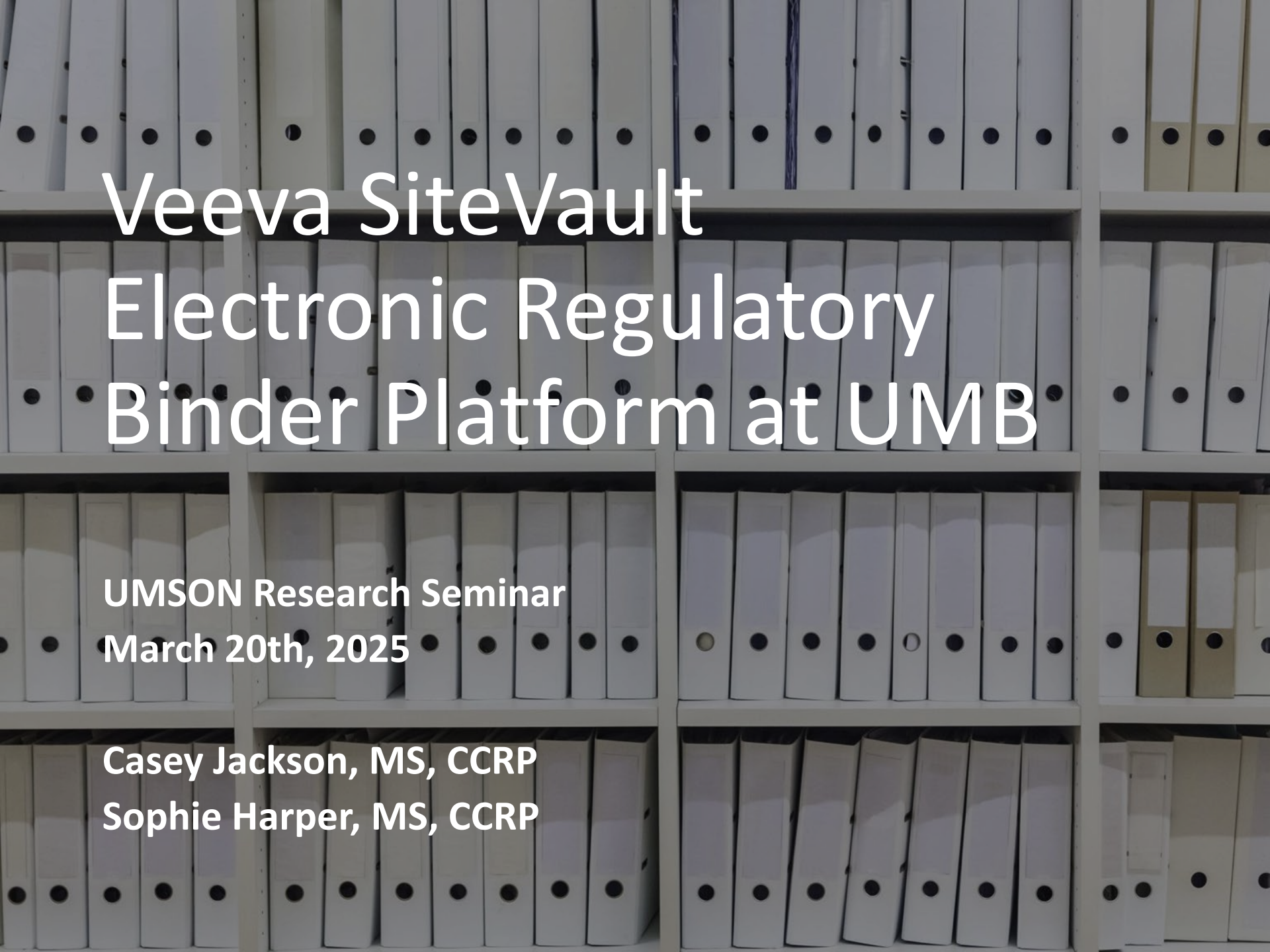
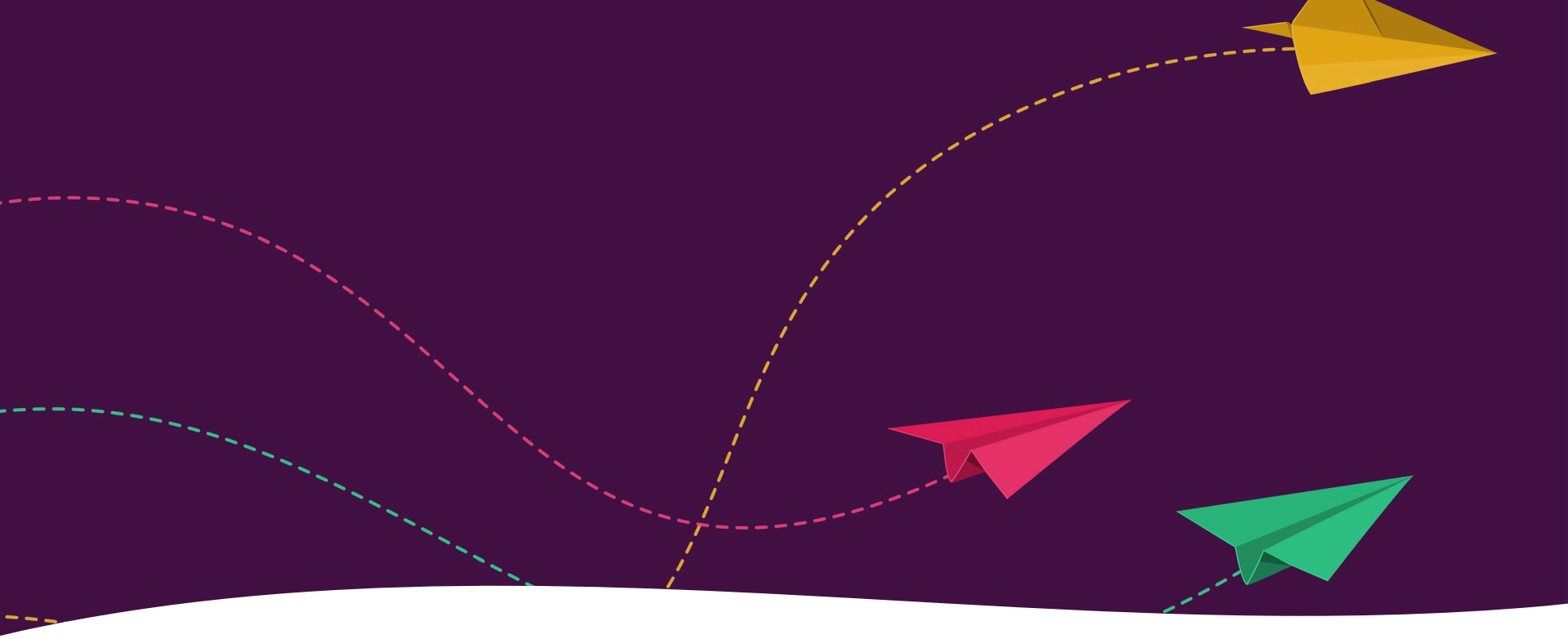


Veeva SiteVault Electronic Regulatory Binder Platform at UMB

UMSON Research Seminar
March 20th, 2025

Casey Jackson, MS, CCRP
Sophie Harper, MS, CCRP



Disclaimer

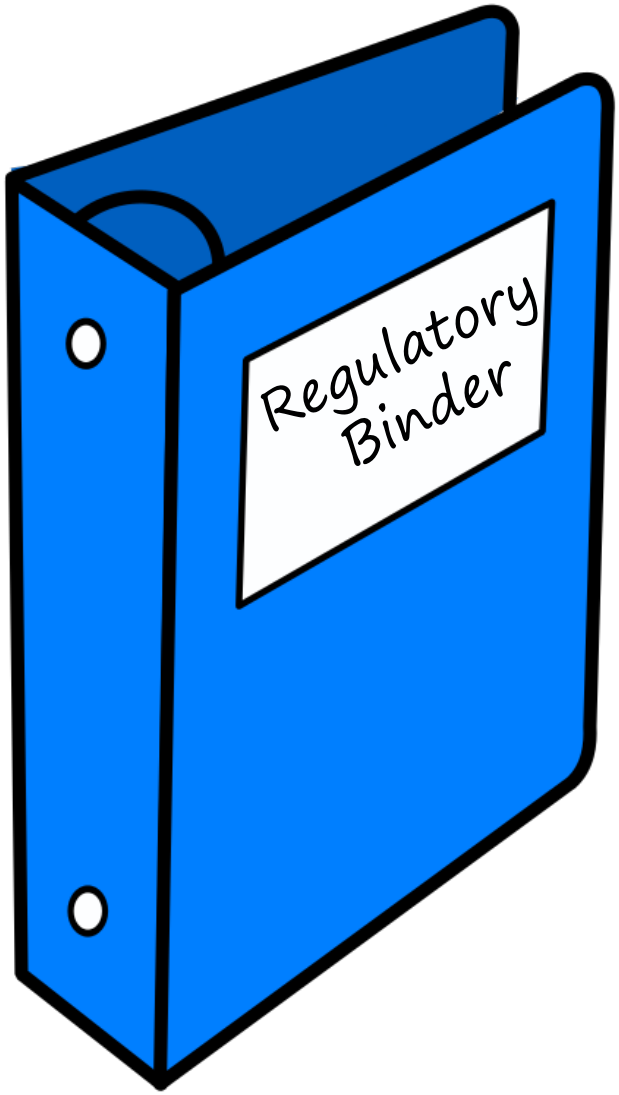
This talk is for informational purposes only and is not intended as an endorsement of Veeva products; It regards the use of Veeva SiteVault specifically at UMB/UMMC.

The speakers are not affiliated with Veeva and have no conflicts of interest to disclose.

The speakers are not campus contacts for Veeva.

Objectives

- Discuss the importance of the regulatory binder in human subjects research.
- Share a campus-wide eRegulatory binder opportunity to be weighed by appropriate research department representatives.
- Dive into user perspectives and experiences from early campus adopters.


Regulatory
Binder


Investigator binder
Essential Document Binder
Investigator File
Site File
Study File
Investigator Site File

Requirements

ICH/GCP Section 4.9.4:	Investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (Section 8) and as required by the applicable regulatory requirements.
FDA 21 CFR Part 312 (Investigational Drug Studies):	Investigators must maintain study records, ensure source documents and case report forms are accurate and complete, and retain records for at least 2 years after the study ends or the drug's approval is withdrawn.
FDA 21 CFR Part 11:	Electronic records and electronic signatures in place of paper records Must meet integrity, security, and compliance standards
HHS 45 CFR Part 46:	Maintain essential documents, including IRB approvals & correspondence, ICF documentation, study participant records, regulatory & compliance documents, and investigational product documents.
UMB HRPO	All previously stated, plus general training documentation and delegation of authority logs

Why eReg Binder / eISF ?

- Paperless
- Centralized Storage
- Instant Access
- Audit Trails
- Data Security & Access Control
- Document Tracking

Veeva SiteVault: An Opportunity

Study eBinder and Site eBinder

Not mandatory; other options available

Department Head/Research Admin clearance

Veeva SiteVault Features

- Free eRegulatory for up to 20 active studies per site*
- Approved for use by UMB and UMMC
- Web-based
- 21 CFR Part 11 and HIPAA compliant
- Electronic signatures
- Automated process for certifying copies of original source
  - Delegation of Responsibility Log
- Training workflow
- Folders not customizable (standardized, automated filing and nomenclature)
  - Site-level validation not indicated
- Reporting Dashboard (open tasks, metrics)
- Remote monitoring (access to all official, auditable study regulatory documents)
- Storage (studies maintained for 25 years)
- No limit to number of users
- Veeva assigns an internal contact person for organizational assistance

Our PBC Objectives

Our Board of Directors has established the following objectives as we pursue our public benefit purpose. They may change over time as our business and our relationship with the industries we serve evolves.

Veeva PBC Purpose (Part 1): *To provide products and services that are intended to help make the industries we serve more productive.*

Objective 1: Enable faster and less expensive clinical trials that are less burdensome and more accessible to patients

By connecting clinical trial stakeholders through Veeva's integrated clinical technology solutions, we intend to make clinical trials more efficient with connected processes and automated data flow to benefit clinical trial participants, sites, and sponsors. We take a long-term view and are working to fundamentally improve the burdensome clinical trial processes, not just sell products that are short-term fixes for short-term gain.

Representative progress for fiscal 2024:

- *Veeva Vault EDC* has now been used in more than 1,000 clinical trials globally, bringing much-needed innovation to the industry that has enabled faster clinical trial study builds and more efficient ongoing maintenance of the study design. In an industry first, we also migrated the entire core portfolio of in-process studies of a top 20 biopharma company from a legacy EDC provider to *Vault EDC*. *Vault EDC's* migration capability is an important step toward enabling the industry to take advantage of modern innovative technology for clinical trials.
- We continue to invest in *Veeva SiteVault*. *SiteVault* is a free technology that over 7,000 clinical trial sites have signed-up to manage their regulatory information and share information with clinical trial sponsors. More than 650 clinical research sites serving patients use this free technology daily.

https://www.veeva.com/pbc/

~$375 per study annually if site* >20 studies

SiteVault Pricing

Free Limits

- 20 or fewer active studies
- Active studies are any study that has not been canceled or archived, regardless of sponsor
- *No limits to documents or users*

Tiered Licensing

- Licensing tiers based active studies managed in SiteVault

# of Active Studies License Tier	Total Annual Licensing:
0 - 20	Free
21 - 39	$10,000
40 - 59	$18,000
60 - 79	$24,000
80 - 99	$28,000
100 - 149	$30,000
150 - 199	$45,000
200 - 299	$60,000
300 - 399	$90,000
400 - 499	$120,000
500 - 599	$150,000
600 - 699	$180,000
700 - 799	$210,000
800 - 899	$240,000
900 - 999	$270,000
1,000+	$300,000

**A site in SiteVault is meant to be a distinct research team, department, institute, or location within a research organization.*

What is in place now?

- Approved through procurement
- Approved through CITS
- Research Admins aware

What Do You Need to Start?

- Discussion with Department Head/Research Admin
- Assign compliant internal contact (and backup) within each dept/division for requesting a Veeva SiteVault account with Veeva (initial start-up) and vetting internal requests for users (ongoing)
- A policy on the Use of Certified Copies in Research
- Develop SOPs related to and on the use of Veeva SiteVault
- A training/onboarding plan

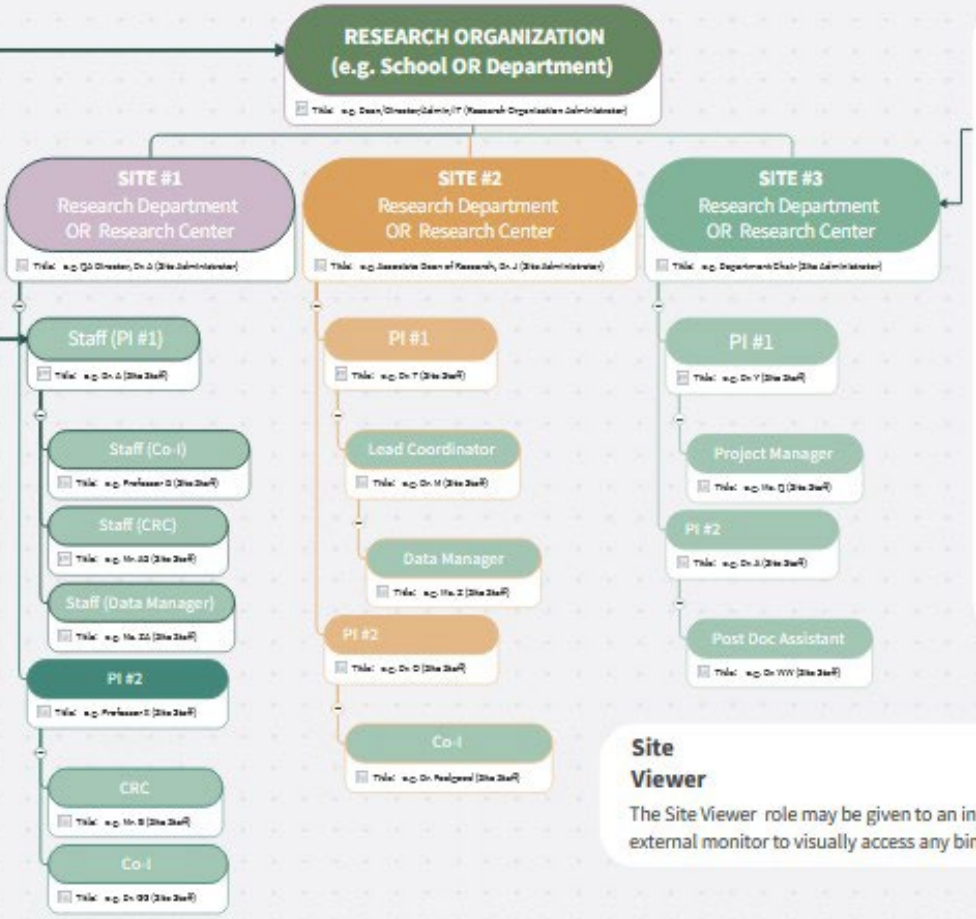
Structure

It is essential that roles align with permissions compliantly. Linked is the below reference to utilize for Veeva SiteVault planning purposes.

1

Research Organization Administrator

Each Research Organization must assign to it a Research Organization Administrator and back-up. These assignee's have control over which underlying centers/departments ("sites") utilize Veeva Site Vault and have visibility access to ALL studies for ALL sites under their umbrella. Responsibilities include ensuring that the school /department has implemented a policy on certified copies, SOPs on the use of Veeva SiteVault; and working with an assigned Site Veeva Rep to create site accounts for the each research center or department under the organization.



2

Site Administrator

Each site must have an assigned Site Administrator and back up. These assignee's have visibility access to ALL studies under their specific site umbrella. This is the only role with the ability to add site study team members to the system (including the PI) and to create site studies in the system.
Site Administrators do not have access to the studies of other sites unless they are specifically assigned to a specific study at another site. Individual PI's within a department cannot act as their own "site"; they must have the resources to be supported by a department/office as PIs under a "site".

3

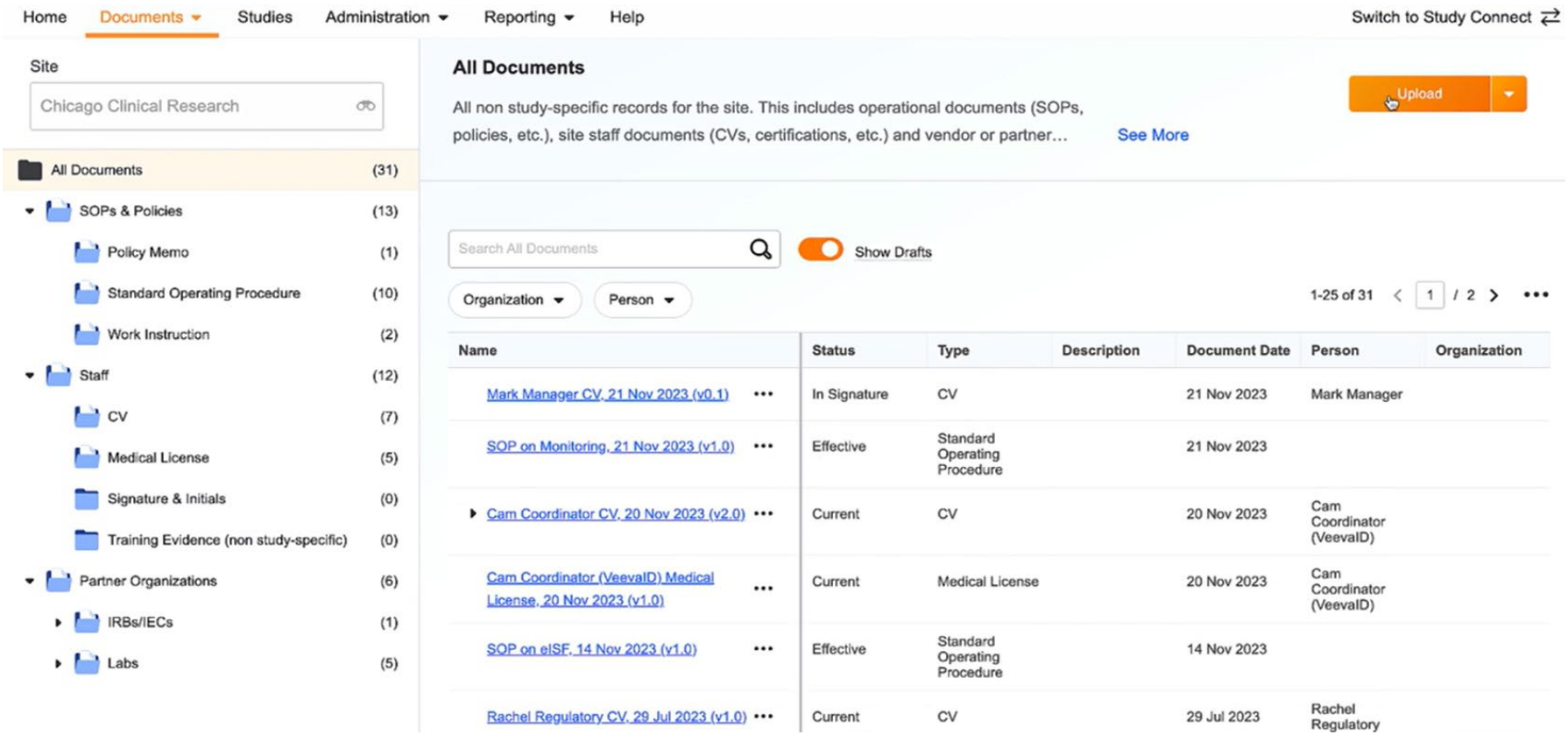
Site Staff

Site Staff are assigned by the Site Administrator. They do not have visibility to any study they are not assigned to. The PI may use the Veeva Digital Delegation feature to assign roles to the site staff.
Site Staff can certify their training in Veeva SiteVault, and route documents for PI signature.

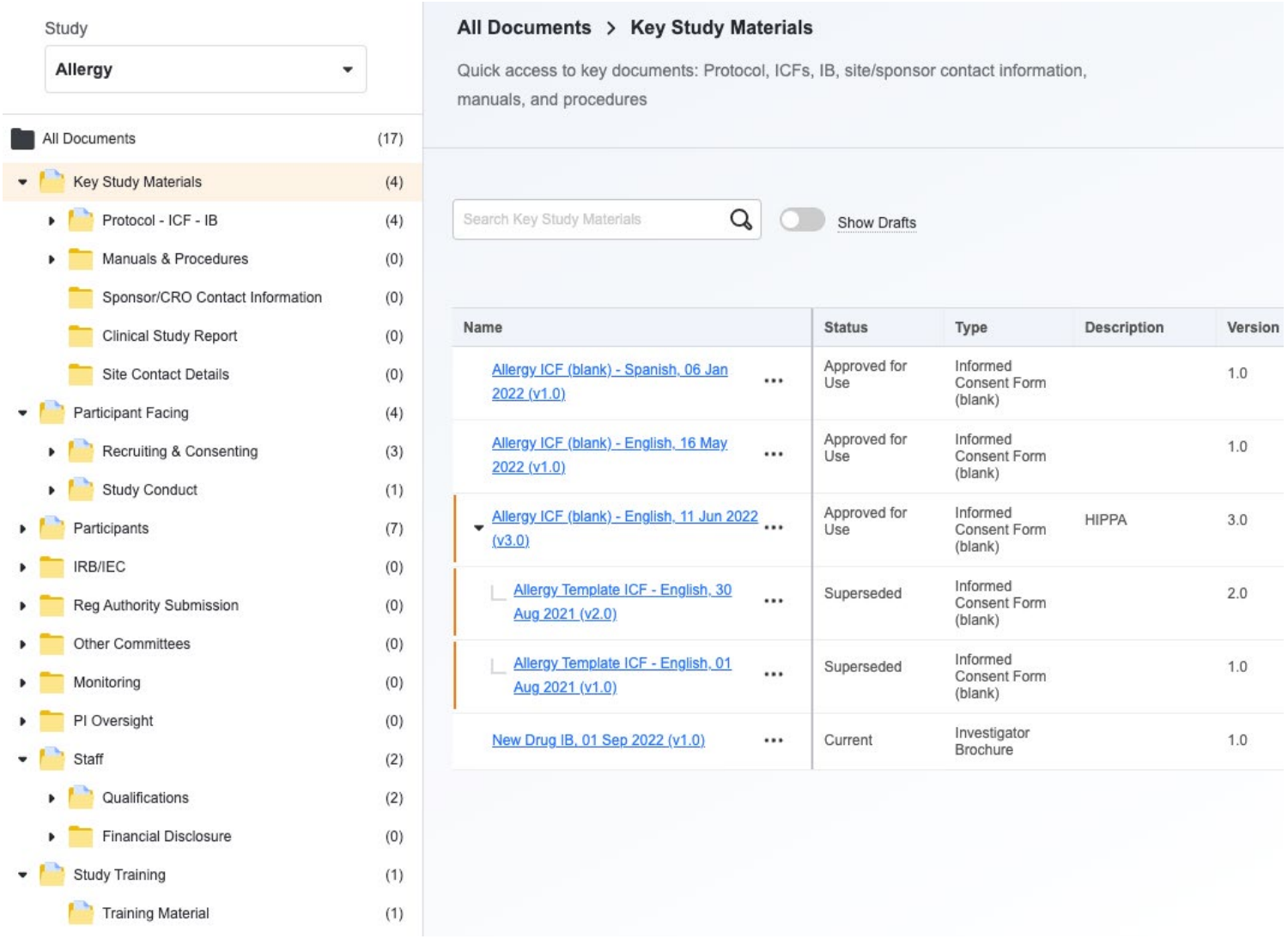
Site Viewer

The Site Viewer role may be given to an internal quality assurance (QA) staff member or external monitor to visually access any binder within their site (no edit rights).

Site eBinder



Study eBinder



Veeva SiteVault Training

- SiteVault Help Center
  - https://sites.veevavault.help/gr/sitevault/
- Electronic signatures
  - https://sites.veevavault.help/gr/resources/videos/ddl/
- Training workflow
  - https://www.youtube.com/watch?v=eYOyWbybEUo

Experiences: CVD (UMSOM)

- 10 studies fully implemented
  - 1 study has gone through entire lifecycle from Pre-Award to archival
- Nearly 3,000 new documents and over 500 completed trainings and eSignatures in 2024
- 103 active accounts created
- SOPs on delegation and signature log, protocol-training, and eISF
- Streamlined workflows – protocol training, eSignatures, and remote monitoring
- Centralized training materials
- Remote monitoring capability

Experiences: UMSON

- Piloted on (2) IITs
- Implemented policy on certified copies
- Optional blanket SOP on use of SiteVault (otherwise PI creates their own)
- Developed SiteVault account and binder request process
- Rolling out now, plan on first come first serve access and wait list


Questions?

Resources

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2016). *Good Clinical Practice (GCP)*. ICH. Retrieved from https://www.ich.org

U.S. Food and Drug Administration (FDA). (2021). *21 CFR Part 312: Investigational New Drug Application*. Code of Federal Regulations, Title 21, Part 312. Retrieved from https://www.ecfr.gov

U.S. Food and Drug Administration (FDA). (2021). *21 CFR Part 11: Electronic Records; Electronic Signatures*. Code of Federal Regulations, Title 21, Part 11. Retrieved from https://www.ecfr.gov

U.S. Department of Health and Human Services (HHS). (2020). *45 CFR Part 46: Protection of Human Subjects*. Code of Federal Regulations, Title 45, Part 46. Retrieved from https://www.hhs.gov

University of Maryland, Baltimore (UMB). (2021). *Human Research Protections Office (HRPO)*. Retrieved from https://www.umaryland.edu