Florence eBinders Training for MCW Investigators

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, investigators 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 Investigator Training

Review the Required Compliance Training Materials

1. The access link to the Florence online training modules can be found **HERE.** Follow the steps to Register to access the training modules once you click the hyperlink. View the four (4) training modules, which walk you through how to locate & e-sign study documents and eLogs in Florence eBinders. **Total online training time should take less than 15 minutes.**

2. Review the **"Use of Florence eBinders™ for Electronic Records and Electronic Signatures" SOP**.

Attestation of Completion of Required Training by Investigator

3. **REQUIRED STEP!** Once all four 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.

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

    **Note: if you would like access to the Florence UAT/training environment, please contact Florence support at Florence@mcw.edu.

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 MCW 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 *1.0 MCW Investigator Credentials (PI and Sub-Investigator)*, then find your name or individual credentials folder.
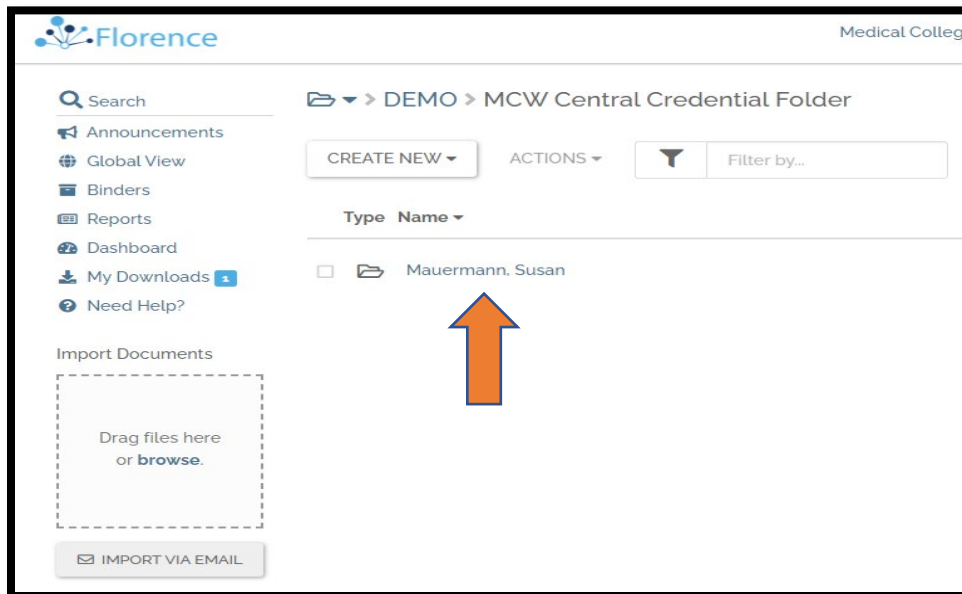
   o Open your personal credentials folder, look for the sub-folder *"1. Florence Training Documents"* all remaining tasks are completed in this sub-folder. The screen shot below shows where your navigation will land.
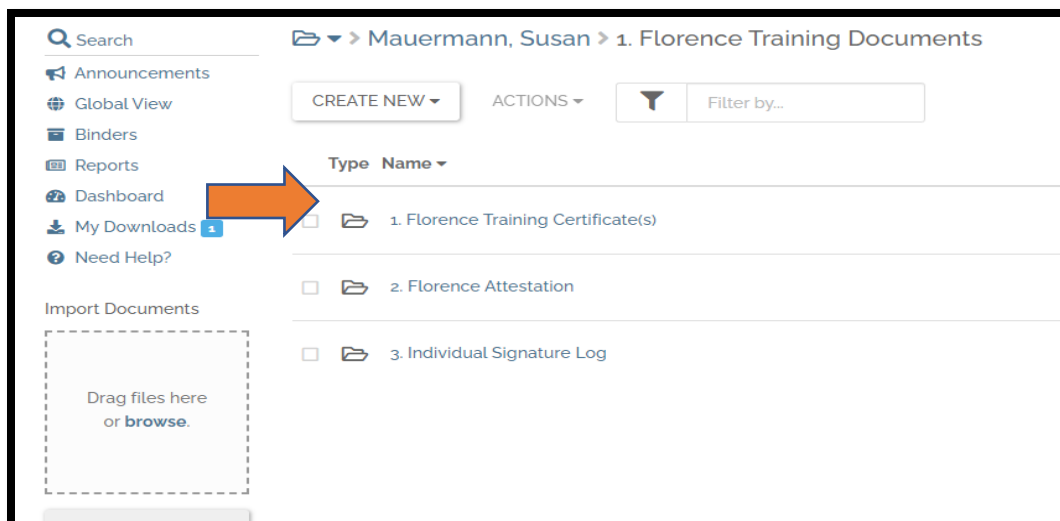
7. Open the first folder, *"1. Florence Training Certificate"*
   - Confirm the spelling of your name and date of training completion (bottom left-hand corner).
   - This information is auditable by the FDA, so accuracy is important. Notify Florence@mcw.edu of any errors.

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 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.
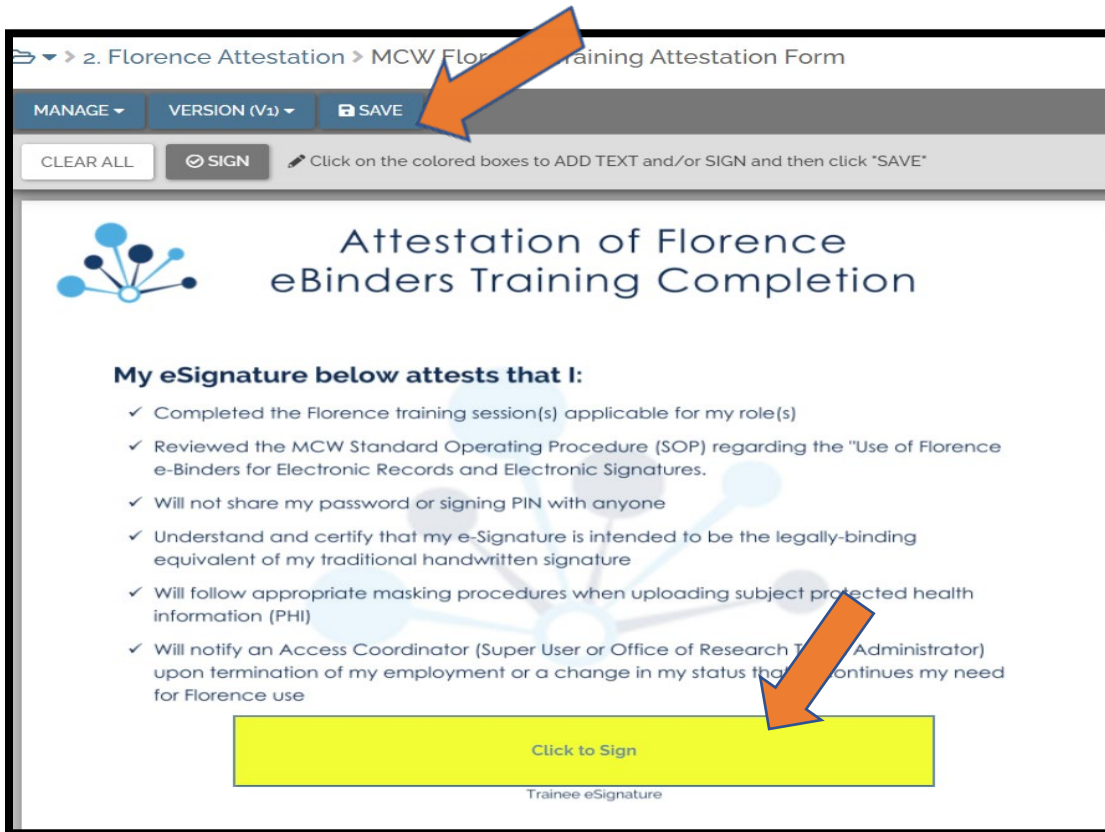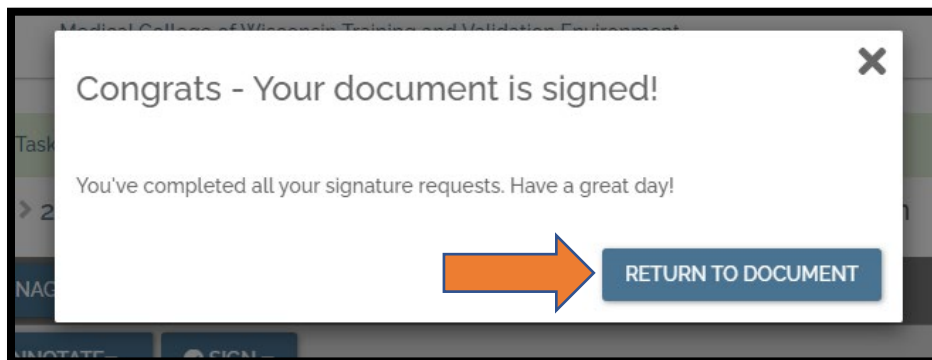

   - You will receive a notification "Finish Setting Up Your PIN" in your MCW Outlook Inbox. This is tied to your MCW single-sign-on credentials and will be required to use this PIN each time you e-sign a document in Florence.
   - Once you have your PIN, go back and e-sign the Attestation form.
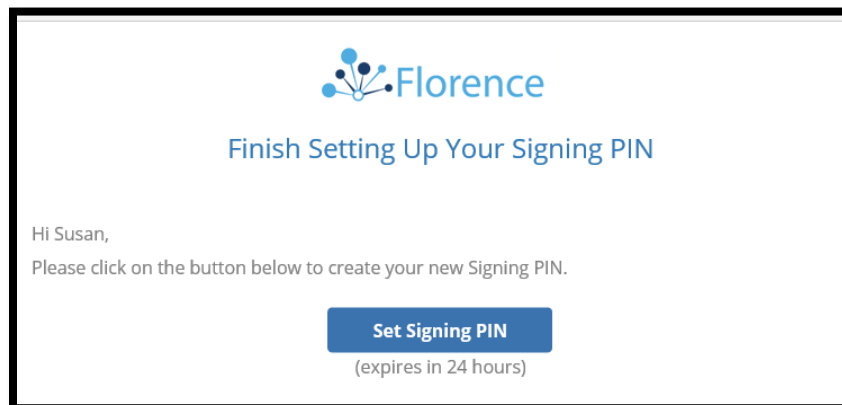
o   After clicking the yellow signature box, you will receive a pop-up window allowing you to complete the e-signature process.
     ❖ Enter the **Reason** of **"Approval"** from the dropdown
     ❖ Enter the **PIN** you just created in box next to the picture of the key. Notice you can always RESET YOUR SIGNING PIN in this field.
     ❖ Then select button **FINALIZE FORM**

⚠ Are You Sure?

This action will create a new version of the document.

FINALIZE FORM:
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.

I, **smauerma@mcw.edu**, am authorizing 1 form signature(s):

* Reason
Approval ▾

* Signing PIN
🔑 | ....

RESET MY SIGNING PIN?

* Required by **21 CFR Part 11**

CANCEL   FINALIZE FORM

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

Congrats - Your document is signed!   ✕

You've completed all your signature requests. Have a great day!

RETURN TO 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.
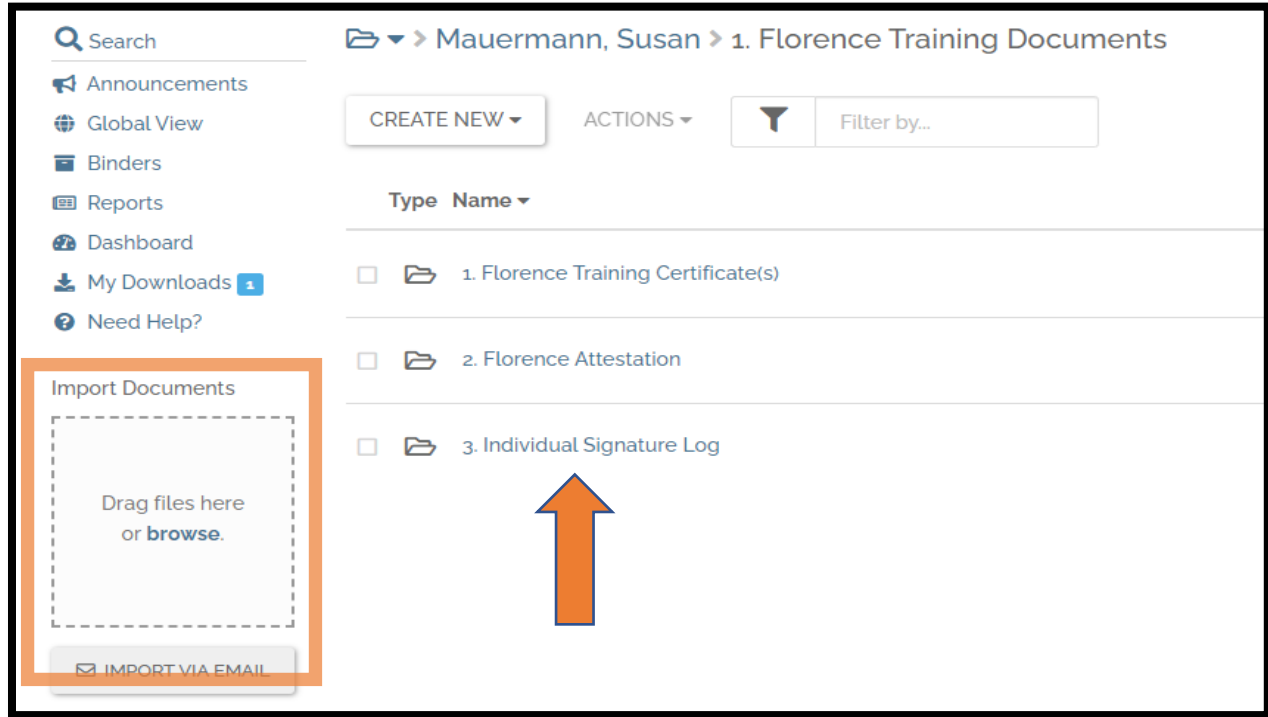
- Click on the folder title to go into the empty "3. Individual Signature Log" folder. This directs Florence where you want the document to be uploaded.
- By using the **Import Documents box**, found on bottom left-hand corner of your screen, **click on browse**, and find the Individual Signature Log 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 the upload is usually a quick process.
- 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. Email Florence@mcw.edu to notify the MCW Florence Support Team that your Florence training is complete.

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