edapp.com/#login> and takes ~1 hour to complete.

The **attached document** outlines step-by step instructions on how to create your training account and access the training module.

Those who have then completed Florence training will then need to complete the Wet-Ink Signature Log.

After you have completed these steps you will receive an invitation to Florence eBinders via email. Please get in touch if you have not received this within 48 hours of returning your Training Certificate.