



Florence eBinders Access for External Monitors

Welcome to Florence eBinders! Florence eBinders will provide an accessible, transparent, cloud-based central repository for all essential regulatory documents to accelerate new study startup and support sponsor access for remote monitoring.

Prior to being provided access to the MCW Florence eBinders Production environment, sponsor/CRO monitors must complete the required training components for MCW to maintain compliance with Federal regulations (21 CFR Part 11) and HIPAA requirements. Contact MCW Florence Support at Florence@mcw.edu for assistance.

+++++

Steps for External Monitor Access

Review the Required Compliance Training Materials

1. View the 4-minute [Monitor training video](#), which walks you through how to locate & e-sign study documents in Florence eBinders.
2. Review the [“Use of Florence eBinders™ for Electronic Records and Electronic Signatures” SOP](#)

Attestation of Completion of Required Training by External Monitor or Auditor

3. **REQUIRED STEP!** Copy, paste and email the following statement to the Florence@mcw.edu: *“I am providing electronic attestation that I have completed the required review of the Find & Sign training video and have read the MCW SOP -Use of Florence eBinders™ for Electronic Records and Electronic Signatures”, attesting to the Office of Research and MCW Compliance that you have completed these required training elements.*

Access to Florence eBinders Production Environment

4. Once your attestation email 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.

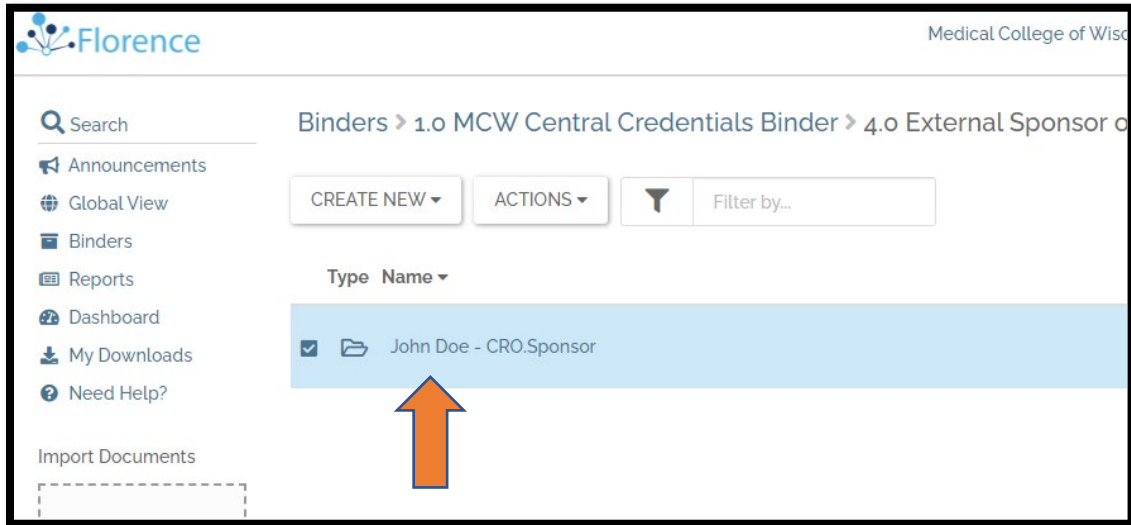
Your Production account will be created by MCW Florence support within 3-5 business days. Your Florence eBinders invite to register & log in will expire after 24 hours of receipt. If your invite expires contact Florence@mcw.edu request a second invite be sent because yours expired.

Training Application & Documentation

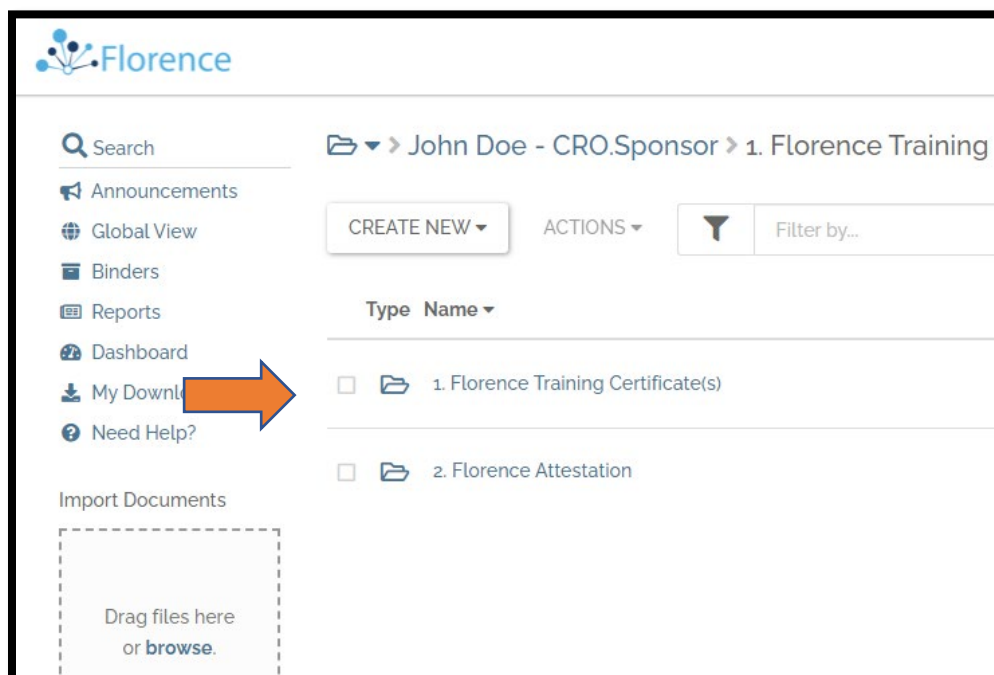
5. Prior to entering the Florence eBinders Production environment:
 - o Accept your Invite to register & access the Florence Production environment.
 - o **Bookmark** this [link to eBinders Production Login page](#) for easy accessibility.

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

- 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.
 - To locate, open the Folder, open *4.0 External Sponsor or Delegates Credentials*, then find your name or individual credentials folder.



- 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.
- 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.

5 / FL
Fo

MANAGE ▾ VERSION (V2) ▾ SAVE

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

External Monitor Attestation of Florence eBinders Training Completion

My eSignature below attests that I:

- ✓ Completed the Florence training session(s) applicable for my role as external monitor/ sponsor representative.
- ✓ 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 confidentiality procedures when reviewing subject protected health information (PHI)
- ✓ Will notify Study Coordinator and/or MCW Florence Support Team upon termination of my employment or a change in my status that discontinues my need for Florence use

Click to Sign

Trainee eSignature

9. 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 **PASSWORD** you use to access Florence as you PIN.
- ❖ 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, **l. smauerma@mcw.edu**, am authorizing 1 form signature(s):

* Reason
Approval

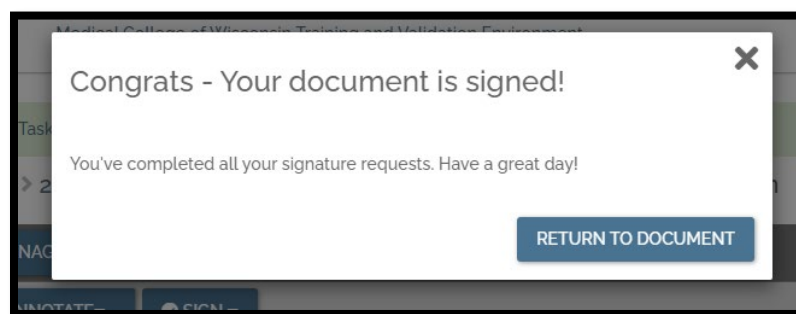
* Signing PIN

[RESET MY SIGNING PIN?](#)

* Required by **21 CFR Part 11**



- 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.



10. Email your MCW study coordinator and MCW Florence Support Team (Florence@mcw.edu) to confirm that your training is complete.