



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.

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Steps for External Monitor Access

Review the Required Compliance Training Materials

1. The access link to the Florence online monitor training modules can be found [HERE](#). Follow the steps to Register to access the training modules once you click the hyperlink. View the four (6) training modules. Total online training time should take 30 minutes. **Please note that if you have already completed Florence Monitor training, we will accept your existing certificate.**
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!** Once all 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. **Please make sure to include the name of the study you will be monitoring and copy the MCW clinical research coordinator/contact that you have been corresponding with on this email.**

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

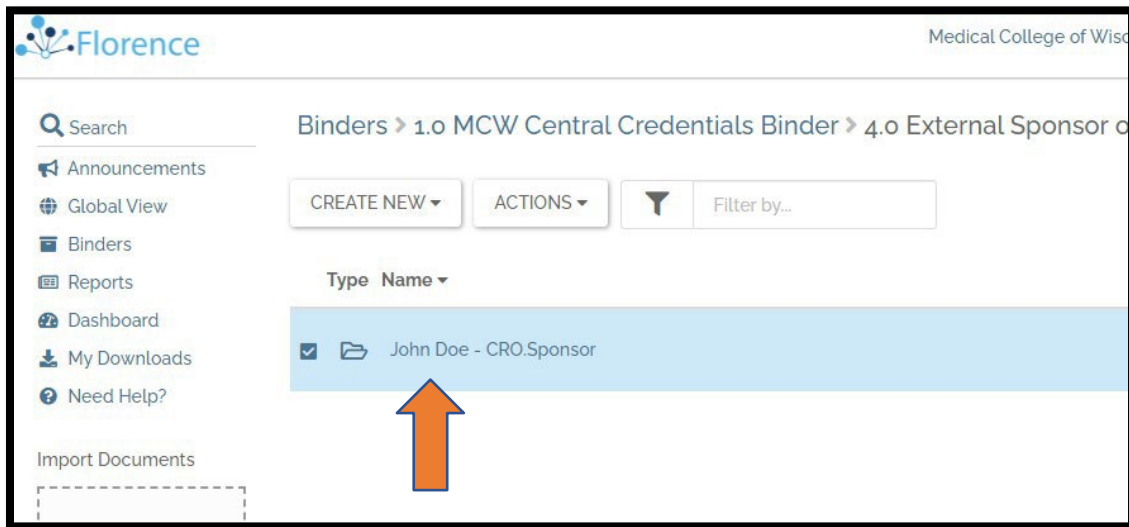
5. Prior to entering the Florence eBinders Production environment:

- Accept your Invite to register & access the Florence Production environment.
- **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.

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.

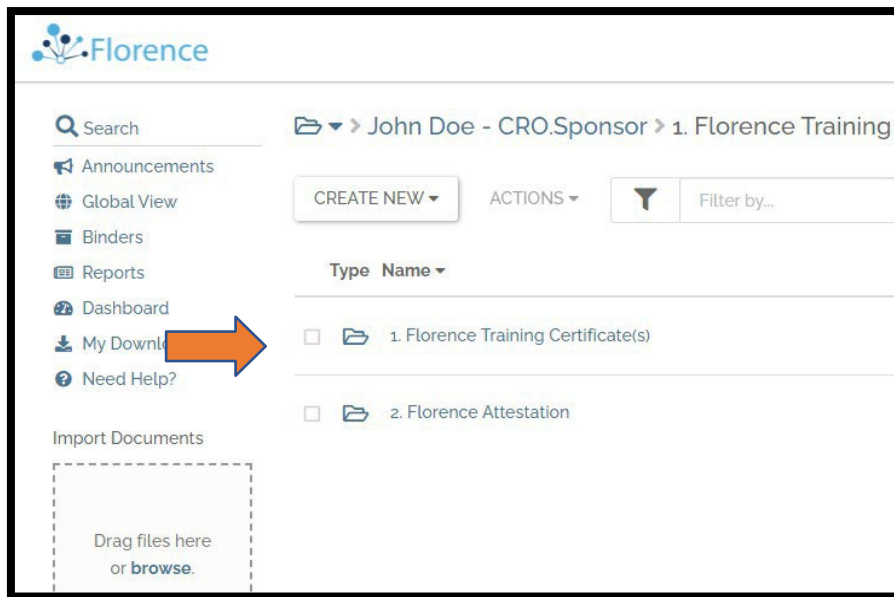
- To locate, open the Folder, open *4.0 External Sponsor or Delegates Credentials*, then find your name or individual credentials folder.



- 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.

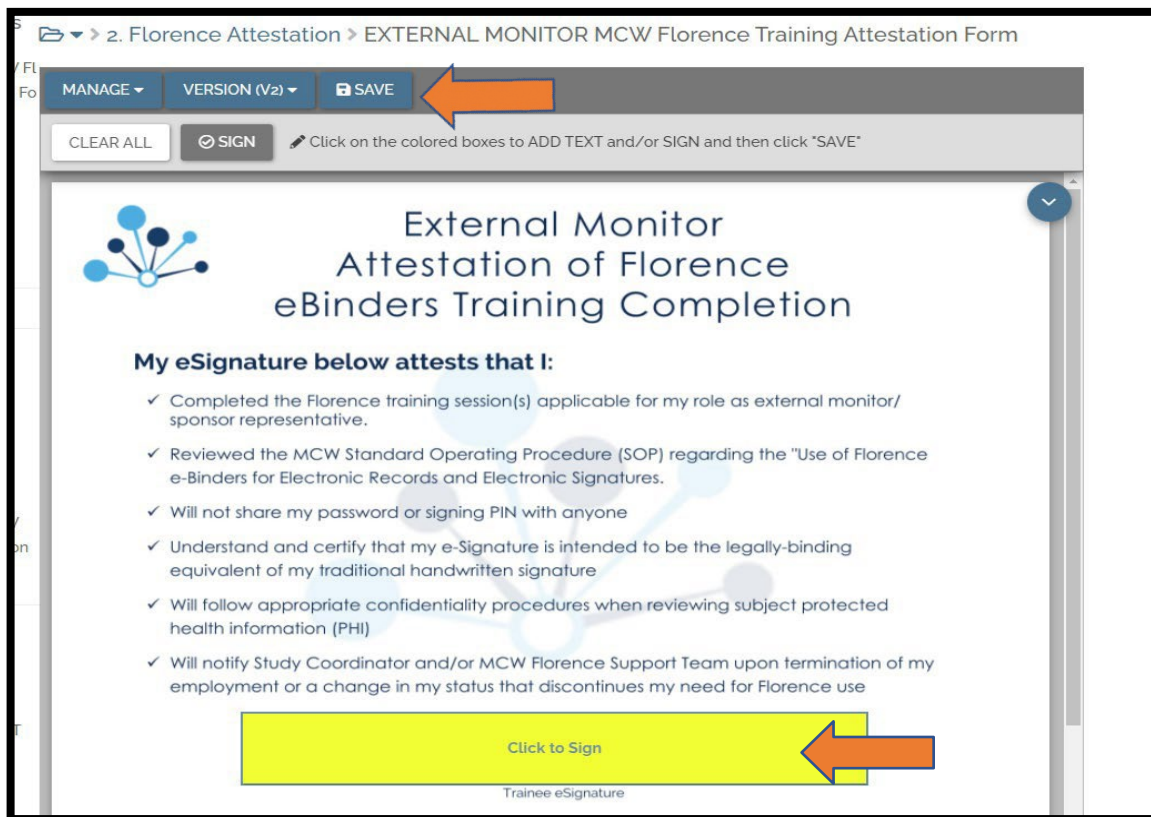
7. Open the first folder, "*1. Florence Training Certificate*"

- 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.

- o 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.



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.

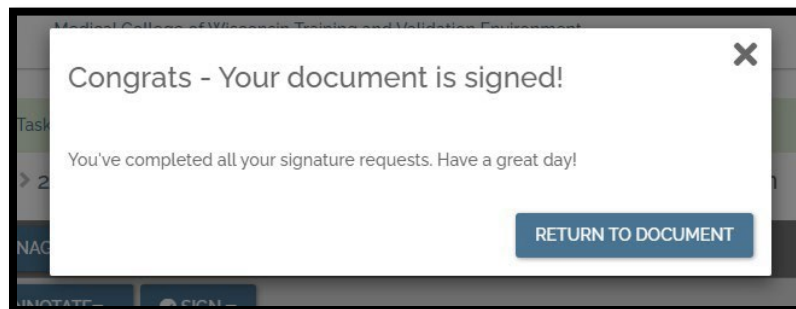
I, smauerma@mcw.edu, am authorizing 1 form signature(s):

* Reason
Approval

* Signing PIN
[Key icon] [....] [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.