



Florence eBinders Training for MCW Research Staff

Welcome to Florence eBinders! Florence eBinders will provide an accessible, transparent, cloud-based central repository for all essential regulatory documents, improving MCW's regulatory compliance, accelerating new study startup and improving overall efficiencies. Features of eBinders include transparent task management, electronic signature collection, compliance with Federal regulations, redaction of personal health information (PHI), facilitate multi-center study coordination, manage investigator/research staff profiles and support sponsor access for remote monitoring.

Prior to being provided access to the MCW Florence eBinders Production environment, research staff must complete the required training components for MCW to maintain compliance with Federal regulations (21 CFR Part 11) and HIPAA requirements. Contact your [Department's Florence Superuser](#) or email Florence@mcw.edu for assistance.

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10 Steps for Research Staff Training

Review the Required Compliance Training Materials

1. View the 12 online training modules, which cover key features and workflows for the use of Florence eBinders and takes approximately 2 hours to complete (can be done in multiple sessions). The access link to the Florence online training modules can be found. [HERE](#)
2. Review the ["Use of Florence eBinders™ for Electronic Records and Electronic Signatures" SOP](#).

Attestation of Completion of Required Training

3. **REQUIRED STEP!** Once all 12 modules have been completed, email a PDF copy of your training certificate to Florence@mcw.edu. This will be the trigger to the Florence Support Team in the Office of Research to create your account in the Production environment.

Your Production account will be created by MCW Florence support within 24 hours!

Access to Florence eBinders Production Environment

4. Once your training certificate is received by the MCW Florence Support Team in the Office of Research, you will be provided with access to eBinders Production environment and receive an email invitation to register & log in.

Training Application & Documentation

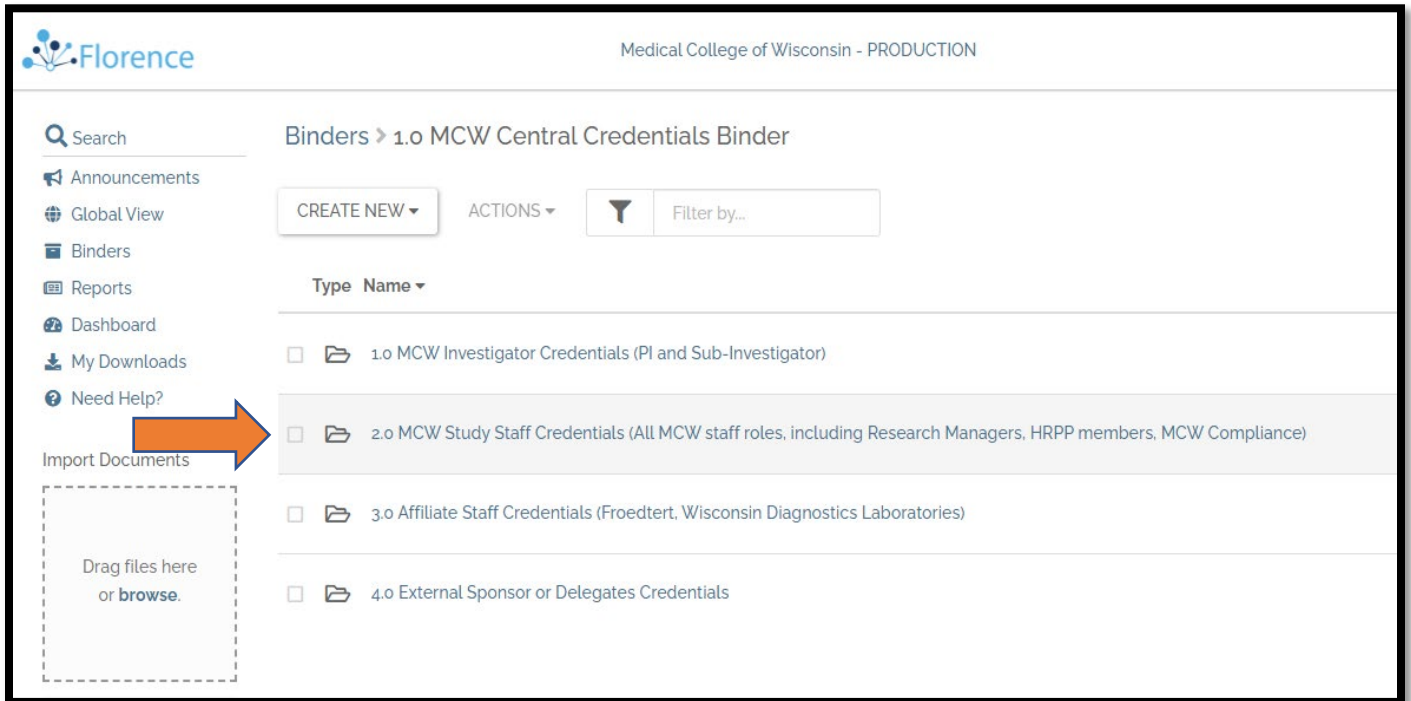
5. Prior to entering the Florence eBinders Production environment:
 - o Print, complete and scan the [Individual Signature Log](#) in preparation for an upload into the eBinders Production environment. This document is a wet ink document and needs to be legible to the reader.
 - o Accept your Invite to register & access the Florence Production environment.

- o **Bookmark** this [link to eBinders Production Login page](#) for easy accessibility. It will also be added on the Quick Links banner on Infoscope at the time of Go-Live.

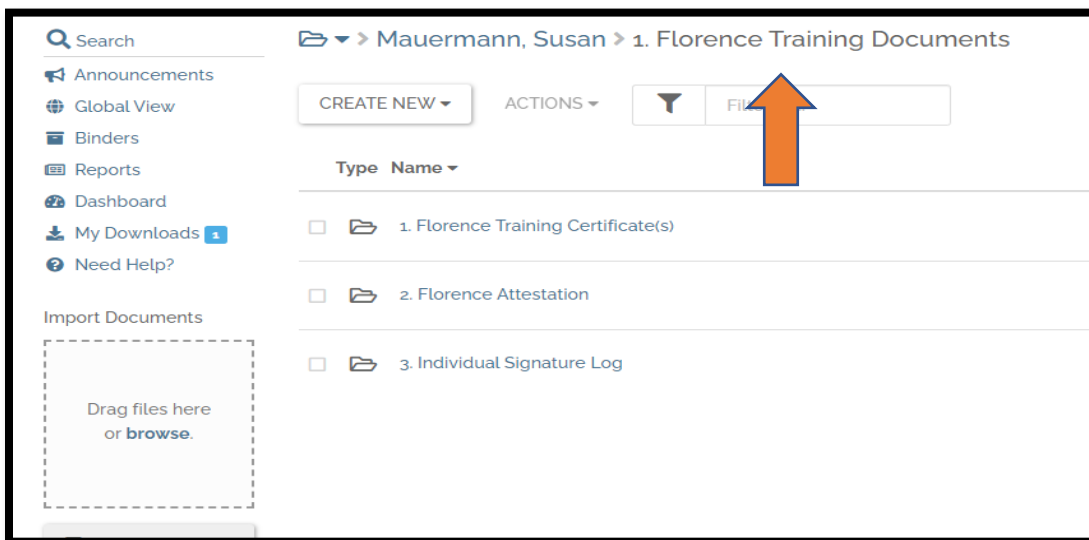
The remaining steps of **Application of eBinders Training** will be completed in the Florence Production environment.

6. The Florence Support team will create a Personal Credentials Folder for you, it is identified with your name and found within the MCW Central Credentials Folder.

- o To locate, open the Folder, open *2.0 MCW Study Staff Credentials (All MCW staff roles, include Research Managers, HRPP members, MCW Compliance)*, then find your name and individual credentials folder.



- o Open your personal folder, look for the sub-folder "1. Florence Training Documents" all remaining tasks are completed in this sub-folder. The screen shot below shows where your navigation will land.



7. Open the first folder, "1. Florence Training Certificate"

- Confirm that your training certificate is in your folder. Verify the spelling of your name and date of training completion (bottom left-hand corner).
- This information is auditable by the FDA, so accuracy is important. Notify Florence@mcw.edu of any errors.

8. Open the second folder, "2. Florence Attestation." You will use the e-Signature Type-Stamp to execute this document. **See the next series of screen shots to walk you through this process.**

- After reading through the "Attestation of Florence eBinders Training Completion," notice & click the yellow "Click to Sign" box and hit the SAVE button at the top of your screen.

2. Florence Attestation > MCW Florence Training Attestation Form

MANAGE VERSION (V1) SAVE

CLEAR ALL SIGN Click on the colored boxes to ADD TEXT and/or SIGN and then click *SAVE*

Attestation of Florence eBinders Training Completion

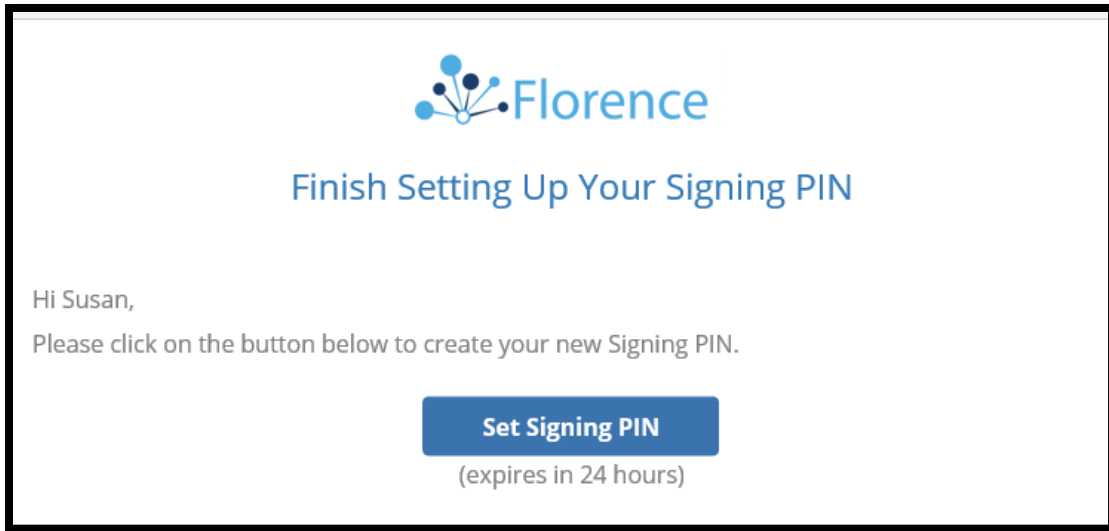
My eSignature below attests that I:

- ✓ Completed the Florence training session(s) applicable for my role(s)
- ✓ Reviewed the MCW Standard Operating Procedure (SOP) regarding the "Use of Florence e-Binders for Electronic Records and Electronic Signatures."
- ✓ Will not share my password or signing PIN with anyone
- ✓ Understand and certify that my e-Signature is intended to be the legally-binding equivalent of my traditional handwritten signature
- ✓ Will follow appropriate masking procedures when uploading subject protected health information (PHI)
- ✓ Will notify an Access Coordinator (Super User or Office of Research Team Administration) upon termination of my employment or a change in my status that discontinues my need for Florence use

Click to Sign

Trainee eSignature

- You will receive a notification Finish Setting Up Your PIN in your MCW Outlook Inbox. Use of this PIN is tied to your MCW single-sign-on credentials and will be required each time you e-sign a document in Florence.
- Once you have your PIN, go back to the Attestation form.

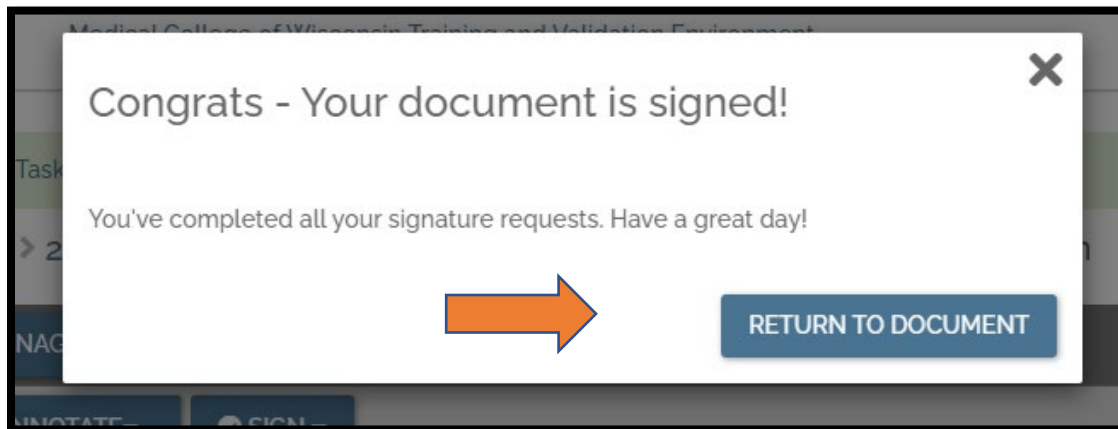


- After clicking the yellow signature box, you will receive a pop-up window allowing you to complete the e-signature process.
 - ❖ Enter a **Reason** of **“Approval”** from the dropdown
 - ❖ Enter the **PIN** you just created in box next to the picture of the key. Notice you can **RESET YOUR SIGNING PIN** in this field.
 - ❖ Then select button **FINALIZE FORM**

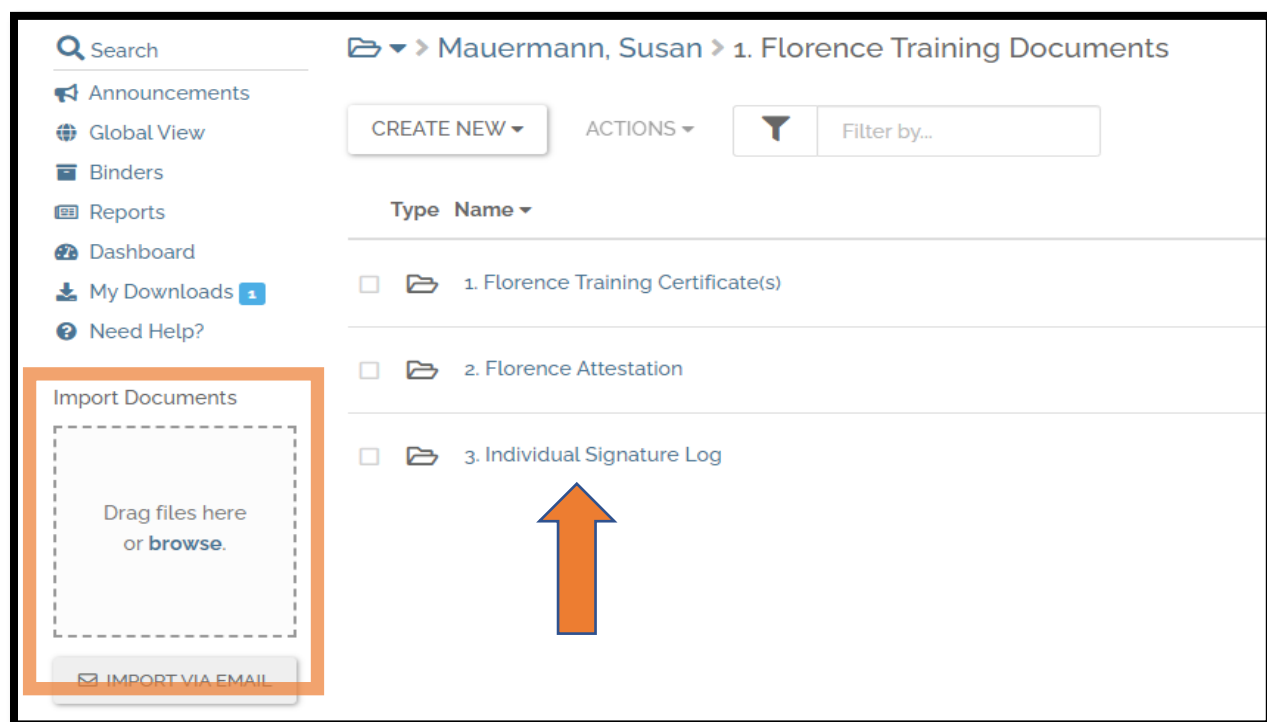
The screenshot shows a pop-up window titled "Are You Sure?" with a warning icon. The text inside reads: "This action will create a new version of the document." Below this, it says "FINALIZE FORM:" followed by "Signature(s) and any text added to form fields will be placed on the document as permanent annotations. Form fields will no longer be fillable." The user is identified as "I, smauerma@mcw.edu, am authorizing 1 form signature(s):". There are three required fields: "Reason" (a dropdown menu with "Approval" selected), "Signing PIN" (a text box with a key icon and a "..." placeholder), and a "RESET MY SIGNING PIN?" link. At the bottom, there are "CANCEL" and "FINALIZE FORM" buttons.



- You will receive a pop-up indicating e-signature success.
 - ❖ Select button, RETURN TO DOCUMENT in bottom right corner.
- You will now see your fully executed Florence Attestation document.



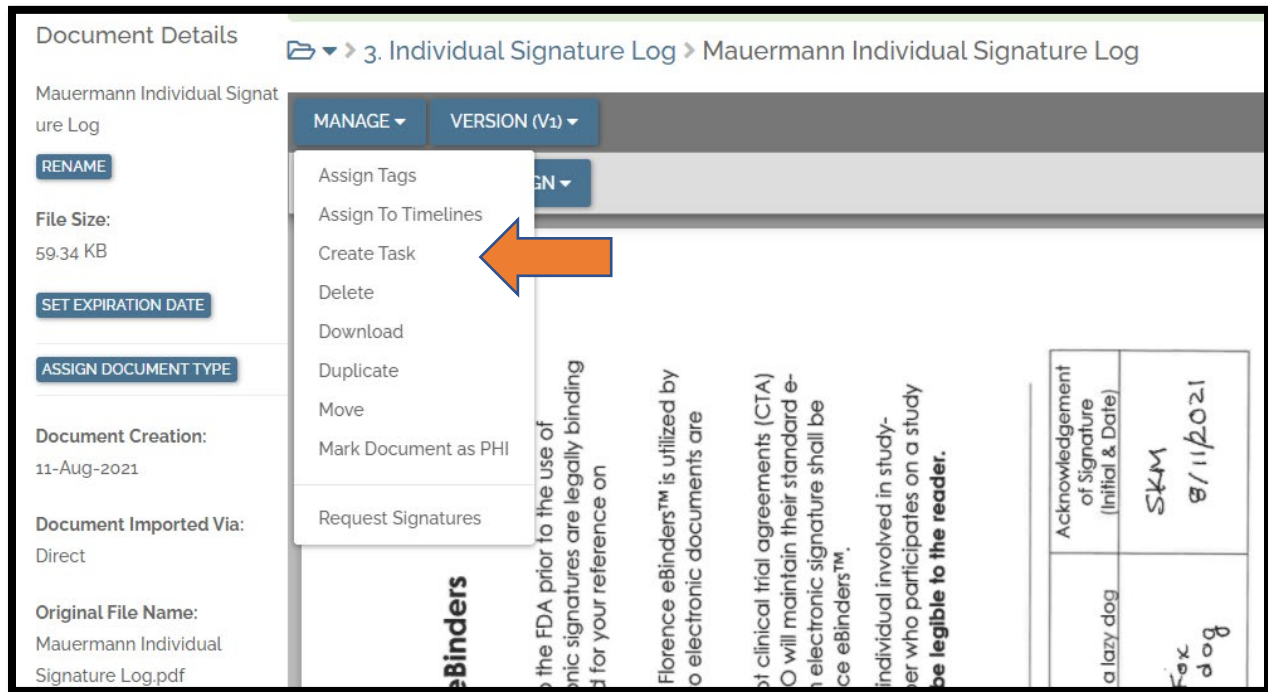
9. Go to the third folder, "**3. Individual Signature Log.**" With the next series of actions, you will upload the "Individual Signature Log" you completed as a wet-ink document.



- Click on the folder title to go into the empty "3. Individual Signature Log" folder. This directs Florence where you want the document to be uploaded.
- By using the **Import Documents box**, found on bottom left-hand corner of your screen, click on browse, and find the Individual Signature Log you completed and scanned/saved into your MCW device or drag and drop the selected document into the Import documents box and allow the upload to occur. It may take a couple minutes but is usually a quick process.
- Once you have confirmed your document is in place, by you specifically uploading this document it is considered a certified copy and the hard/wet-ink paper version is no longer needed.

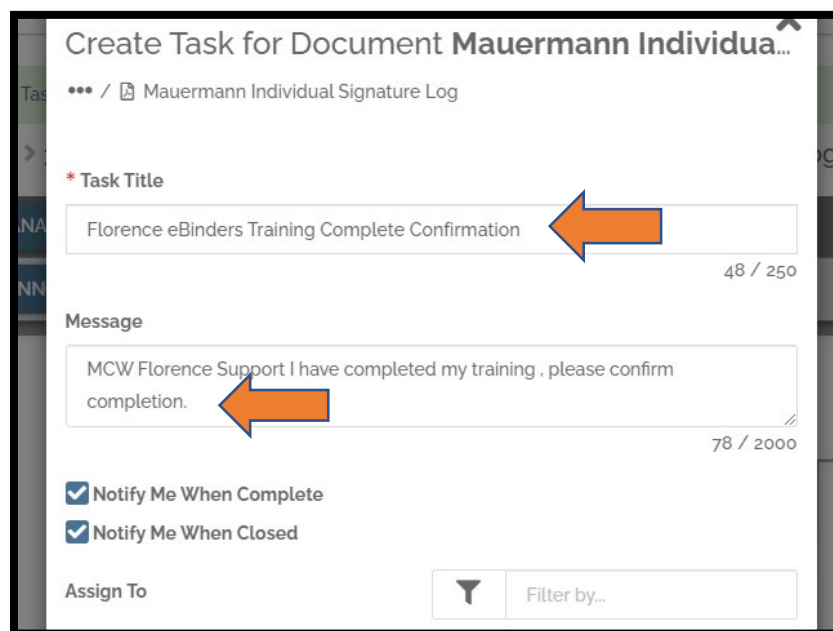
10. Notification of MCW Florence Support Team by Florence Task of training process completion.

- Open your Individual Signature Log, then select the Manage tab
- From Dropdown select Create Task



The Task pop-up will appear.

- In Field Task Title enter "Florence eBinders Training Complete Confirmation"
- In Message field enter "MCW Florence Support: I have completed my training, please confirm completion."
- Select **Susan Mauermann & Jennifer Brown** from the "Assign To" selections.
- Push the **SAVE** button in the bottom to submit.



Your Florence eBinders training is complete! Thank you for completing the training and thank you for helping improve the efficiencies of MCW clinical research.