



Training Companion Guide: Managing Your Florence Study eBinders

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This step-by-step guide will review options for filling a study eBinder established using the MCW minimum footprint. Workflows reviewed in this guide will include template duplication, creating folders, applying shortcuts, uploading or moving documents, and use of the Florence ePrinter function.

Prior to being provided access to the MCW Florence eBinders Production environment, research investigators & staff are required to 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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Based on the user role assigned to you (Manager, Coordinator, Superuser, etc.) will determine which eBinders will appear on your eBinders home page in the MCW production environment. The following Central eBinders are available to all MCW users. Role appropriate access is provided to Affiliate or External Users (monitors or auditors).

MCW Central eBinders

- 1.0 MCW Central Credentials Binder
- 2.0 MCW Central Templates Binder
- 3.0 MCW Central Resources Binder

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1.0 Duplication

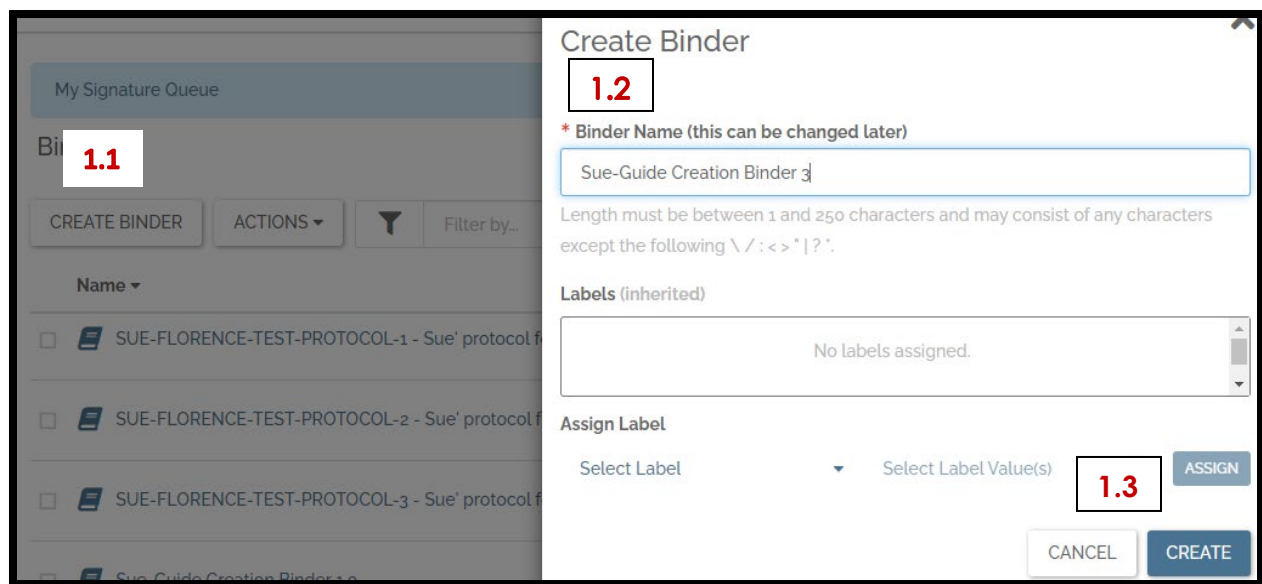
Florence Reference-Article Duplicating folders & documents

Duplication is the primary method used to manually create a new eBinder shell if one is not created automatically by OnCore. **Note: manual creation of a new eBinder is only allowed to those assigned a Florence super user or Florence Admin Team role. If you need an eBinder created, contact your dept. Superuser or Florence@mcw.edu.**

Duplication is also used when adding additional folders to an existing eBinder (i.e., when adding a new participant folder, or IRB submission). For your convenience, applicable templates can be found in the 2.0 MCW Central Templates Binder for your use to duplicate and apply to your study binders.

Manually create new eBinder Shell

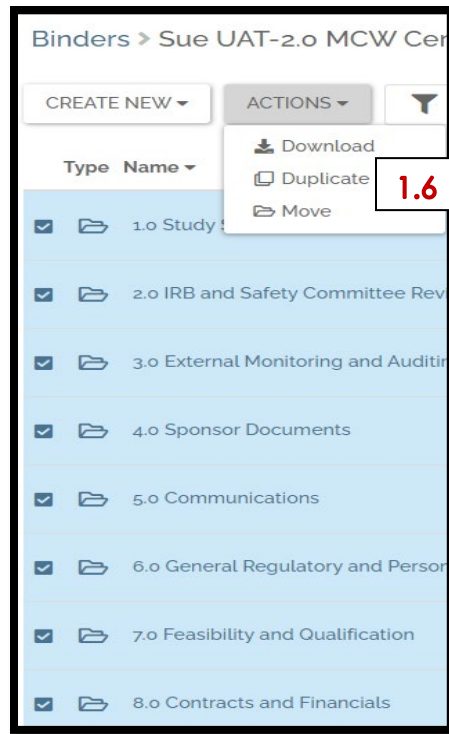
- 1.1 On the Florence eBinders home page, select **Create Binder** button
- 1.2 Enter **eBinder Name for the new study** binder you wish to create, for consistency, use the same naming convention as outlined in Appendix A.
- 1.3 Finalize by selecting **CREATE** in the bottom right-hand corner of the pop-up



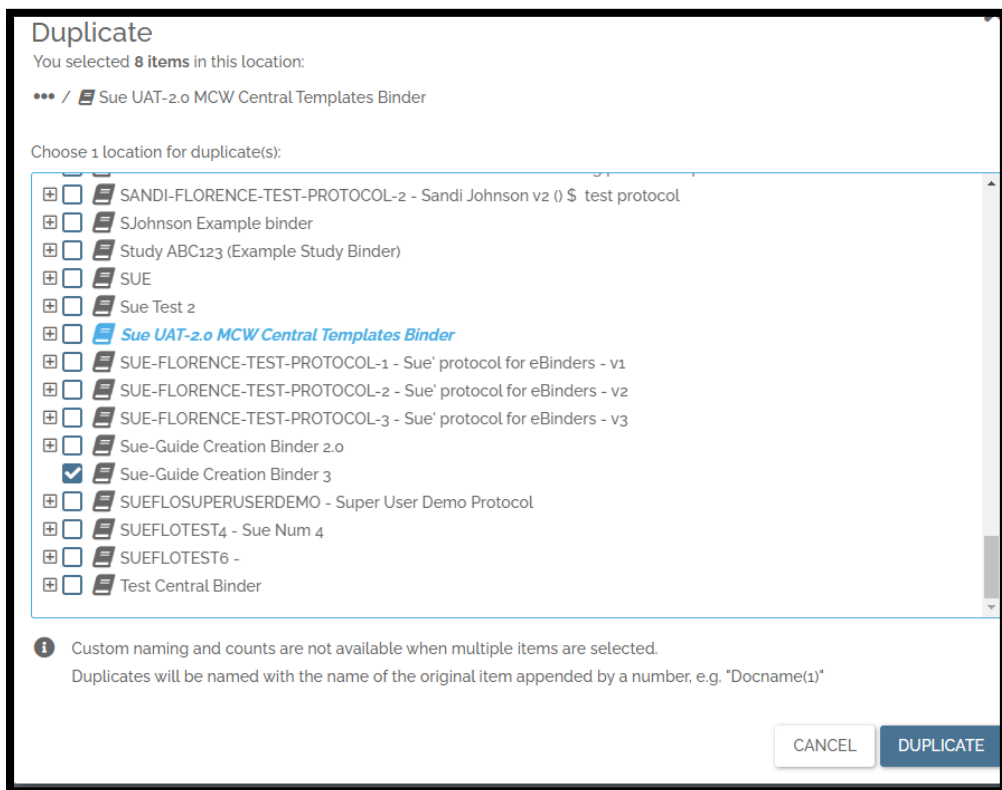
Duplication of the Basic Study Binder Footprint

Open "2.0 MCW Central Templates Binder"

- 1.4 **Open 1.0 Basic Study Binder Footprint** to reveal the sub-folders
- 1.5 Click the checkbox next to each sub-folder
- 1.6 Select **Duplicate** from the **Action's tab** dropdown list above the folder's list



- 1.7 When the pop-up window appears, locate the name of the new study binder you created in step 1.3 and check that box
- 1.8 Select the blue Duplicate box on the bottom corner of your screen



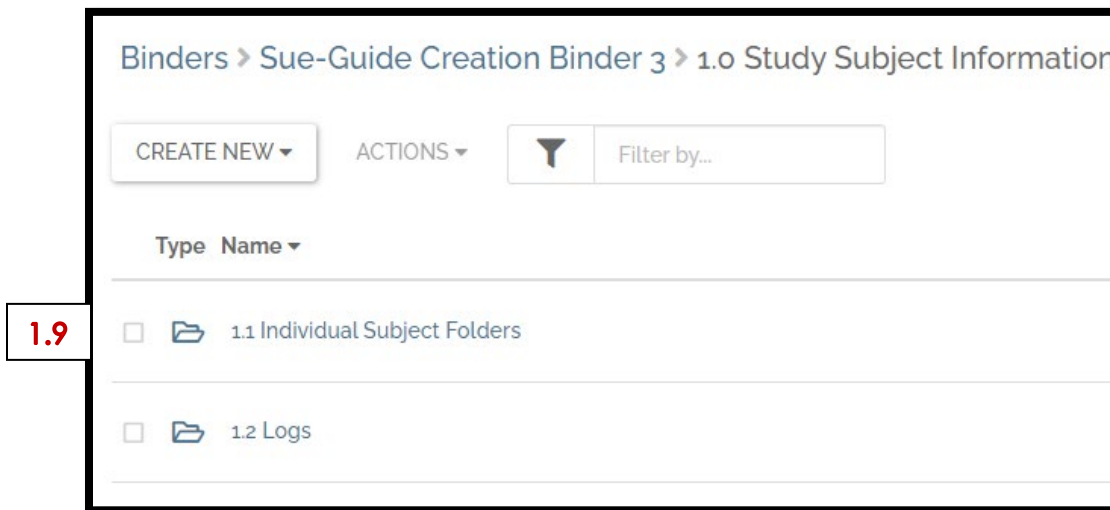
Congrats! You have now applied the Basic Study Binder Footprint for your new study eBinder & it is ready to be filled with your study documents!!

Duplication of a MCW template with purpose of adding to an existing eBinder Shell

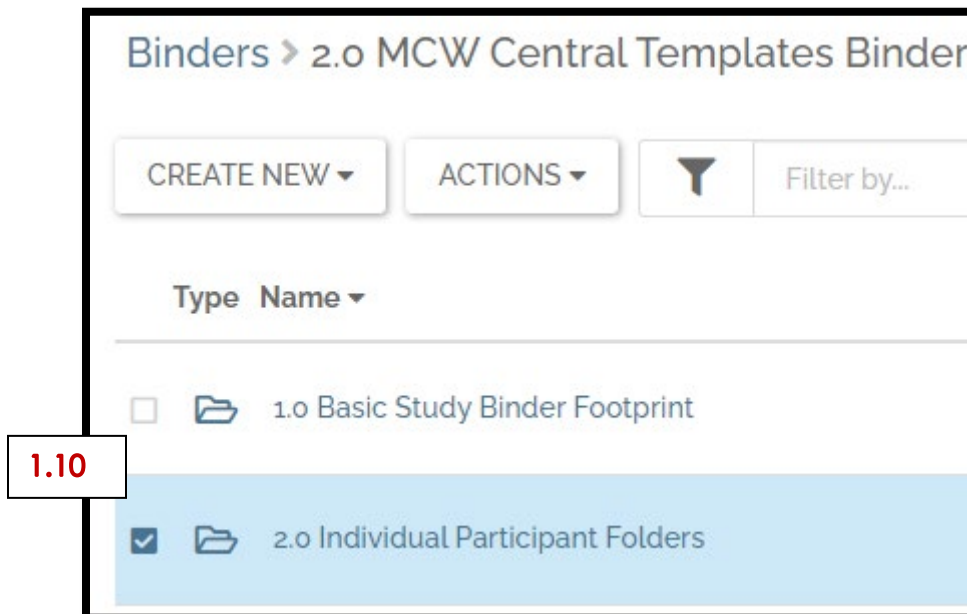
These steps allow you to add individual subject folders (Individual Participant Folder), IRB amendment (full or administrative), IRB Continuing Progress Reports or other current and future templates into a study eBinder.

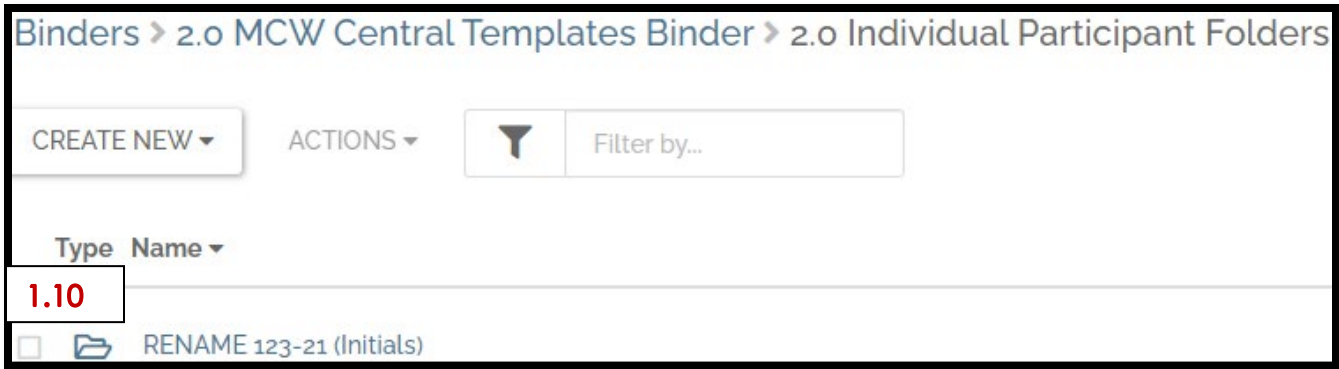
Adding an Individual Participant Folder template to the study eBinder

- 1.9 In your study eBinder, locate sub-folder "1.1 Individual Subject Folders." This sub-folder is where each research subject folder will be added in the study eBinder.



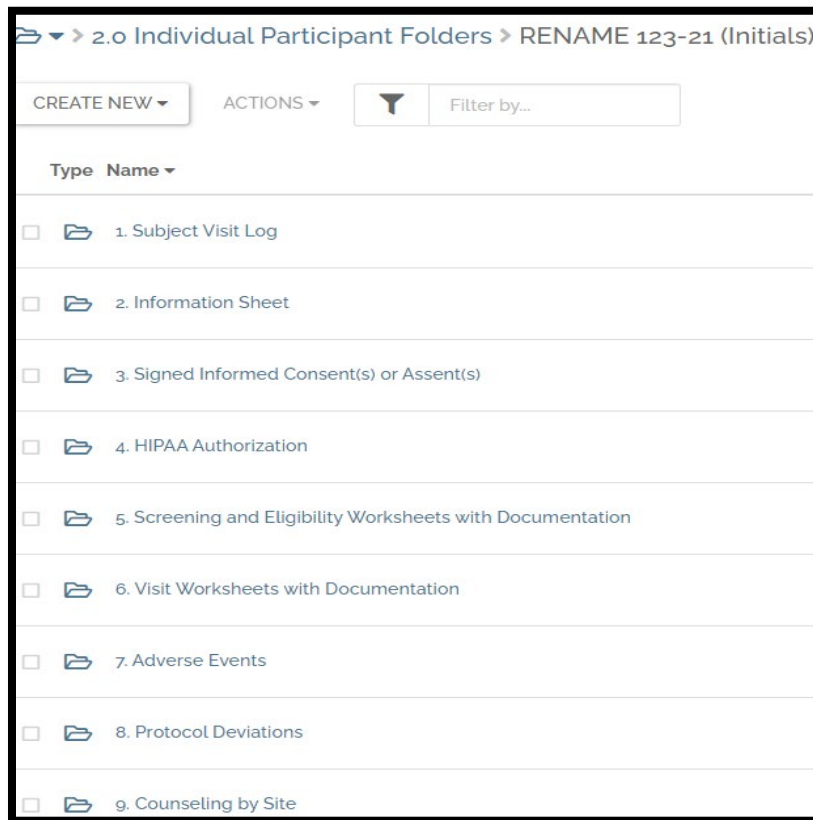
- 1.10 Return to the home page and open the MCW Central Templates eBinder. Click on 2.0 Individual Participant Folders to reveal the first sub-folder





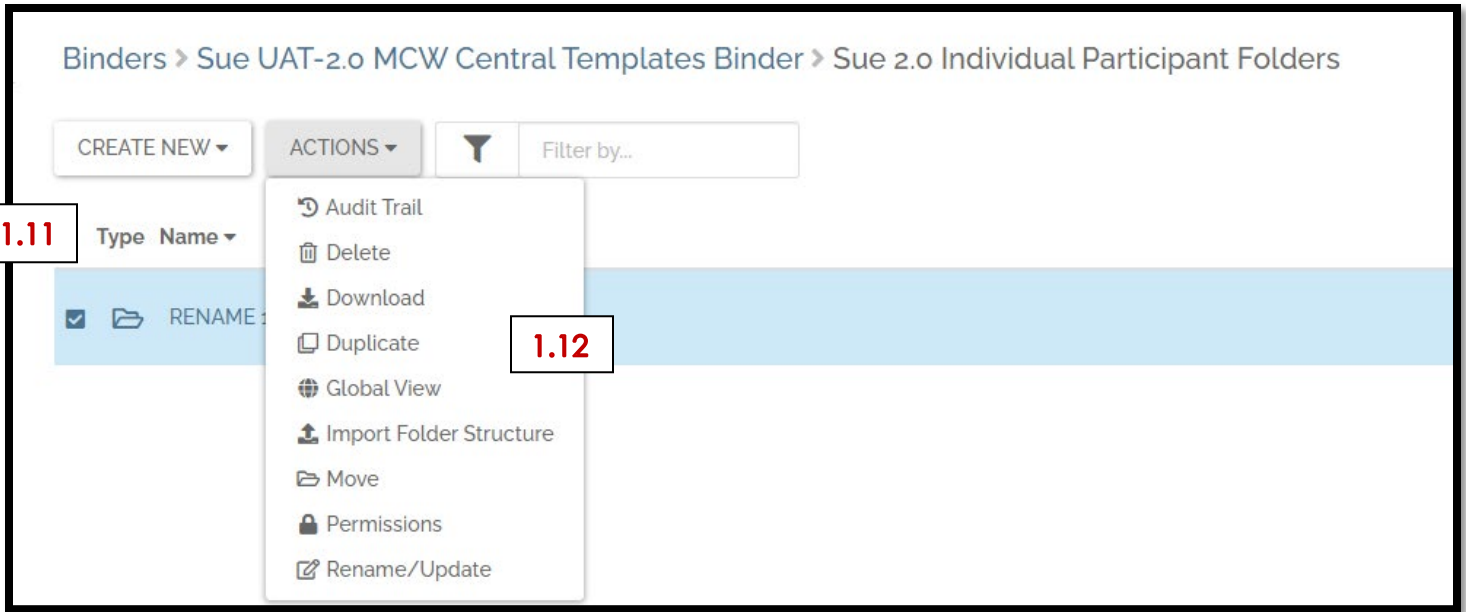
Within the template folder, you will find additional sub-folders/placeholders for subject-related documents. If any components of an individual subject binder are missing, you can rename or add a sub-folder, as necessary. If there are components you consider unnecessary, you do not need to use or delete them.

+++++The contents of the Individual Participant Folder eBinder template+++++

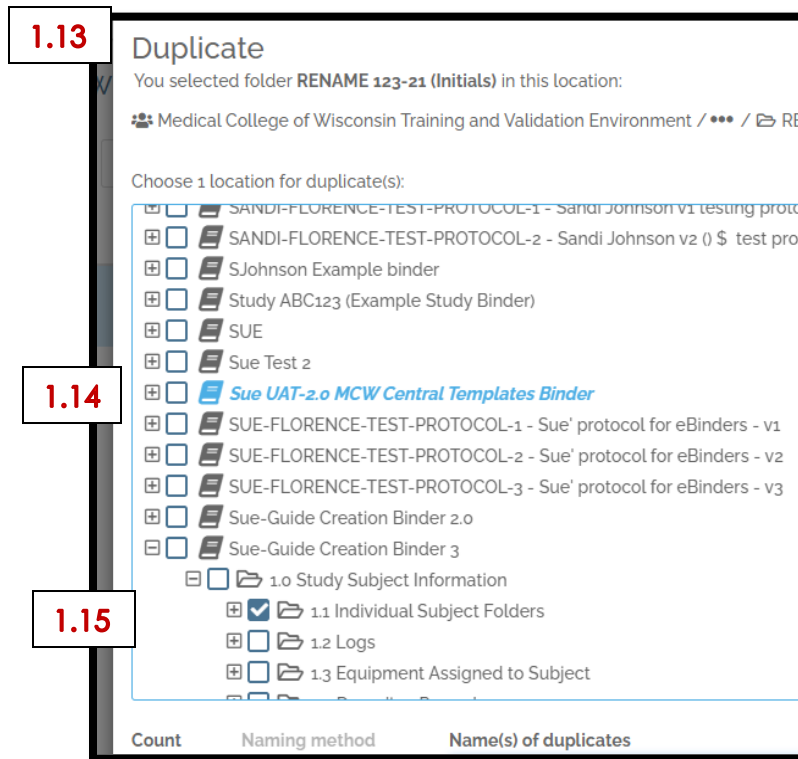


Duplicating the first sub-folder you see, “RENAME 123-21 (Initials)”, allows you secure a separate folder for each individual subject and all the contents of the sub-folder-

- 1.11 **Check box** next to “RENAME 123-21 (Initials)”
- 1.12 Select **Duplicate** from the **Actions tab** dropdown list above



- 1.13 When the pop-up window appears, locate the study binder where you will add the subject folder, click the + sign next to the folder name to open the branching. Continue opening the branches by clicking the + sign next to 1.0 Study Subject Information.
- 1.14. Folders with italicized blue font in the pop-up represent the source of the template you have duplicated.
- 1.15 The **destination sub-folder** within your study binder is "1.1 Individual Subject Folders" Check the box next to this sub-folder.



1.16 When Duplicate is initially selected, the name of the template you have selected appears in the box identified below, under "Name(s) of duplicates". This is where the unique Study ID/initials is added for each subject in the study. The option to change the contents of the box only opens once you have checked the box of the **destination sub- folder**.

Count	Naming method	Name(s) of duplicates
1	Same for all	RENAME 123-21 (Initials) 1.16

Max length 250. These characters are not allowed:
\\/:<>\"/>

CANCEL DUPLICATE

1.17 Enter the unique identifier for your subject, the first subject example entered Study ID 123-01 (SKM).

*****IMPORTANT*****

This is a critical step because if you use the default name in the template:

- **The subject is not uniquely identified**
- **If you do it a second time, Florence will simply copy the new duplicate subject template folder over the contents of the pre-existing folder in your binder with the same name.**

Subjects should only be added in Florence when they are issued a Unique Study ID. If subjects receive a separate Screening ID and Enrollment ID, the folder can be re-named in your eBinder after they are enrolled in your study. We will review renaming a folder in a later section.

1.18 Once complete, press the blue Duplicate box on the bottom corner of your screen.

Duplicate

You selected folder **RENAME 123-21 (Initials)** in this location:
Medical College of Wisconsin Training and Validation Environment / ... / RENAME 123-21 (Initials)

Choose 1 location for duplicate(s):

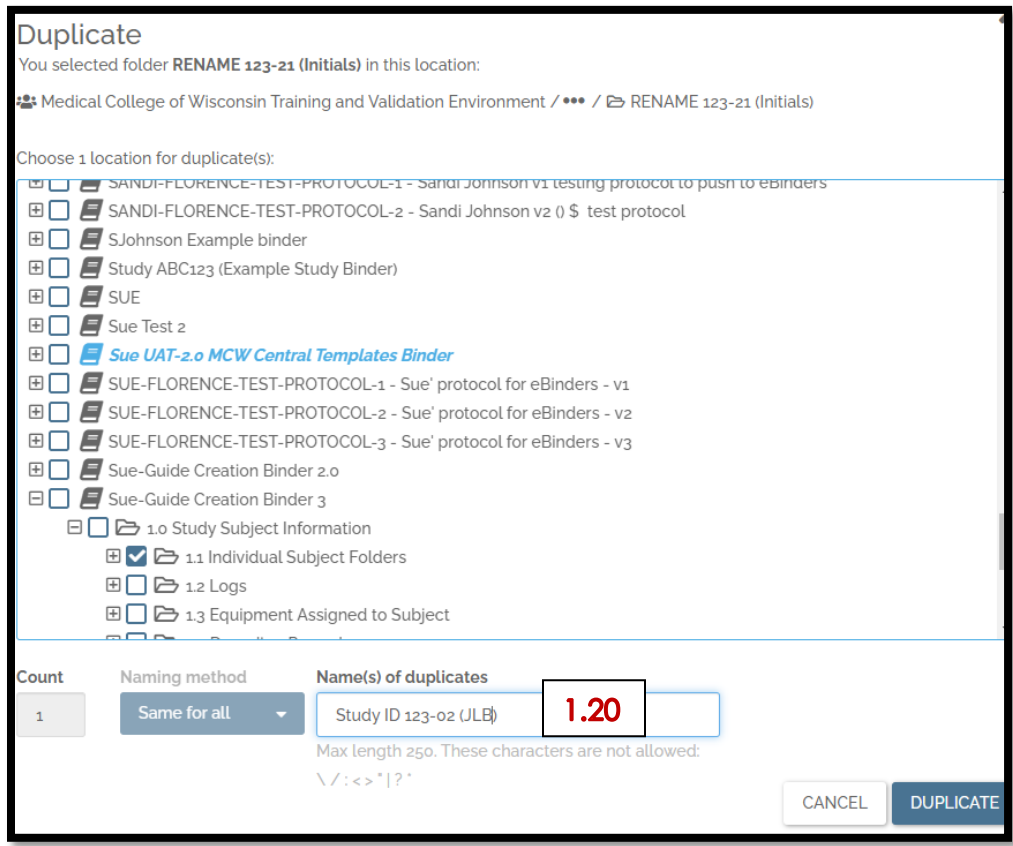
- SANDI-FLORENCE-TEST-PROTOCOL-1 - Sandi Johnson v1 testing protocol to push to ebinders
- SANDI-FLORENCE-TEST-PROTOCOL-2 - Sandi Johnson v2 () \$ test protocol
- SJohnson Example binder
- Study ABC123 (Example Study Binder)
- SUE
- Sue Test 2
- Sue UAT-2.0 MCW Central Templates Binder**
- SUE-FLORENCE-TEST-PROTOCOL-1 - Sue' protocol for eBinders - v1
- SUE-FLORENCE-TEST-PROTOCOL-2 - Sue' protocol for eBinders - v2
- SUE-FLORENCE-TEST-PROTOCOL-3 - Sue' protocol for eBinders - v3
- Sue-Guide Creation Binder 2.0
- Sue-Guide Creation Binder 3
- 1.0 Study Subject Information
 - 1.1 Individual Subject Folders
 - 1.2 Logs
 - 1.3 Equipment Assigned to Subject

Count	Naming method	Name(s) of duplicates
1	Same for all	Study ID 123-01 (SKM) 1.17

Max length 250. These characters are not allowed:
\\/:<>\"/>

CANCEL **DUPLICATE** **1.18**

- 1.19 When adding you next subject you will repeat steps 1.10-1.18
- 1.20 Enter the unique identifier for your next subject, the second subject example entered as Study ID 123-02 (JLB), look to the bottom of the following screen shot



+++This example shows how each of the two enrolled subjects have their individual study folders, which clearly identifies each subject++++



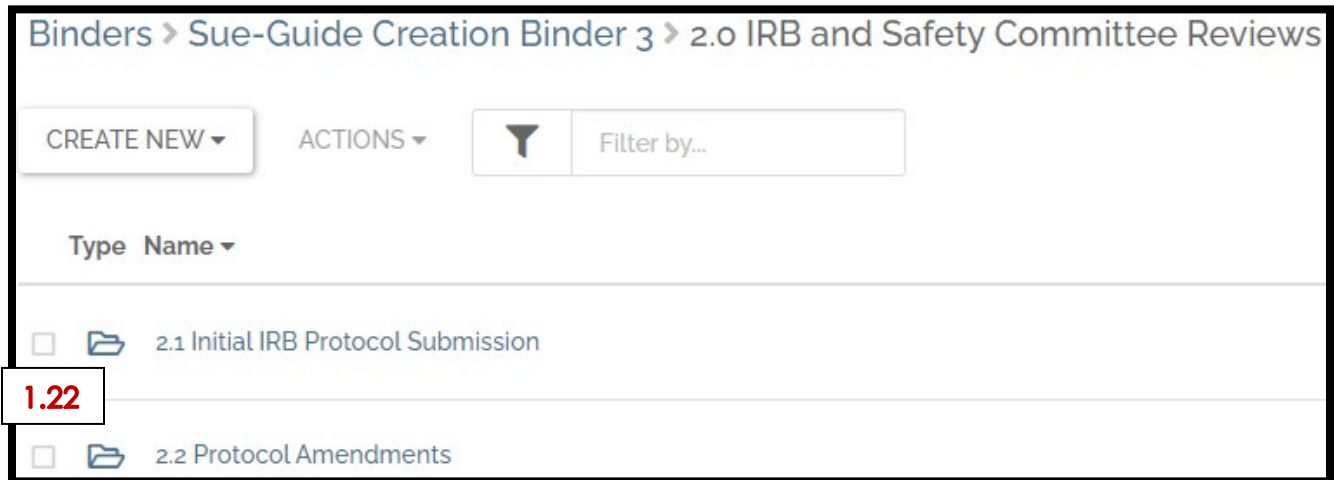
Congrats! Now that you have created your individual subject folder(s) to your new eBinder, it is ready to be filled with your subject's study documents!!

Duplicating MCW IRB templates (AME, CPR, RE)

For this example, adding an IRB Amendment will be used. The same steps would be used to duplicate any template or form included in **2.0 MCW Central Templates Binder**.

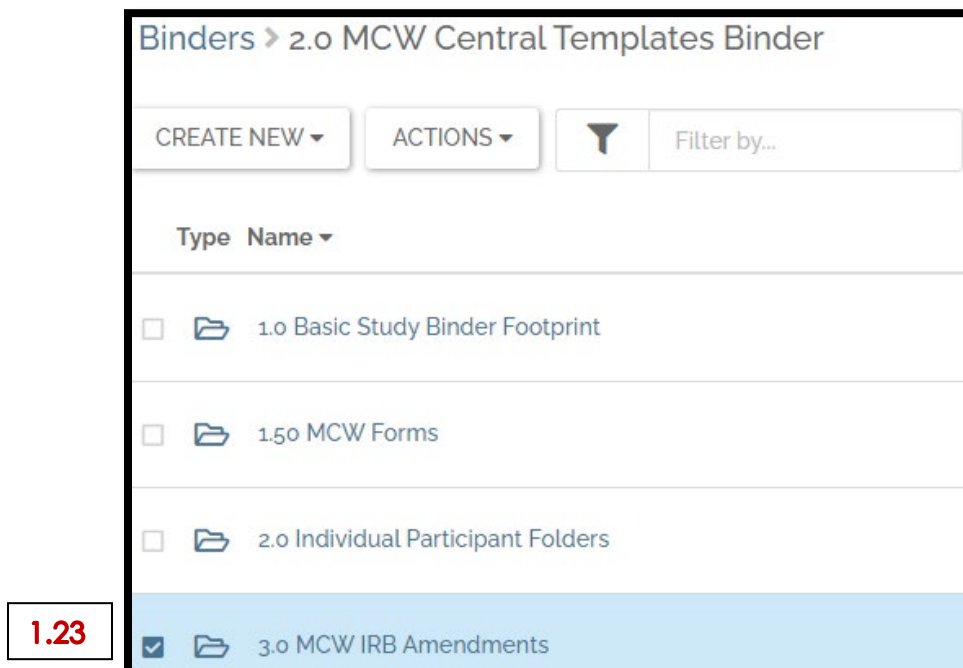
In your study eBinder (the one you are adding the template to)-

- 1.22 Locate sub-folder 2.2 Protocol Amendments. This sub-folder is where each amendment folder will be added in the study eBinder. Consider this to be the equivalent to the amendment section of the paper Regulatory.

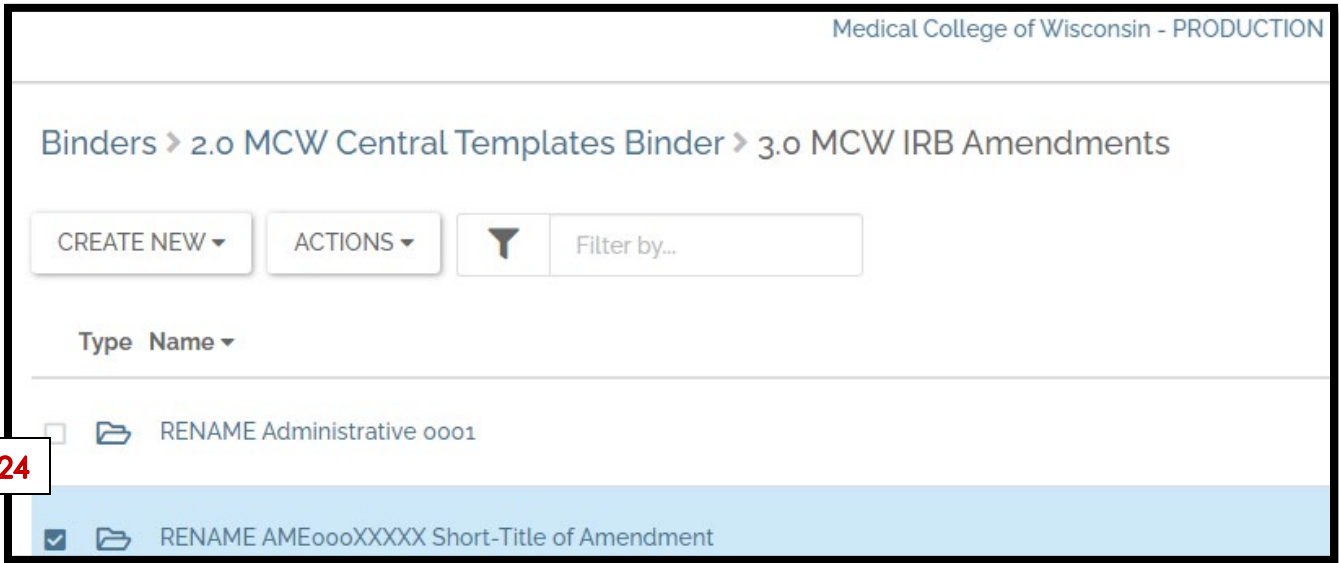


Open the MCW Central Templates eBinder (eBinder 2.0 MCW Central Templates Binder)-

- 1.23 **Click on** 3.0 MCW IRB Amendments folder title to reveal the first layer of sub-folders



- RENAME Administrative 0001- is used for IRB Administrative or Expedited reviews to the project (i.e., study staff changes)
- RENAME AME000XXXXX Short-Title of Amendment- is used for a full committee IRB amendment review

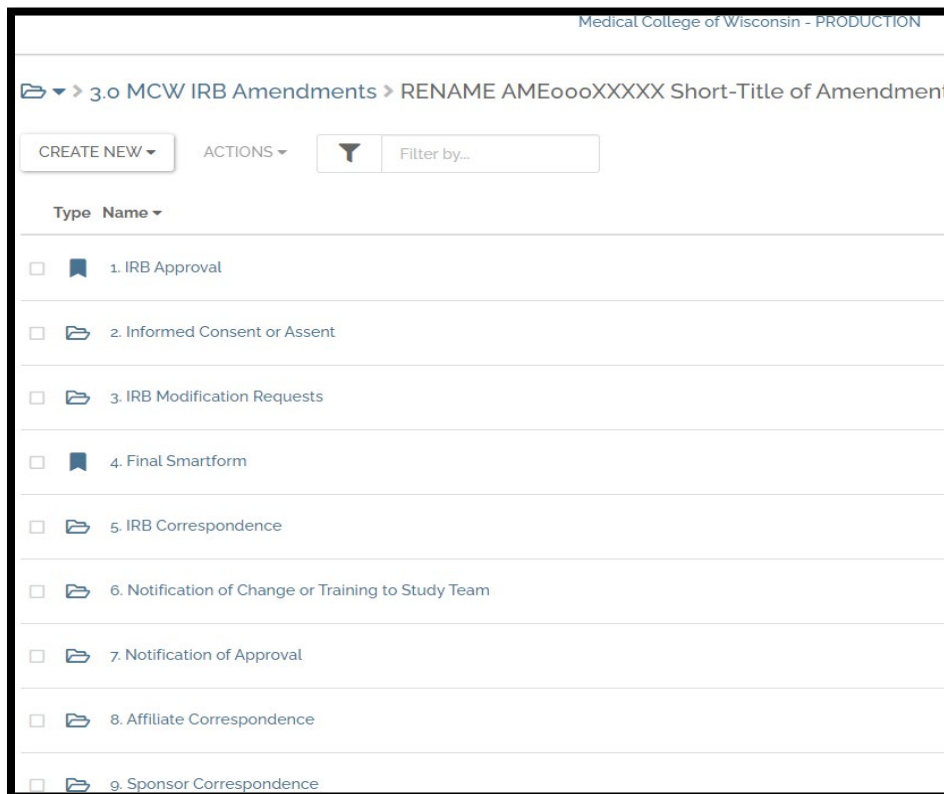


1.24

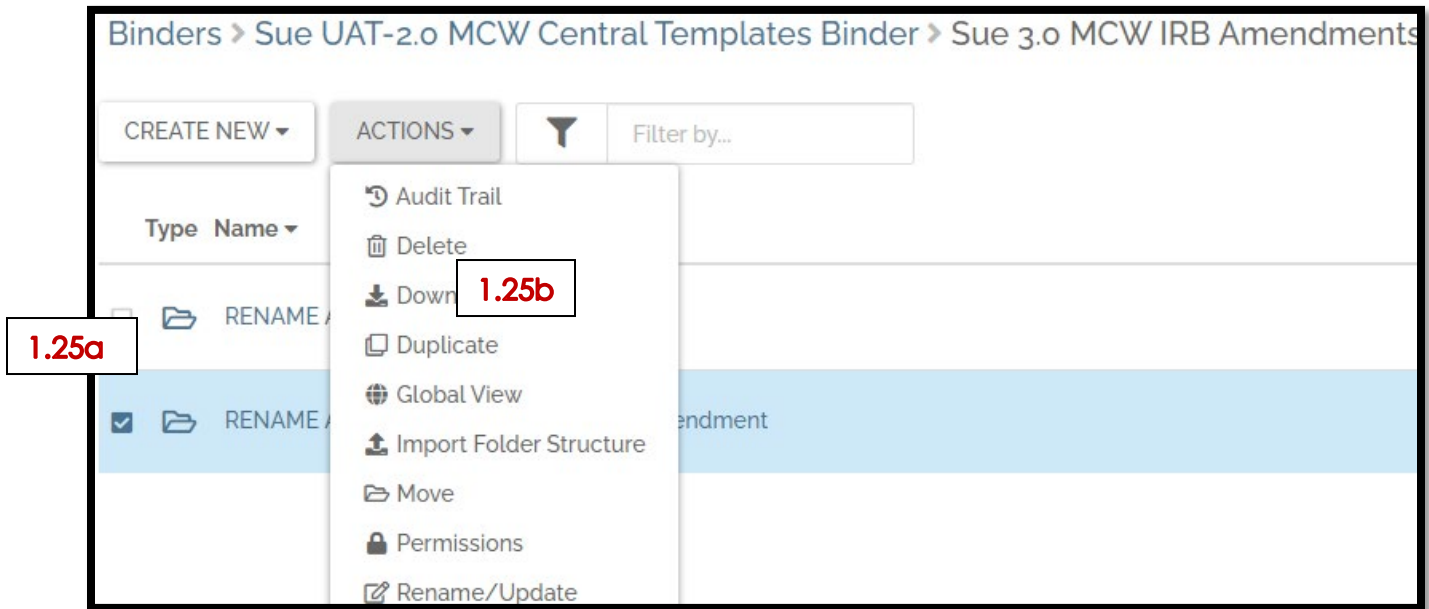
For purposes of this guide the IRB full committee amendment review will be used.

1.24 Click on RENAME AME000XXXXX Short-Title of Amendment to reveal the contents of this template. Once you have reviewed the content return to the previous sub-folder before beginning the duplication process.

+++++The contents of the IRB full committee amendment review eBinder template+++++



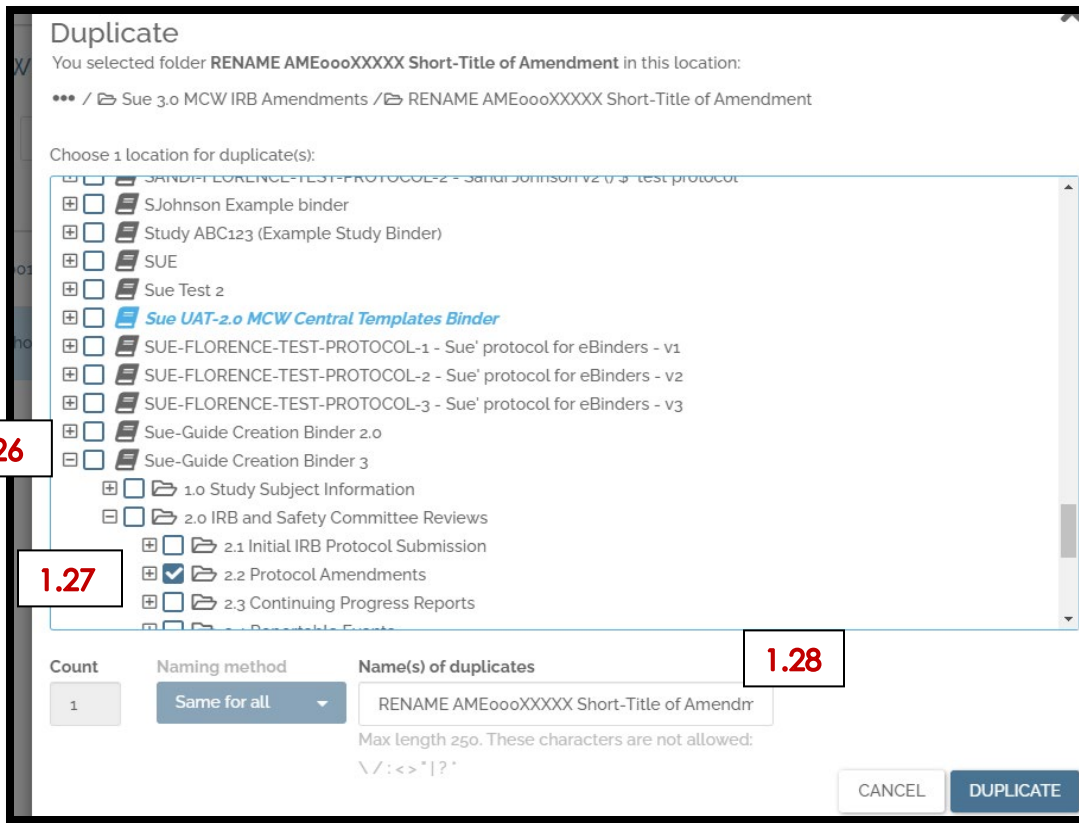
- 1.25 **Check box** next to RENAME AME000XXXXX Short-Title of Amendment, then Select **Duplicate** from the **Action's tab** dropdown list above the folder's list



- 1.26 When the pop-up window appears, locate the study binder name where you will add the amendment template, click the + sign next to the folder name to open the branching. Continue opening the branches by clicking the + sign next to 2.0 IRB and Safety Committee Reviews.
- 1.27 The **final destination sub-folder** is 2.2 Protocol Amendments, check the box next to this sub-folder.

It is anticipated that you may have more than one amendment in your study. You will identify each amendment as your next step of this process.

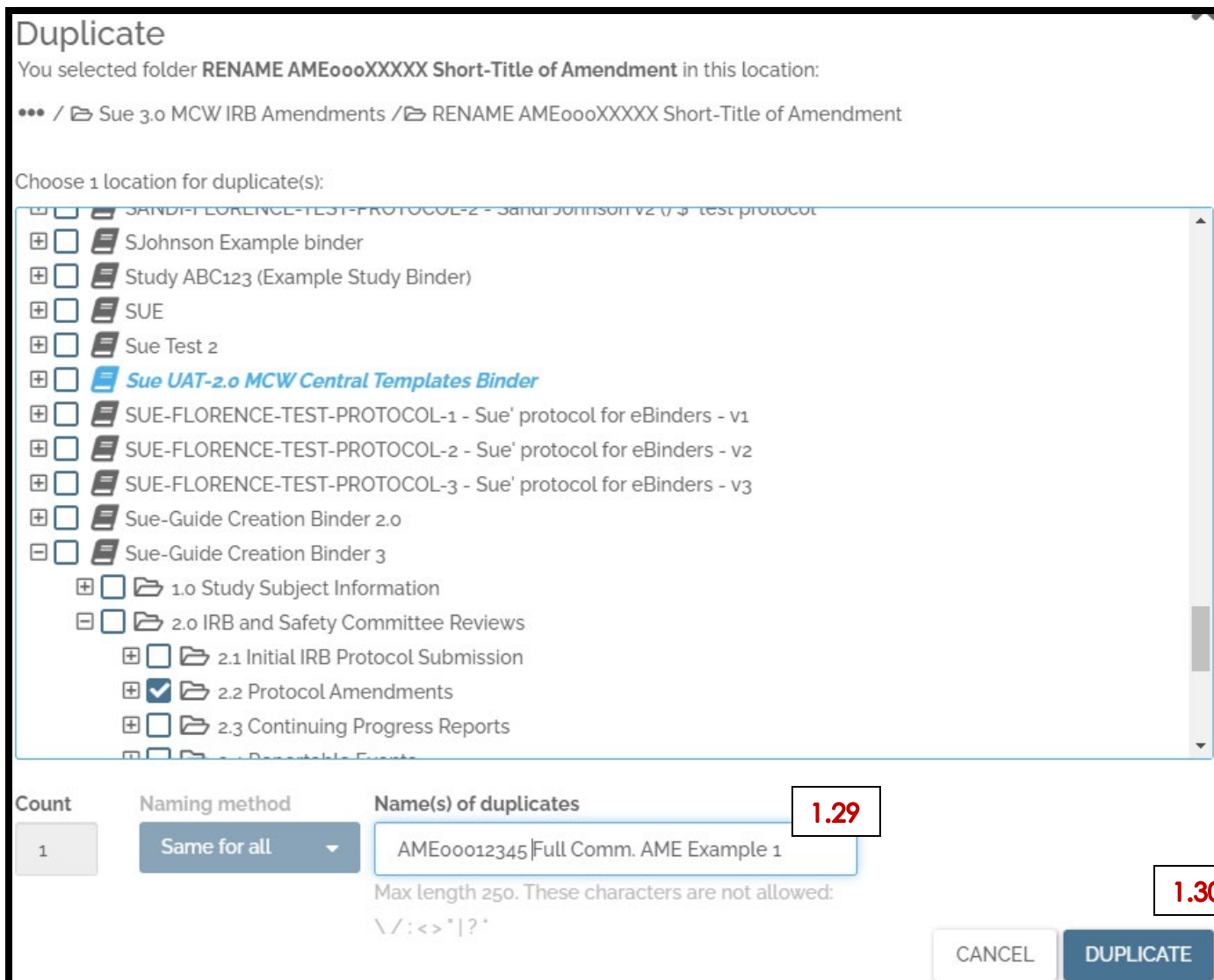
- 1.28 When Duplicate is initially selected, the name of the template you have selected appears in the box identified below -Name(s) of duplicates. This is where the unique Study ID is added for each subject in the study. They option to change the contents of the box only opens once you have checked the box of the **destination subfolder**.



1.29 Enter the unique identifier for each amendment, using the AME number associated with the amendment in eBridge, the first amendment is identified **AME00012345 Full Comm. Example 1**, look to the bottom of the following screen shot

This is an important step as you use the default name in the template

- **The amendment is not uniquely identified**
- **If you do it a second time, Florence will simply copy all the contents the new duplicate folder over pre-existing folder in your binder with the same name. A painful error on the end user part, Florence is only doing a duplicate (copy & paste) as the user is directing it to do.**



Amendments should only be added in Florence when they are issued a Unique amendment ID.

1.30 Select the blue Duplicate box on the bottom corner of your screen.

The screen shot below shows placement of the Amendment in the study eBinder, when duplication is complete.



Steps 1.22-1.30 will be repeated when adding any of the templates to your study eBinder.

2.0 Adding or Deleting a Folder within the eBinder

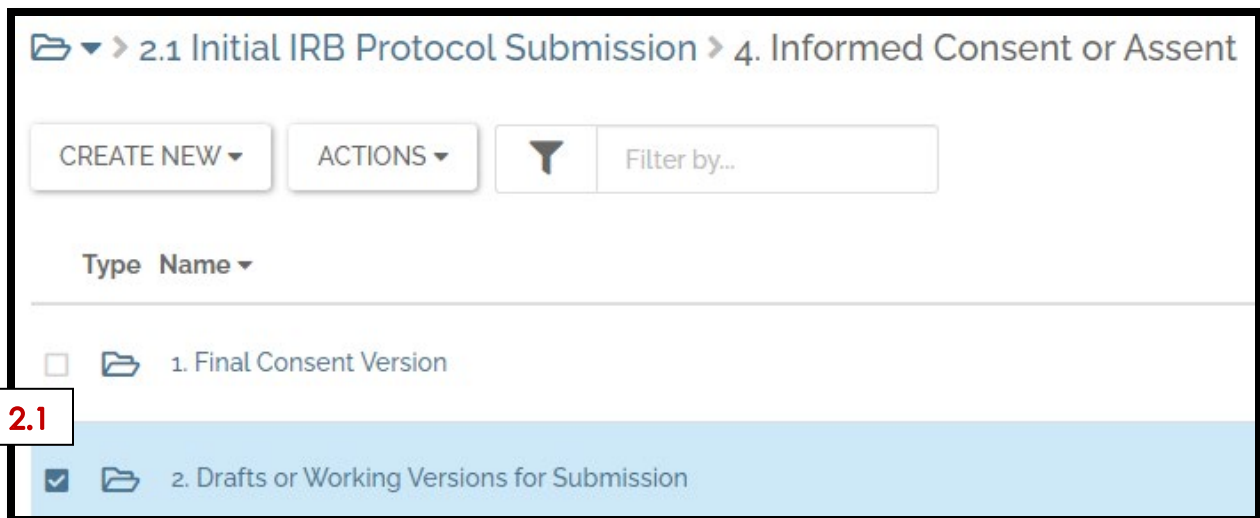
The Basic Study Binder Footprint was created with input and consensus of the MCW Florence Superuser's group with a purpose to create a standard template which would fit the structure for most study eBinders. This basic template may include more or fewer folders than necessary for your study. Each person with a Florence coordinator or Super User role can create folders within an individual study eBinders to replicate folder structure of a paper regulatory binder to accommodate for those missing folders.

To eliminate the chance for an accidental manipulation of the MCW Central Templates, templates and forms can only be duplicated from that eBinder.

++++Only a user assigned Florence Study Coordinator, Super User Admin or Admin Team role can delete a folder or document within their assigned study eBinders, except the MCW Central Binders++++

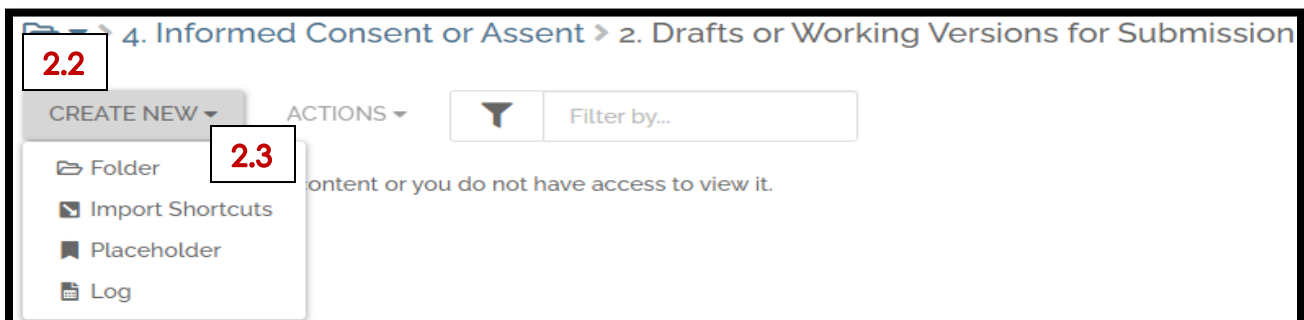
Adding a New Folder

- 2.1 Identify the location where a new folder will be added, then click the folder title to open the folder & reach the desired location for the new folders. For purpose of this guide, a check box is added to highlight the desired location.



- 2.2 After the reaching the desired location for the new folders, open the Create New tab

- 2.3 Select Folder from the dropdown



2.4 In the pop-up Enter the Folder Name in the first box, then select CREATE in the bottom right-hand corner of the pop-up. In this example, find the "Final Working Version"

Create Folder

* Folder Name (this can be changed later)

Final Working Version

Length must be between 1 and 250 characters and may consist of any characters except the following \ / : < > " | ? *

Labels (inherited)

No labels assigned.

Assign Label

Select Label Select Label Value(s) ASSIGN

CANCEL CREATE

2.5 Using this process, any number of folders can be added. In the screen shot below, find the second folder was added "Drafts for Submission."

4. Informed Consent or Assent > 2. Drafts or Working Version

CREATE NEW ACTIONS Filter by...

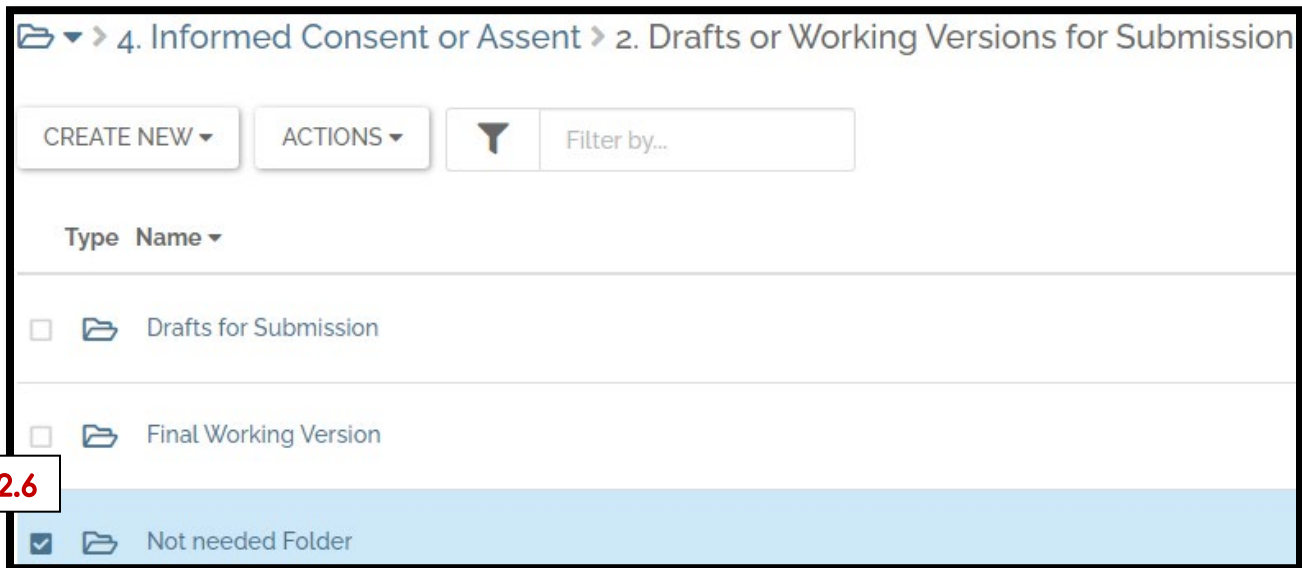
Type Name

<input type="checkbox"/>	Final Working Version
<input type="checkbox"/>	Drafts for Submission

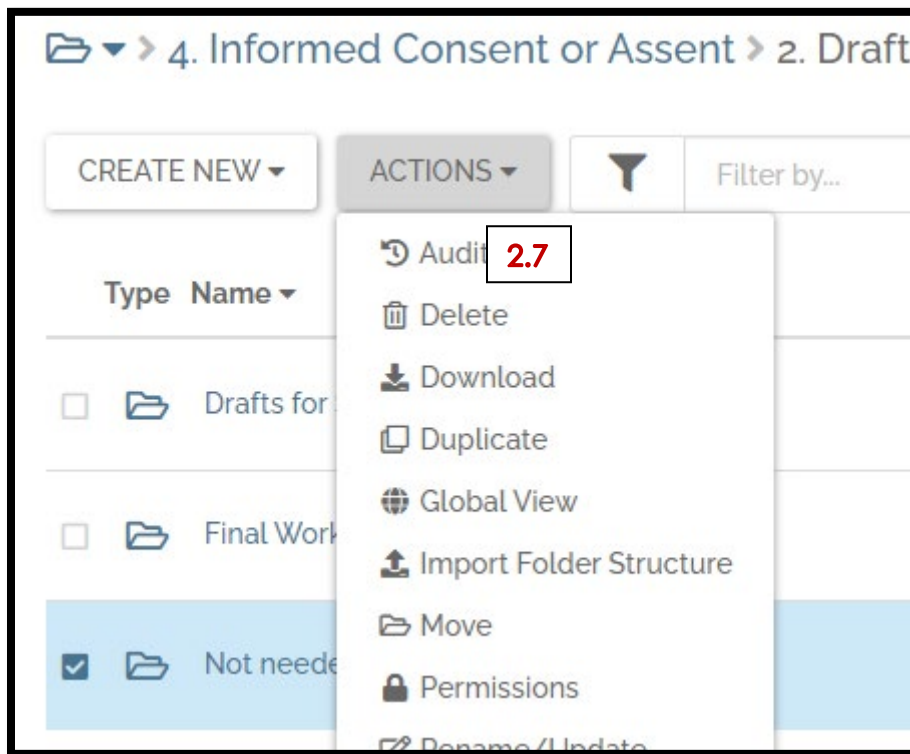
Deleting an unnecessary folder in the study eBinder

+++++Only a user assigned Florence Study Coordinator, Super User Admin or Admin Team role can delete a folder or document within their assigned study eBinders+++++

2.6 After reaching the location of the unnecessary folder, check the box next to the folder



2.7 From the Actions tab, select Delete from the dropdown



- 2.8 Complete the required (asterisked) fields in the pop-up.
- The name must be typed exactly how presented in the folder in the top box to be recognized, if the name is not typed exactly as how presented an error message will show when attempting to select the Delete button.
 - A reason for deletion must be provided. Reminder, this is an FDA Part 11 compliant platform, it is important to retain folders & documents as part of the Audit trail. Ability to show the complete story or activities (via folders & documents) at the time of a FDA or other regulatory audit, is far more important than a tidy study eBinder.
 - Audit trail will document who, what and when each entry was completed, or document was manipulated.
 - **Once a document is deleted, there is no opportunity to get it back, whatever it was!!!!**
- 2.9 After each field is completed select Delete in bottom right-hand corner of the pop-up

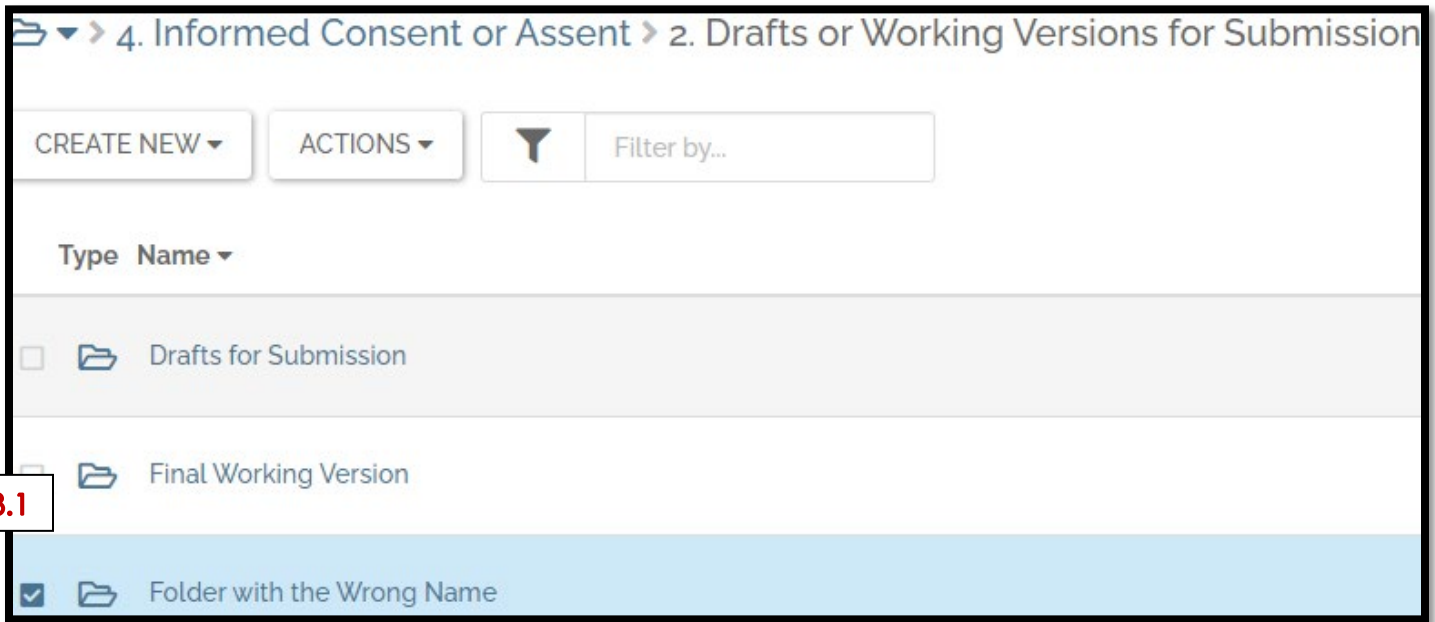
The image shows a confirmation dialog box with a black border and a close button (X) in the top right corner. The title is "Are you ABSOLUTELY sure?". The main text reads: "This action CANNOT be undone. This will permanently delete Not needed Folder and all of its contents except Audit Trail events." Below this, there are two required fields marked with asterisks. The first field is labeled "* Type in the name of the folder to confirm." and contains the text "Not needed Folder". A red box labeled "2.8a" is positioned over the end of this text. The second field is labeled "* Reason (to be stored in Audit Trail):" and contains the text "Folder not needed for this study". A red box labeled "2.8b" is positioned over the end of this text. At the bottom right of the dialog, there are two buttons: a white "CANCEL" button and a red "DELETE" button. A red box labeled "2.9" is positioned over the "DELETE" button.

3.0 Renaming

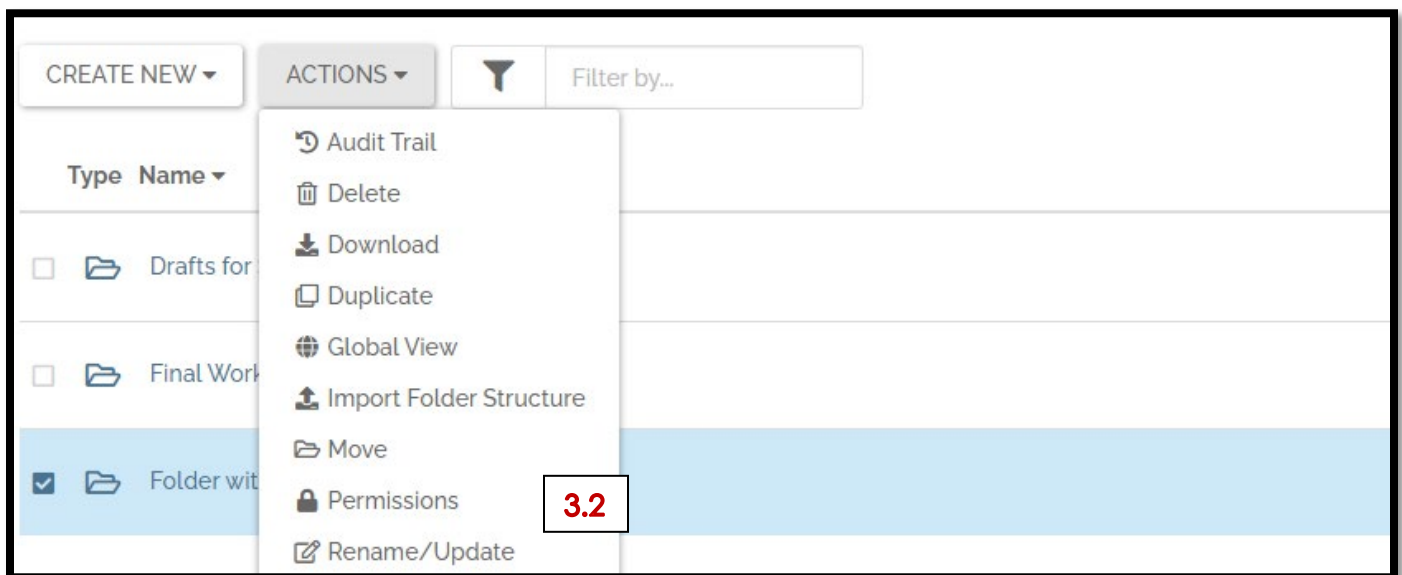
Renaming a folder or document allows the end user to closely replicate the regulatory binder structure familiar to their team, while still utilizing a Basic Study Binder Footprint demonstrating consistency across all projects.

The function of renaming a document or folder is completed as follows-

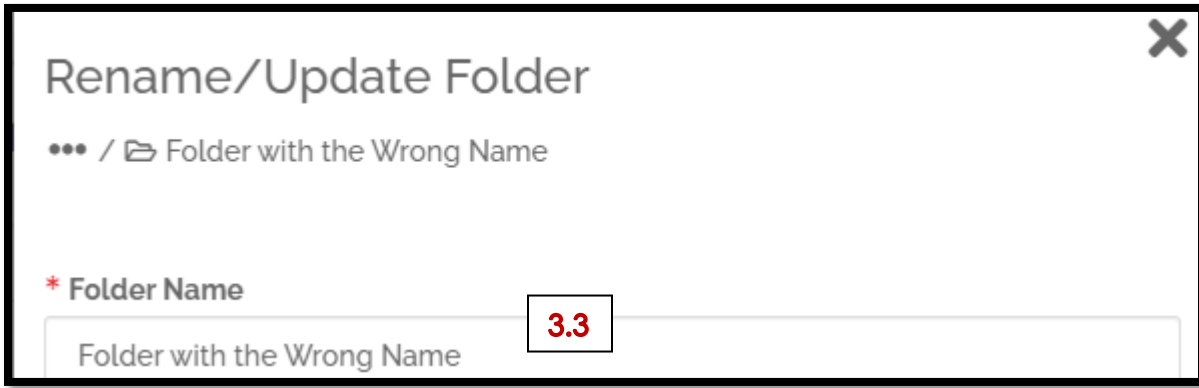
- 3.1 Go to the location of the folder (document) which will be renamed, check the box next to the folder. By checking the box, the Action tab becomes usable.



- 3.2 Select Rename/Update (last on list) from the Actions dropdown

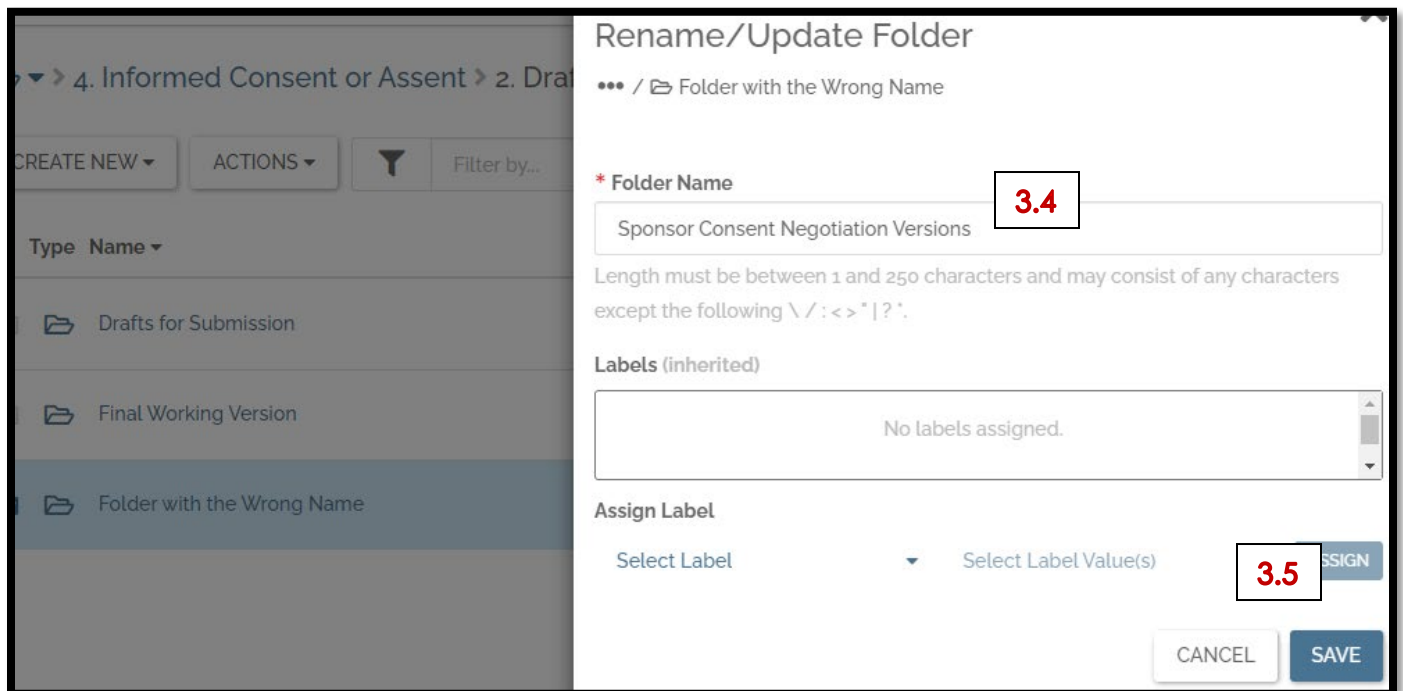


3.3 When the Rename / Update pop-up appears, the current folder (document) name appears



3.4 Enter the desired name of the folder (document) in the Folder Name field

3.5 Select the Save button in the bottom right-hand corner of the pop-up



3.6 The update name will appear as previously entered in the study eBinder

4. Informed Consent or Assent > 2. Drafts or Work

CREATE NEW ▾ ACTIONS ▾ Filter by...

Type Name ▾

<input type="checkbox"/>		Drafts for Submission
<input type="checkbox"/>		Final Working Version
<input checked="" type="checkbox"/>		Sponsor Consent Negotiation Versions

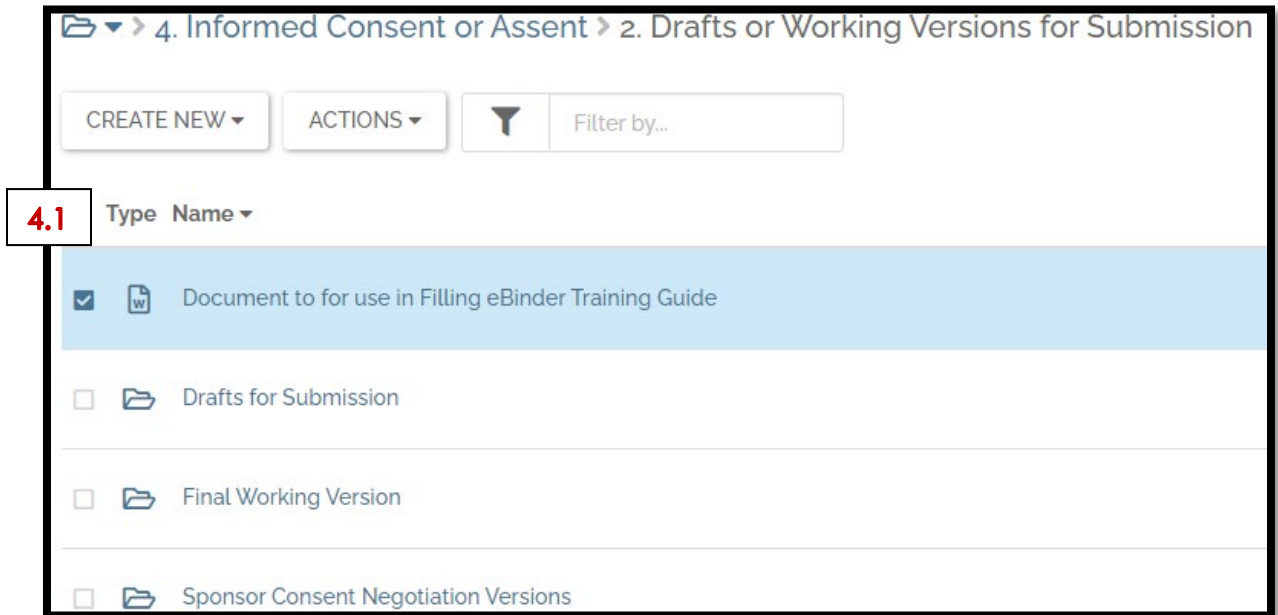
3.6

4.0 Moving

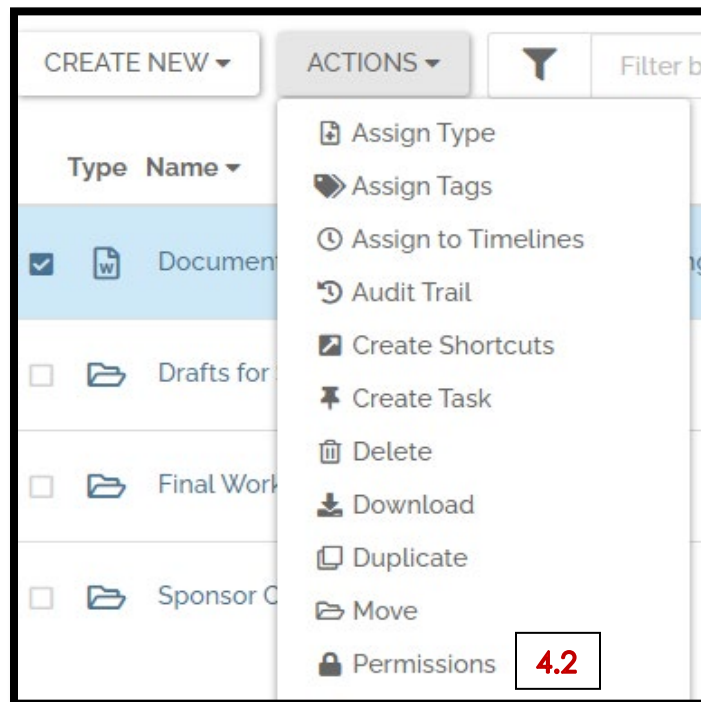
Folders and documents can be moved within study Binders you have permission to access. The exception is the MCW Central Binders.

To move documents and folders within the study eBinder-

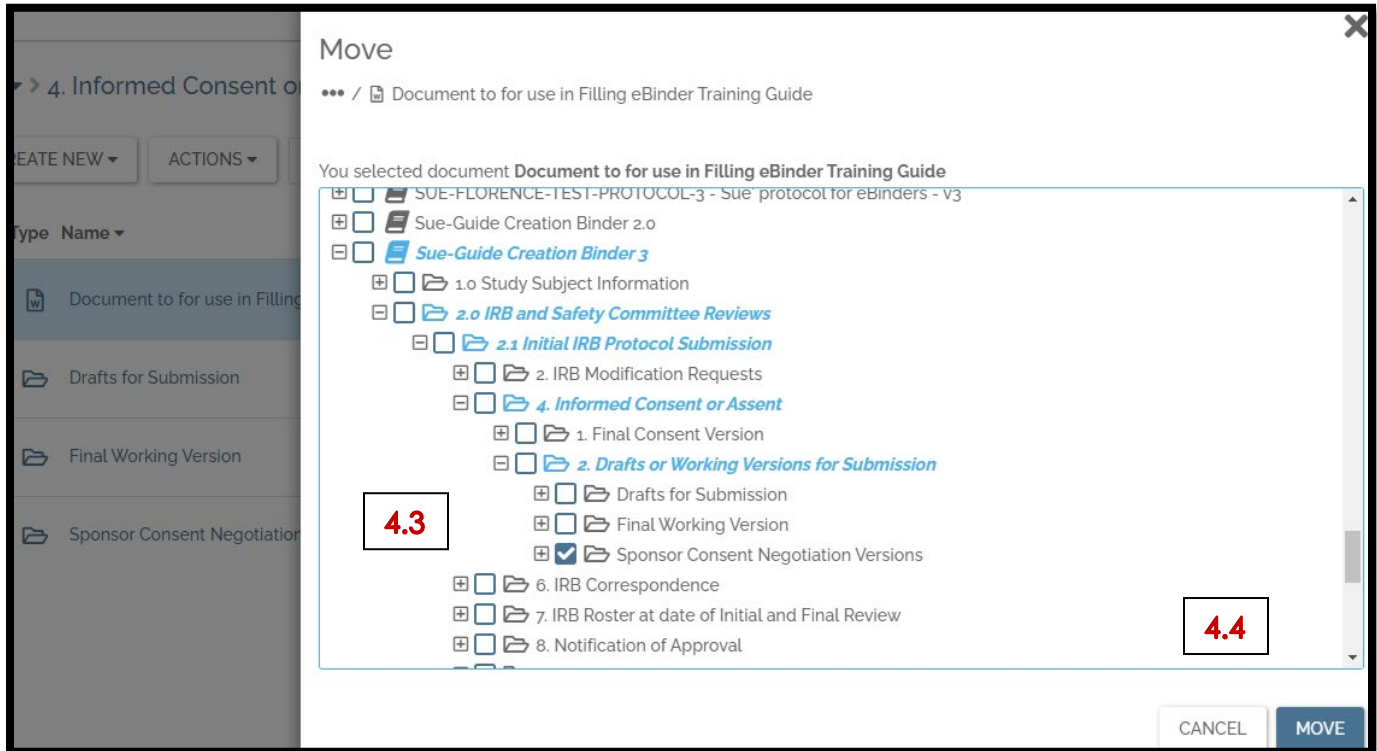
4.1 Check the box next to document or folder to be moved



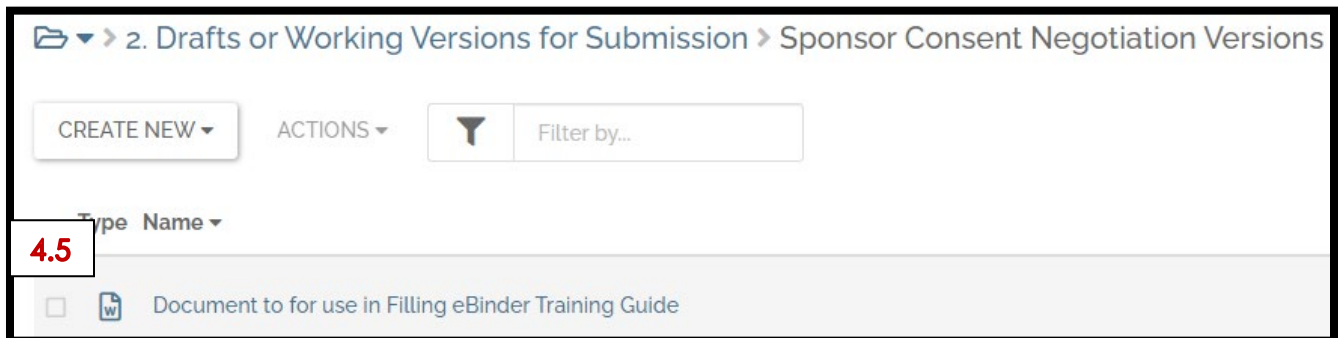
4.2 Select Move from the dropdown in the Actions tab



- 4.3 When the pop-up window appears, locate the study binder name to where the document will be moved, click the + sign to the folder name to open the branching. Continue opening the branches by clicking the + sign next to each layer of folders in the study eBinder **until the final destination is reached**, check the box next to this folder.
- 4.4 Select the MOVE button at the bottom right-hand corner of the pop-up.



- 4.5 Now the document is found in the folder 2.4.2 Sponsor Consent Negotiation Versions



5.0 Shortcuts

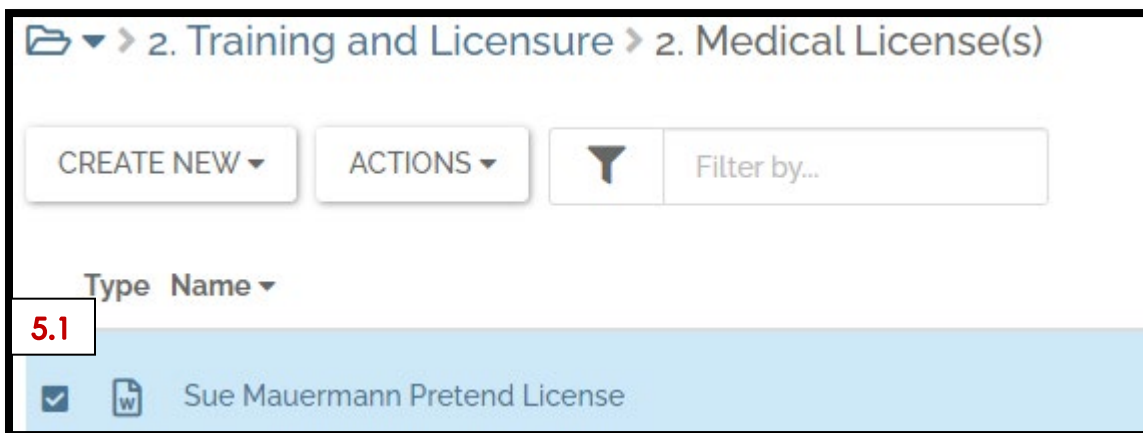
Used to establish a link from a Central Binder (Credentials or Resources) to the appropriate location in an individual study eBinder.

- A single document, located in a Central Binder, can have a shortcut to an unlimited number of studies.
- Each time the document is updated in the Central Binder, it will simultaneously be updated in each binder where a shortcut has been created.

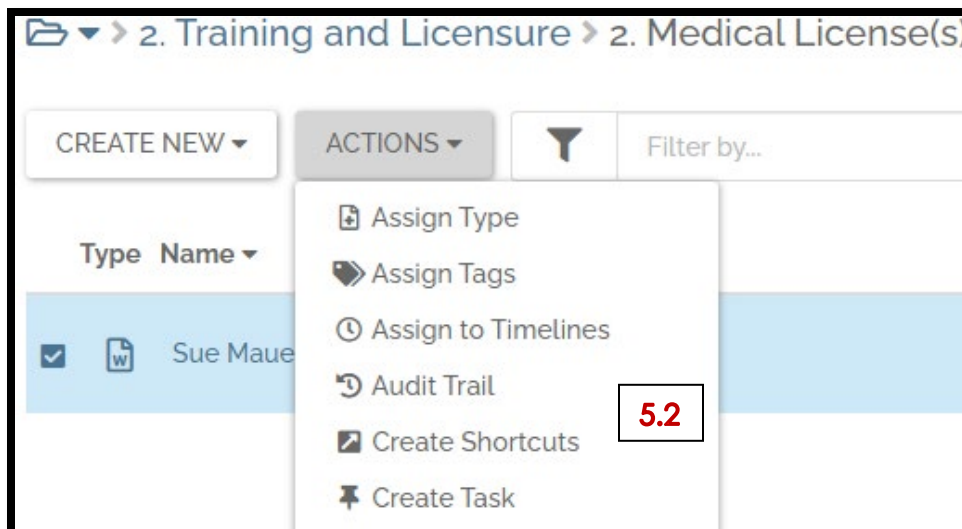
Please note-shortcuts continue to be updated even after a study closes unless the shortcut is removed. Once the shortcut is removed, all documents associated with that shortcut will disappear from the study binder. Recommendation, prior to archiving the study eBinder, place a duplicate version of document in the study binder. This practice assures all appropriate documents are included in the study eBinder, but unnecessary auditable documents are not included.

Shortcut from Credentials Folder to Study eBinder

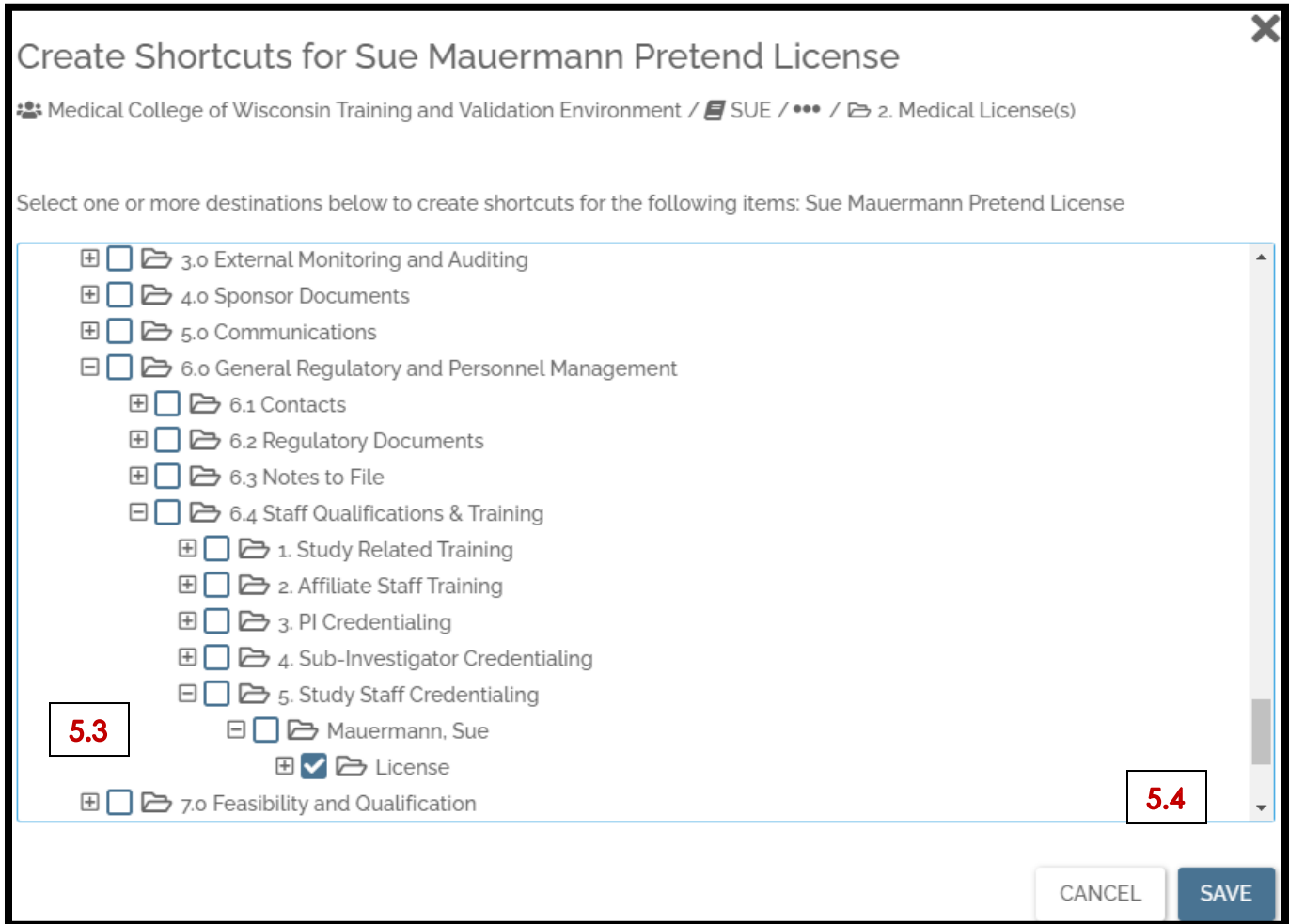
- 5.1 Locate the document in the **1. MCW Central Credentials Binder** which will have a Shortcut to the study eBinder, check the box next to the document.



- 5.2 From the Actions dropdown, select Create Shortcuts

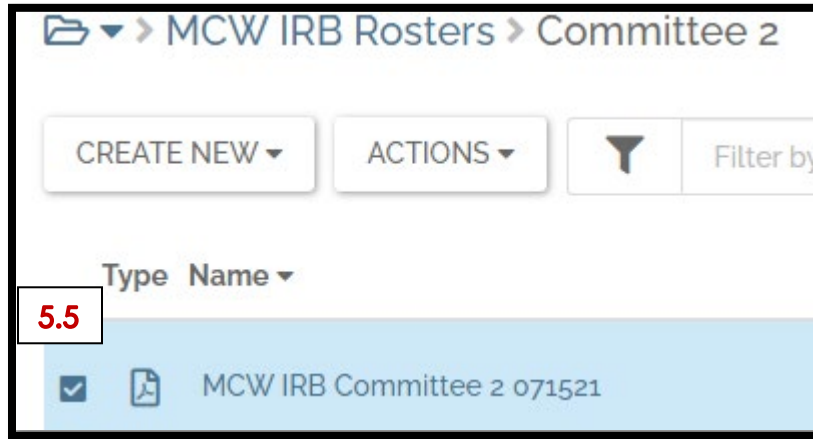


- 5.3 When the pop-up window appears, locate the study binder name where the shortcut should be located, click the + sign to the folder name to open the branching. Continue opening the branches by clicking the + sign next to each layer of folders in the study eBinder **until the final destination is reached**, check the box next to this folder.
- 5.4 Select the SAVE button at the bottom right-hand corner of the pop-up.

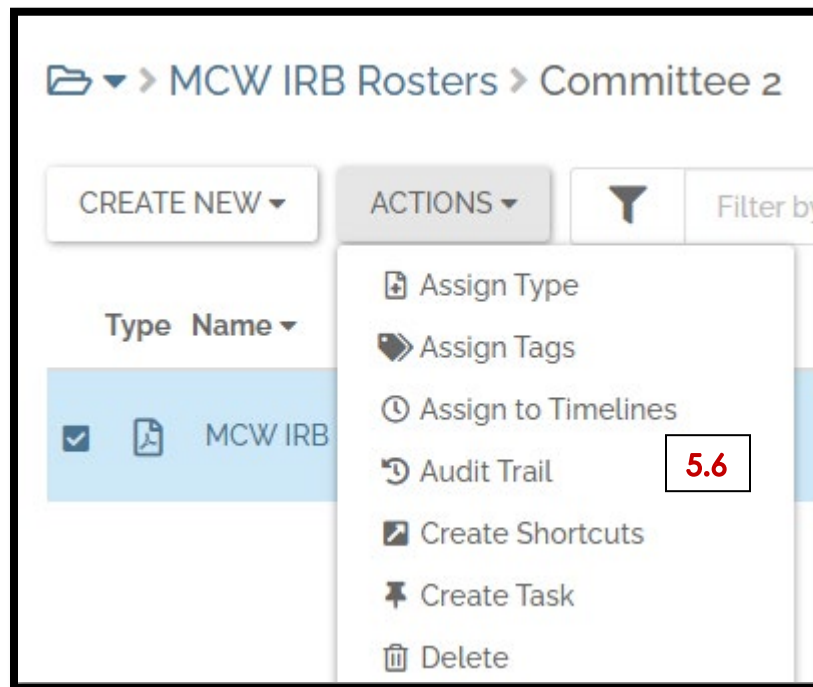


Example for IRB Roster

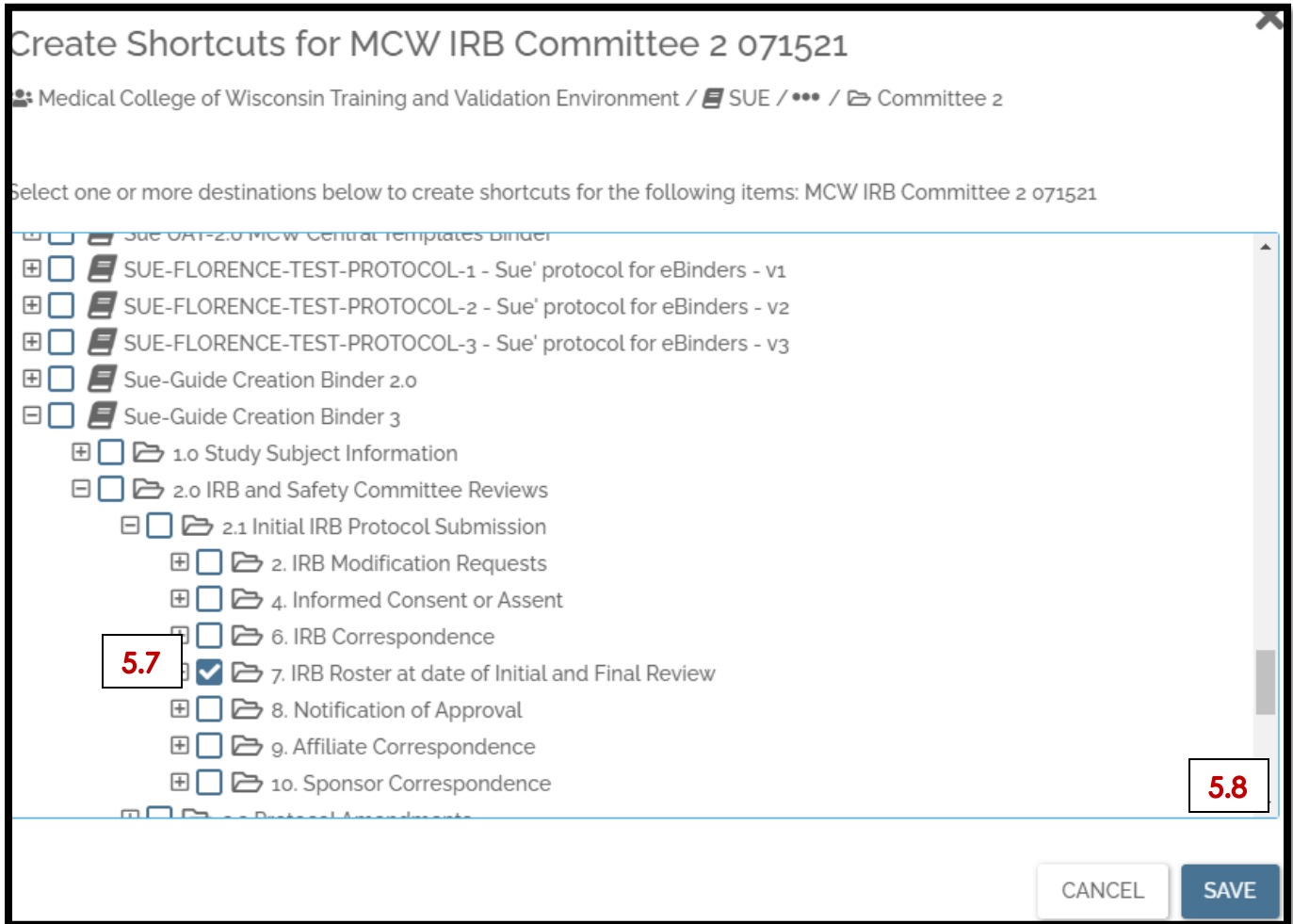
5.5 Locate the document in the **3. MCW Central Resources Binder** which will have a Shortcut to the study eBinder, check the box next to the document.



5.6 From the Actions dropdown, select Create Shortcuts



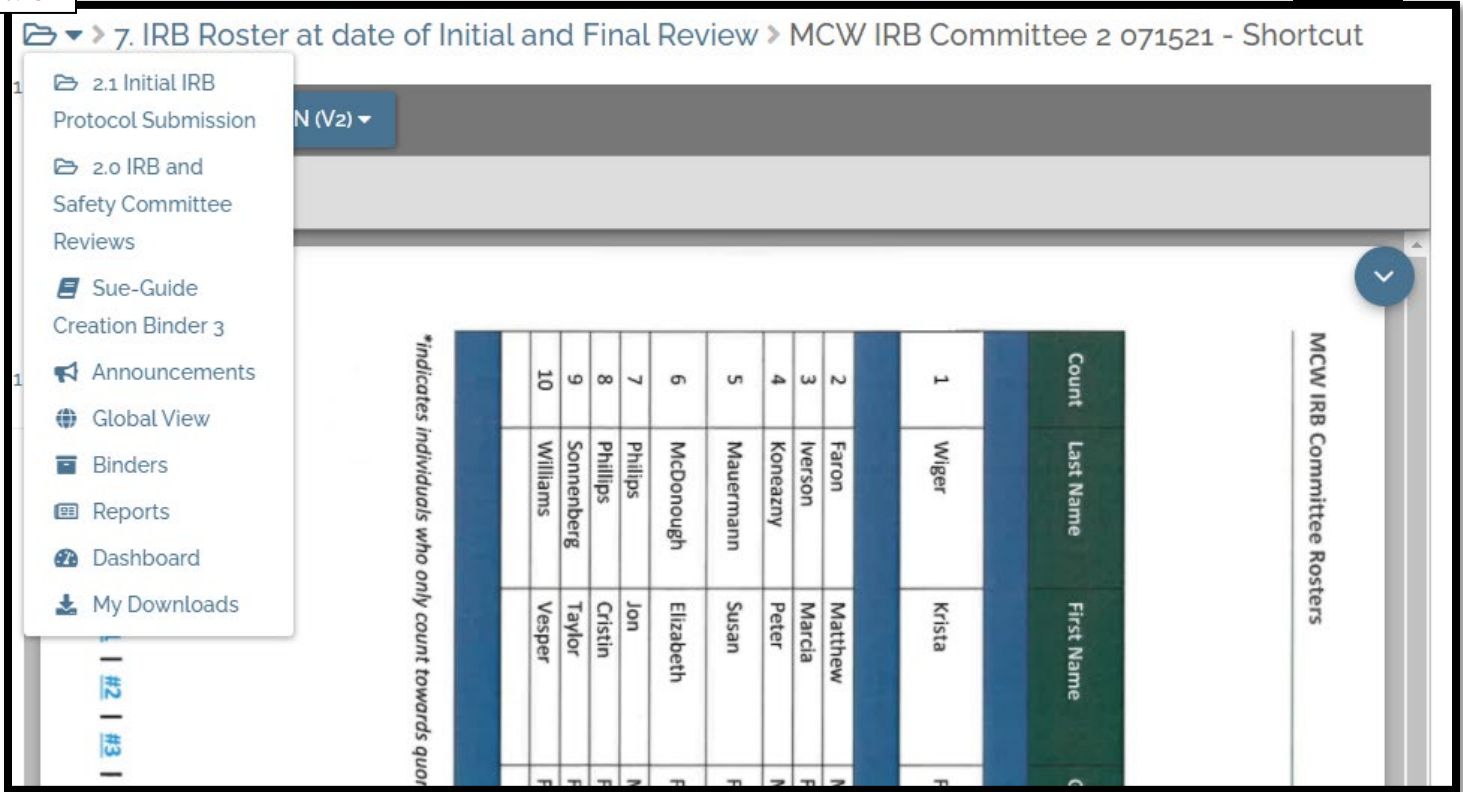
- 5.7 When the pop-up window appears, locate the study binder name where the shortcut should be located, click the + sign to the folder name to open the branching. Continue opening the branches by clicking the + sign next to each layer of folders in the study eBinder until the final destination is reached, check the box next to this folder.
- 5.8 Select the SAVE button at the bottom right-hand corner of the pop-up.



5.9 The following screen shot identifies success of creating a shortcut to the study eBinder Sue-Guide Creation Binder 3, the study eBinder used for creating this guide.

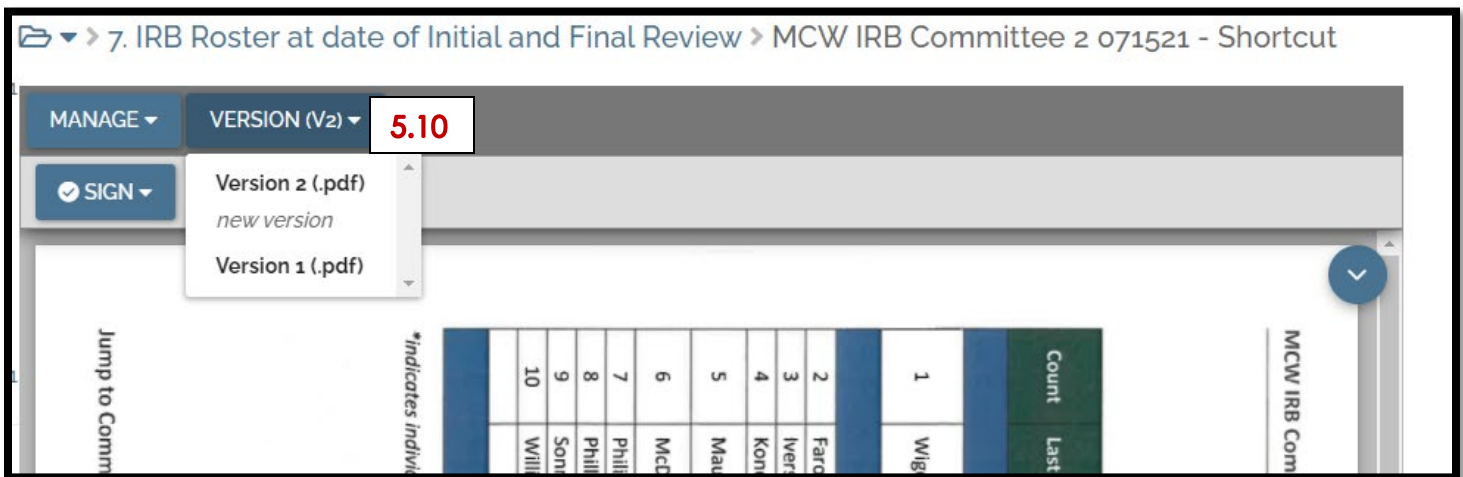
5.9a

5.9b



5.10 Notice in the next screen shot, this is the second version -VERSION (v2) of the IRB Roster for this committee, that means the document was updated since initially being placed in the Central Resources Documents for Committee 2.

These documents have been "Stacked" or the latest version was added on top of first version. Stacking is required for all versions of a single document to appear when creating a shortcut. The processes of Stacking will be reviewed in the next section, Uploading a Document.



6.0 Placing Documents (Uploading) in your Study eBinder

Documents can be Imported to your study eBinder using multiple options from your MCW device, these include Browse, Drag & Drop, Stacking, Import via Email or Florence eBinder Printer.

Browse or Drag & Drop

6.1 Locate the section in the Study eBinder where the document will be added.

6.2 Open the branches of the section until the correct sub-folder is located, check the box next to this folder. As the last step in reaching **the final destination** for the document, **Click** the hyperlink opening the sub-folder where the original document will be placed, or an updated document is added. *Follow the instructions for Moving a document, if the document is not placed in the correct sub-folder (Section 4.0)*

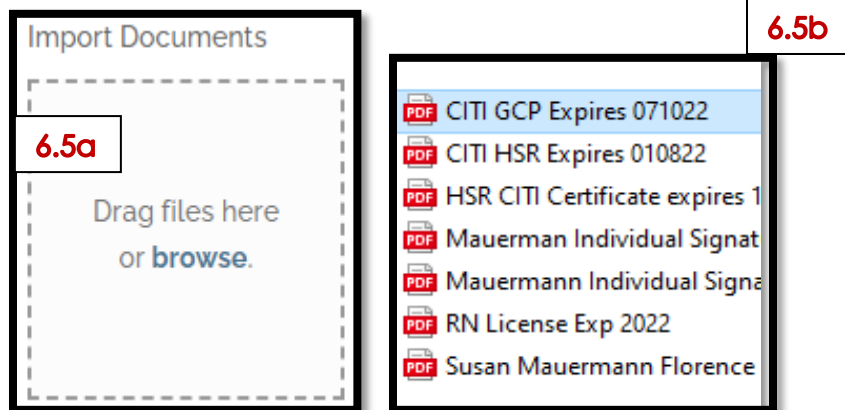
6.3 Identify the **Import Documents** box on the left side of your screen

6.4 Within that box, the two options to retrieve a document from your desktop are found. That includes **Browse** or **Drag & Drop**.

The screenshot displays the Study eBinder interface. On the left, a navigation sidebar includes 'Import Documents' (6.3), 'My Downloads' (3), and 'Need Help?'. The main content area shows a breadcrumb path: '5. Study Staff Credentialing > Mauermann, Sue'. Below this are buttons for 'CREATE NEW', 'ACTIONS', and a filter dropdown. A table lists folders: '1. CITI Biomedical Research Certificate (s)', '2. CITI Good Clinical Practice Certificate (s)' (6.2, selected), and 'License'. At the bottom left, a dashed box labeled 'Import Documents' (6.3) contains the text 'Drag files here or browse.' (6.4) and an 'IMPORT VIA EMAIL' button.

Browse

6.5 By clicking **browse** access in the Import Documents box, you will open access to your desktop & thereby access to the document you will place in the study eBinder.



The document as up-loaded in the sub-folder selected in 6.2-



Drag & Drop

- 6.6 Follow steps 6.1- 6.3 to locate the **final destination** for the document
- 6.7 Open the document on your desktop, next drag that document to the Import Documents box as identified in step 6.3.

The screenshot shows a file management interface with a sidebar on the left containing navigation options: Search, Announcements, Global View, Binders, Reports, Dashboard, My Downloads, and Need Help?. The main area displays the breadcrumb path: 3. Research Trainings > 1. CITI Biomedical Research Certificate (s). Below the path are buttons for 'CREATE NEW', 'ACTIONS', and a filter dropdown. A message states: 'This Folder either has no content or you do not have access to view it.' In the bottom left, there is an 'Import Documents' section with a dashed box containing the text 'Drag files here or browse.' and a callout '6.7b'. A callout '6.7a' points to a list of PDF files:

File Name	Status
CITI GCP Expires 071022	✓
CITI HSR Expires 010822	✓
HSR CITI Certificate expires 12.1.2024	✓
Mauerman Individual Signature Log 08.1...	✓
Mauermann Individual Signature Log	✓
RN License Exp 2022	✓
Susan Mauermann Florence Training Cert...	✓

Once up-load is complete, document found in target sub-folder-

The screenshot shows the same file management interface as above, but now the document 'CITI HSR Expires 010822' is visible in the main area. The breadcrumb path remains: 3. Research Trainings > 1. CITI Biomedical Research Certificate (s). The 'CREATE NEW', 'ACTIONS', and filter buttons are still present. Below them is a table header 'Type Name' and a single row with a checkbox, a document icon, and the file name 'CITI HSR Expires 010822'.

Type	Name
<input type="checkbox"/>	CITI HSR Expires 010822

Stacking (Up-Loading a New Version of Existing Document)

6.8 In Florence, Open the document to be updated

6.9 Under the Version tab, select Upload a New Version

6.8

The screenshot shows a web interface for document management. At the top, a breadcrumb path reads: 1. CITI Biomedical Research Certificate (s) > CITI HSR Expires 010822. Below this is a navigation bar with buttons for 'MANAGE', 'VERSION (V1)', and 'ANNOTATE'. The 'VERSION (V1)' dropdown menu is open, showing three options: 'Upload a New Version', 'Email a New Version', and 'Version 1 (.pdf)'. A red box labeled '6.9' highlights the 'Upload a New Version' option. The main content area displays the 'CITI PROGRAM' logo, a world map, and the text 'This is to certify that: Susan Mauermann'. On the right side, there is a table of metadata: Completion Date 09-Jan-2019, Expiration Date 08-Jan-2022, and Record ID 29360217.

6.9

- 6.10 In your desktop, open the document to be Up-Loaded in the study eBinder
- 6.11 Click **browse** or **Drag & Drop** the document to the Import Documents box, in the pop-up which appeared when completing step 6.9.
- 6.12 Indicates the document file name being Up-Loaded
- 6.13 Indicate the Reason the document was updated
- 6.14 Document Names should be generic, if date or visit specific would require correction with each version
- 6.15 Select SAVE in the bottom right of the pop-up

6.11

Drag your new file here or **browse**.

6.12 Selected file:
HSR CITI Certificate expires 12.1.2024.pdf

6.10

* Reason
Updated CITI HSR Certificate

6.13

Document Name
CITI HSR Certificate

6.14

Clear Expiration Date
 Rename Shortcuts

6.15

CANCEL SAVE

PDF	CITI GCP Expires 071022	✓
PDF	CITI HSR Expires 010822	✓
PDF	HSR CITI Certificate expires 12.1.2024	✓
PDF	Mauerman Individual Signature Log 08.1...	✓
PDF	Mauermann Individual Signature Log	✓
PDF	RN License Exp 2022	✓
PDF	Susan Mauermann Florence Training Cert...	✓

Completed process provides example of **Stacking** as a method to assure current version of a document is the first to appear in a folder (Version Control)-

The screenshot displays a document management interface for a 'CITI HSR Certificate'. The breadcrumb path is '1. CITI Biomedical Research Certificate (s) > CITI HSR Certificate'. A 'VERSION (V2)' dropdown menu is open, showing options: 'Upload a New Version', 'Email a New Version', 'Version 1 (.pdf)', and 'Version 2 (.pdf)'. The 'Version 2 (.pdf)' option is highlighted with the text 'Updated CITI HSR Certificate'. The document content includes the 'CITI PROGRAM' logo, a world map, and the text 'This is to certify that: Susan Mauermann'. Metadata on the right includes: 'Completion Date 02-Dec-2021', 'Expiration Date 01-Dec-2024', and 'Record ID 43552692'.

Import via Email

- 6.16 Locate the **final destination** for the document in the study eBinder, this will include opening the destination sub-folder. In the example below, I need to open the Test 2 sub-folder. This step has not been completed for this example so reader can identify target location.
- 6.17 Click on the IMPORT VIA EMAIL button at the bottom of your screen.
- 6.18 The Import via Email pop-up appears
- 6.19 The blue email address is the link associated with this transfer of documents
- 6.20 Click the button OPEN DEFAULT MAIL CLIENT (for MCW users this is your MCW Outlook account)
- 6.21 See that email address link from 6.19 has automatically been loaded in the To field. Enter a Subject (to eliminate the prompt to do so from Outlook). Attach the document to be uploaded in the Florence final destination sub-folder (see next page)
- 6.22 Press the Outlook Send button (see next page)
- 6.23 Go back to the pop-up which will still be open (step 6.18) and select DONE.

The screenshot shows the Florence application interface with a pop-up window titled "Import via Email". The pop-up contains the following text and elements:

- Header: "Import via Email" with a close button (X).
- Path: "... / 2. Justifications used for Budget Negotiation".
- Text: "Email as few or as many attachments as you'd like. All attachments and the email itself will be uploaded to this location."
- Text: "Copy and paste this email address" followed by a long alphanumeric string: "5ff79cec46a79d00413778d4.616...04715beg4.616foa6e0ae84d004e8".
- Buttons: "COPY TO CLIPBOARD" and "OPEN DEFAULT MAIL CLIENT".
- Bottom right: "DONE" button.

Red callout boxes with numbers 6.16 through 6.23 are overlaid on the screenshot, pointing to specific elements:

- 6.16: Points to the "Import Documents" section in the background.
- 6.17: Points to the "IMPORT VIA EMAIL" button at the bottom left of the background.
- 6.18: Points to the "Import via Email" title of the pop-up.
- 6.19: Points to the "Test 2" folder in the background.
- 6.20: Points to the email address field in the pop-up.
- 6.23: Points to the "DONE" button in the pop-up.

Test Document - Message (HTML)

File Message Insert Options Format Text Review Help Tell me what you want to do

Paste Copy Format Painter Clipboard **6.21a**

Basic Text Names Attach File Link Signature Follow Up High Importance Low Importance Dictate Sensitivity

The following **6.22** your organization: 5ff79cec46a79d00413778d4.616efa89536398004715be94.616f0a6e0ae84d004e83e4fb@us.uat.ebinders.org

To: 5ff79cec46a79d00413778d4.616efa89536398004715be94.616f0a6e0ae84d004e83e4fb@us.uat.ebinders.org


Cc:

Bcc: **6.21b**

Subject: Test Document


TEST DOCUMENT.docx 12 KB **6.21c**

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 knowledge changing life

6.24 The following Florence notification will appear in your MCW Outlook inbox indicating the IMPORT VIA EMAIL function has been used, and includes the documents uploaded in this event.

6.24



We Received Your Email Import

Hi Susan,

We received your email with 2 attachment(s)

All of the documents uploaded have been saved here:

Team	Medical College of Wisconsin Training and Validation Environment
Binder	Sue-Guide Creation Binder 3
Folder	8.0 Contracts and Financials/8.6 Financial Documentation/2. Justifications used for Budget Negotiation/Test 2

Document	Status
TEST DOCUMENT.docx	Imported
Test 2	Imported

Cheers,
Your Florence Team

6.25 Both the email & the document are placed in the Florence sub-folder. Both components are considered a component of Part 11 compliance documentation.

The screenshot shows a file management interface with the following elements:

- Search:** A search bar at the top left.
- Navigation:** A sidebar on the left with options: Announcements, Global View, Binders, Reports, Dashboard, My Downloads (3), and Need Help?.
- Breadcrumbs:** A path at the top right: 2. Justifications used for Budget Negotiation > Test 2.
- Actions:** Buttons for 'CREATE NEW', 'ACTIONS', and a filter icon.
- Filter:** A text input field labeled 'Filter by...'.
- Table:** A table with columns 'Type' and 'Name'. It contains two entries:
 - Row 1: Type is a document icon, Name is 'Test 2' with a red box containing '6.25a'.
 - Row 2: Type is a document icon, Name is 'TEST DOCUMENT' with a red box containing '6.25b'.

Florence eBinder ePrinter

Florence eBinder Printer can be used to upload any document to a specific location in a Florence study folder. This represents a Part 11 & HIPAA compliant option to e-print EPIC documents that have been IRB approved for use in the study from EPIC to the study subject's folder in Florence. Use of eBinder Printer can however be used to upload any document to Florence.

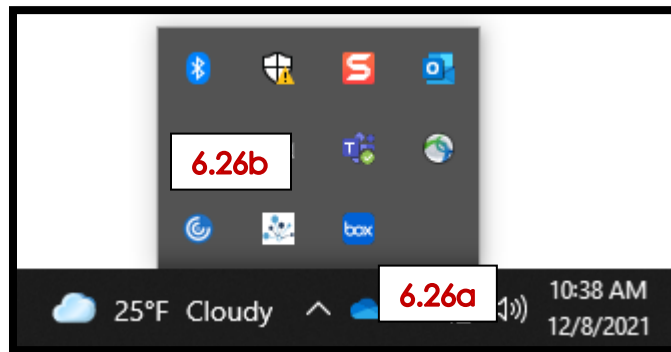
Please refer the installation instructions provided on Train.MCW.edu:

[MCW-Florence-ePrinter-Installation-Guide.pdf](#) This is a self-service install as it is linked to your MCW login credentials.

This function is only available to those who have a MCW SSO (single sign on) account. Meaning affiliates and external users of Florence will not be able to use this function.

6.26 Confirm that you have signed-in to Florence ePrinter. Do this by

- Right click on the up carrot in the lower right-hand corner of your screen
- Select & click the Florence icon



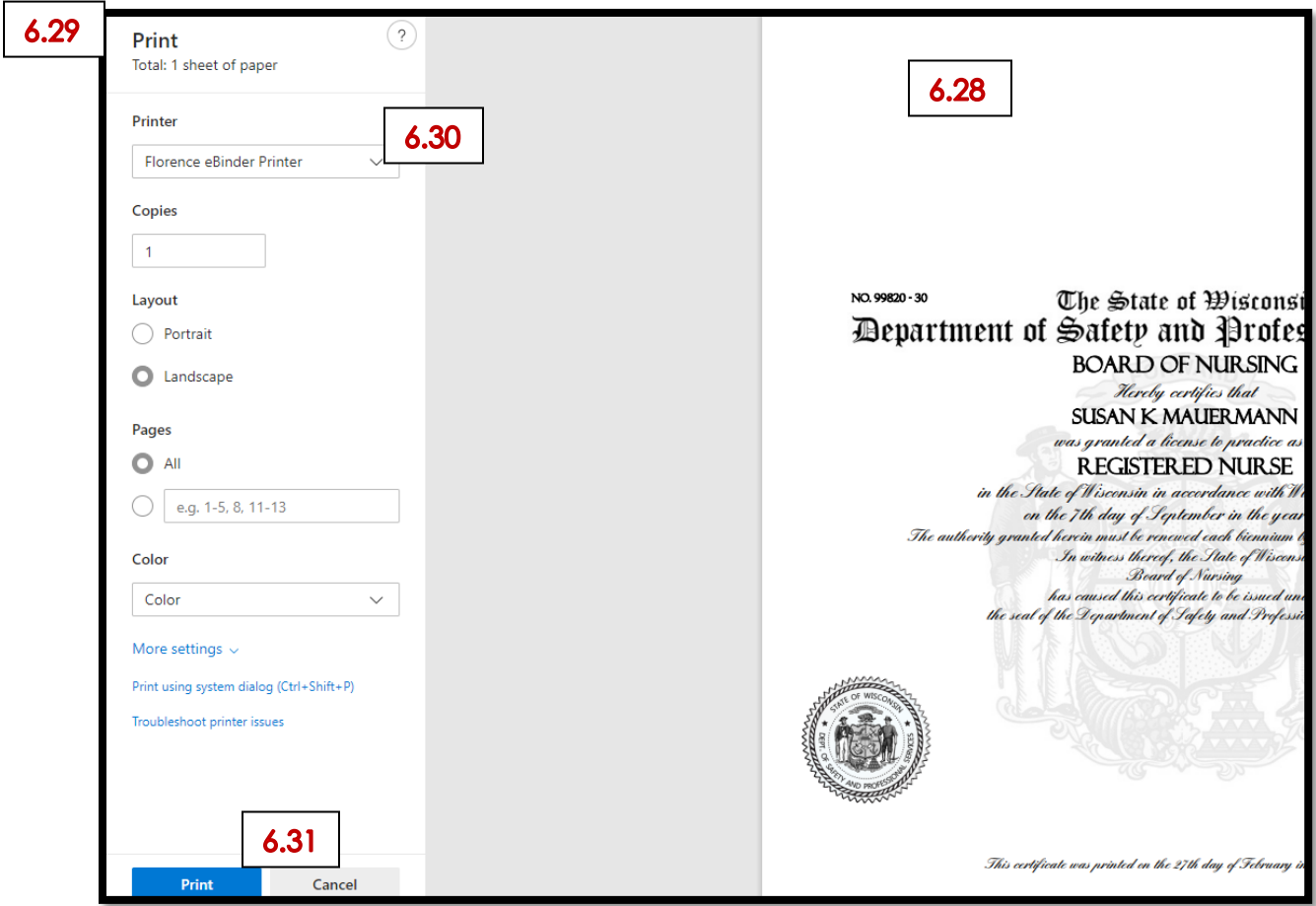
6.27 Follow the instructions on the eBinder pop-up that appears to complete your MCW SSO sign-in steps:

- Enter your email address, select the NEXT button
- The MCW SSO screen will appear, enter your MCW username & password

6.27a

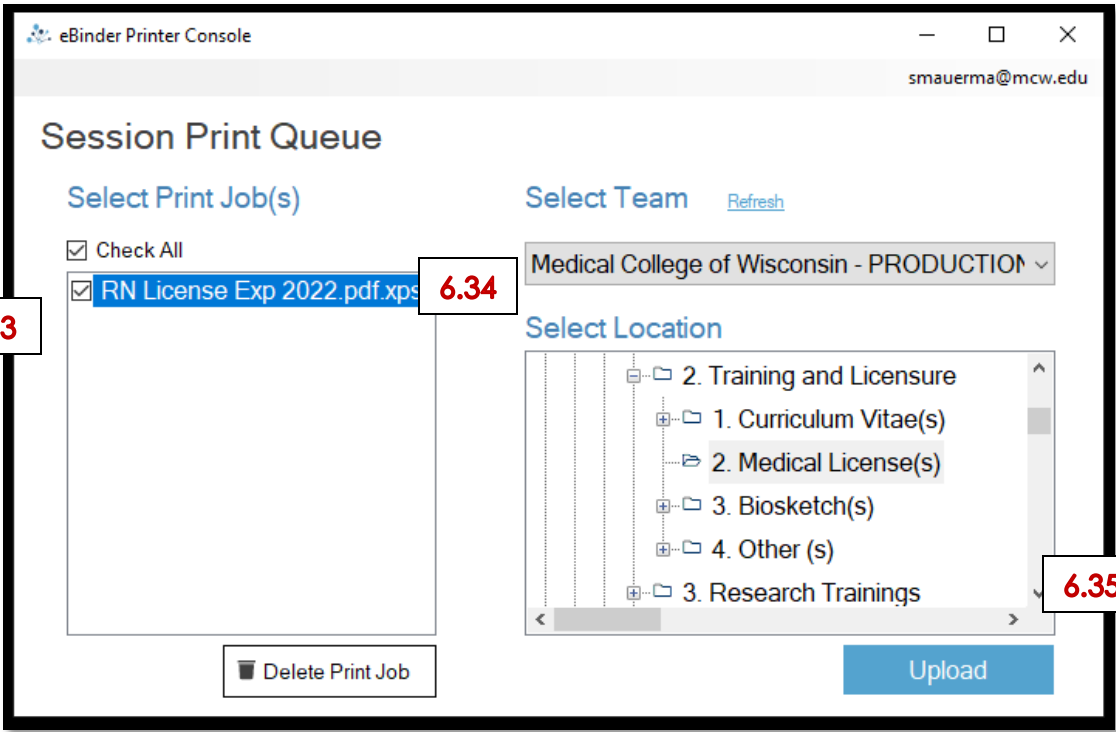
A screenshot of a 'Sign In to the eBinder Printer' pop-up window. The window title is 'Sign In to the eBinder Printer'. On the left is the eBinder Printer logo, which consists of several blue circles of varying sizes connected by lines to a central white circle. Below the logo is the text 'eBinder Printer' and 'By Florence'. At the bottom left, it says 'US1-PROD - Version 4.1.4'. On the right, the text 'Sign In' is displayed. Below it is an 'Email' label and an empty text input field. At the bottom right, there is a blue button labeled 'NEXT'. A red box labeled '6.27b' points to the 'NEXT' button.

- 6.28 Locate the document which will be uploaded in the Florence study folder on your MCW desktop.
- 6.29 Select option to print the document
- 6.30 Locate Florence eBinder Printer from the printer options dropdown
- 6.31 Select Print



- 6.32 The eBinder printer pop-up will appear
- 6.33 Check the box next to the document which will be placed in the study eBinder
- 6.34 Select the location in the study eBinder where the document will be placed
- 6.35 Select the Upload button

6.32



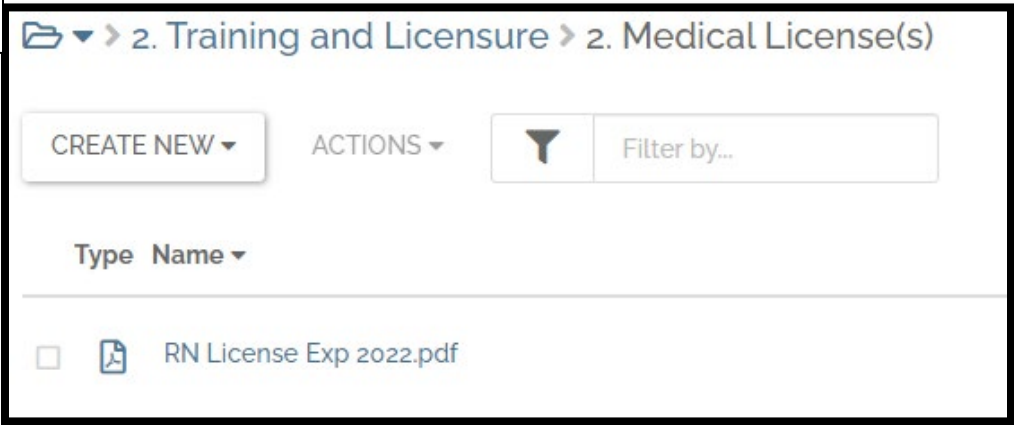
6.33

6.34

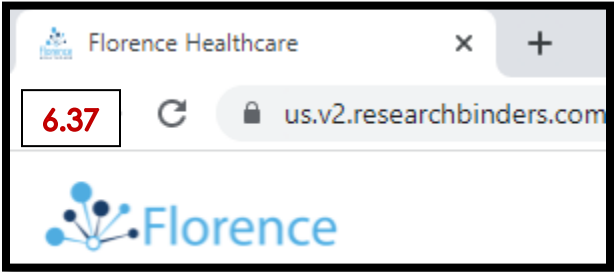
6.35

6.36 The document should be found in the final destination that was identified in step 6.34.

6.36



6.37 If the document is not in the expected folder, click the Florence refresh button the top left corner of the screen, just to the right of box 6.37.



Appendix A

OnCore Protocol Naming Conventions October 1, 2021

- Protocol Name is limited to 25 characters
- There can be no blank spaces in a name
- The only allowable non-alphanumeric character is a dash (-)
- For OnCore, Cancer Center CTO, Pediatric Research Managers and OnCore Support are currently the only users who can enter in a new protocol and therefore enter protocol names.

Cancer Center Naming:

- Pharmacy/Industry Trials: Drug Company Name-Sponsor Protocol Name, e.g., MERCK-055
 - Company names may be shortened due to space limitations, for example AstraZeneca as AZ.
 - Where multiple sponsors, use the funding sponsor in the name.
- Cooperative Group Trials: Group Name-Sponsor Protocol Name, e.g., ALLIANCE-A011203.
- Foundation Trials – Pharmacy/Industry trials that are opened in collaboration with or requiring membership in a cooperative group/consortium: Group Name-Sponsor Protocol Name, e.g., COG-AAML1321. Please review OnCore Communication Memo #25 – Foundation Trials Sponsor Designation.
- Consortium Trials – Pharmacy/Industry trials that are open in collaboration with or requiring membership in a consortium group: Drug Company Name-Sponsor Protocol Name-Consortium Name or initials, e.g., BERG-15-022.
- Investigator-Initiated Trials: IIT-PI Last Name-Commonly Used Protocol Name, e.g., IIT-ATALLAH-LAST-TKI.
- External Investigator-Initiated Trials – IIT (institutional) studies from other colleges/hospitals opened at MCW/Froedtert/CHW, where the external site is the coordinating center: Center name or initials-Protocol or Commonly Used Name, e.g., UMICH-ANTI-PD-1.
- Expanded Access Trials – Facilitates access to drugs or devices where the subject(s) may not be eligible to go on a trial but could benefit from the therapeutic option: EXPACC-Drug Company Name-Sponsor Protocol Name, e.g., EXPACC-JANSSEN-SAR-3002.
- Treatment Use Only Trials (Compassionate Use Trials) – Subject(s) who were enrolled on a study are given IRB permission to continue to use the study drug(s) even though they have gone off-study: TXUSE-Drug Company Name-Sponsor Protocol Name, e.g., TXUSE-GLOBE-G14000-14.
- Emergency Investigative Drug or Device Use Trials – Subject(s) are given IRB permission to emergently use an experimental therapeutic option, not on-study, for a particular disease/diagnosis/symptom: E-IND-Drug Company Name-Drug Name, e.g., E-IND-ANSUN-DAS181.

Non-Cancer Naming:

- Non-cancer studies will follow the same guidelines as above, with the exception that they will add their Department/Division as a prefix to the Protocol Name. Prefixes are as follows (below). This list will be updated as new Departments/Divisions start to use OnCore.

ABA - Abandoned– include after study moves to this status	NEPH - Nephrology
BIOPHY - Biophysics	NEURO - Department of Neurology
BSM - MCW Tissue Bank	NSUR - Neurosurgery
CRI - Children's Research Institute Biobank	OBG - OB/GYN Non-oncology
CVC - Cardiovascular	OPH - Ophthalmology
DERM - Dermatology	OTO - Otolaryngology

ENDO - Endocrinology	P - Pediatric non-oncology studies use the same division names as adult but add a P- as a prefix before the prefix
GI - Gastroenterology	PATH - Pathology
GIM - General Internal Medicine	PULM - Pulmonary
HEMONC - Non-oncology HemOnc	RHEU - Rheumatology
HHI - Herma Heart Institute	SURG - Department of Surgery
INF - Infectious Disease	VIR - Vascular Interventional Radiology

Appendix B

Restricted Special Characters

The following special characters cannot be used in field creation in Florence eBinders. These characters can be included in documents placed in Florence. If used will create error message of substitute the restricted character for an allowable character.

- \ (backslash)
- / (forward slash)
- < (less than/angle bracket)
- > (greater than/angle bracket)
- " (quotation marks)
- | (vertical bar)
- ? (question mark)
- * (asterisk)
- — (em dash)
- ē (macrons)
- ' (prime)
- ° (degree)
- ² (superscript)