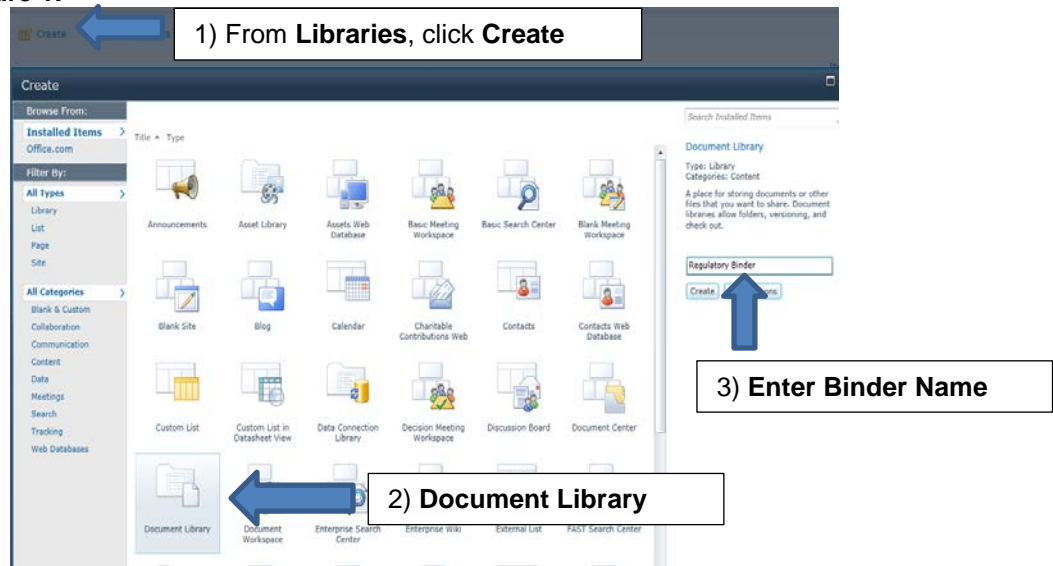


How to create an electronic Regulatory Binder in SharePoint

Check with your department administrator to see if a Departmental SharePoint site is available. If not, complete the SharePoint Request Form and submit to IT (see Attachment 1). The SharePoint Security Officer will set up the website and email the link to the SharePoint site. Please ensure that the persons delegated to conduct regulatory duties throughout the study have “Full Access” rights in order to modify/delete as appropriate.

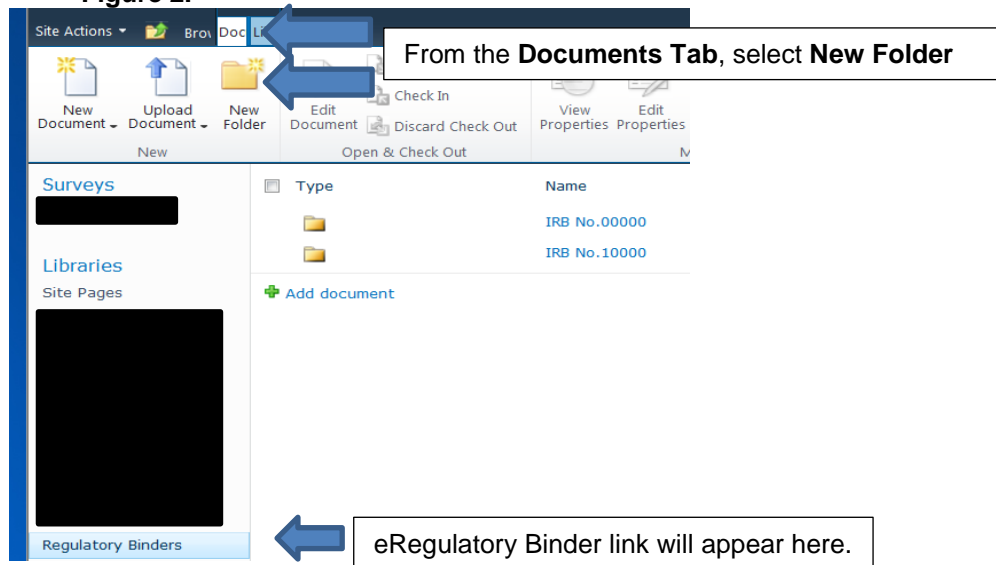
1. **To create an eRegulatory Binder:** From your SharePoint site, click on **Libraries** on the left menu of the screen, then from main menu bar on the top of the screen click **Create** then scroll down and click **Document Library**. This will prompt you to enter a name of your eRegulatory Binder. Commonly used names include “Regulatory Binders”, “Electronic Study Files” or “eRegulatory Binders”. Once complete, click **Create** to save the name (see Figure 1).

Figure 1.



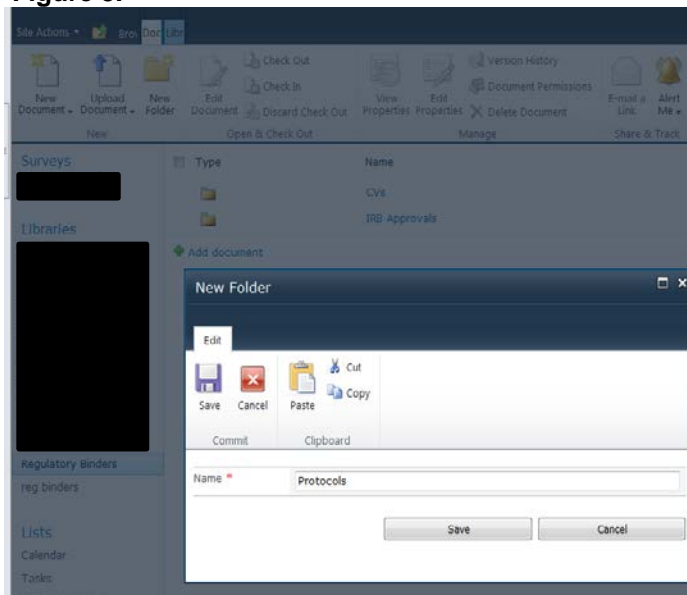
2. **To create a study folder within an eRegulatory Binder:** The name of the newly created eRegulatory Binder is located in the left column of the “Libraries” section (see Figure 2). There are three options on the top menu bar: “Browse”, “Documents”, and “Library”. Click on **Documents** then **New Folder** and a text box to enter the study folder name will open. Repeat this step to create additional eRegulatory binders for other studies.

Figure 2.



3. **To create subfolders within your study folder:** Within your eRegulatory Binder, open the folder of the study you would like to view or modify. Open your study folder, by clicking the **folder icon** or **name of the study**. Now to create a subfolder within the study eRegulatory binder, click **Documents** then **New Folder** (see Figure 3). Repeat to create and name each folder for the study. A list of examples is in Attachment 2. Once complete, upload documents into the appropriate subfolder(s)!

Figure 3.



You have now successfully created an electronic regulatory binder!

Helpful Hint:

To locate your documents most efficiently, it is a good idea to establish a naming convention to use throughout your eRegulatory Binders. SharePoint arranges documents alphabetically per the column selected. One suggestion is to use the date of the document, document name, and version to label your files. For example: “2014.01.30 Protocol v1”

Important Information to Note:

- Access must be limited to authorized individuals.
- Those who use computerized systems must determine that individuals (e.g. employees, contractors) who develop, maintain, or use computerized systems have the education, training and experience necessary to perform their assigned tasks (21 CFR 11.10(i)).
- **There must be a procedure in place for providing “read only” access to the electronic regulatory files at the time of a visit by a monitor or auditor.**
- SharePoint is not a long-term storage solution. You will need to have a procedure in place to archive your files at the end of the study.

21 CFR Part 11 – Defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records.

Applies to e-records created, modified, maintained, archived, retrieved, or transmitted under any records requirements set by the FDA or any e-records sent to the FDA even if not specified in regulations.

HIPAA security still applies.

Source: Guidance for Industry- Part 11, Electronic Records; Electronic Signatures – Scope and Application

Attachment 1:

SharePoint Space Request

Requestor _____

Email Address _____

Phone number _____

Desired site/area name _____

Secondary Sharepoint Contact _____

Email Address _____

Brief description of expected content/usage

Allow external (non-UAMS account holders) access? Y N

Department Name _____

Department Sharepoint Administrator _____

Current Departmental URL _____

Department Approval Signature _____

=====To be completed by IT=====

Approved by _____

Completed date _____

URL _____

Requestor notified date _____

Server location _____

Attachment 2: Examples of sub-folders for you eRegulatory Binder. Please create sub-folders applicable to your study.

- Current Protocol
- Outdated Protocols
- Current ICF & HIPAA Authorization Form
- Outdated ICF & HIPAA Authorization Form
- Investigator's Brochure
- Investigator's Agreement
- IRB Correspondence (IRB submissions and letters)
- Other Committee Correspondence
- Delegation of Authority Log
- FDA Form 1572
- Financial Disclosure Forms
- CVs, Licenses, Training Certificates for PI, Sub-Is, Key Personnel
- Protocol Deviation Log
- Serious Adverse Events (SAEs)
- IND/IDE Safety Reports
- Recruitment
- Laboratory Certification
- Subject Enrollment/Screening Log
- Site Visit Log
- Specimen Sample Logs
- Pharmaceutical Information
- Case Report Forms
- Sponsor Correspondence
- General Correspondence

For a more detailed list of sub-folders email: RSCMonitoringUnit@uams.edu.