SOP Needs Assessment

If your site has implemented SiteVault features, consider updating or creating the following SOPs. Each section represents a recommended SOP that should be filed at your site when using SiteVault. The questions below should be used as guidance to create or update the corresponding SOP.

Document Management

Includes Regulatory Documents, Source Documents, Copy Certification, and Archiving and Record Retention

Regulatory Documents

- What is the process for managing, uploading, and organizing documents to the eISF?
- How are versions managed in the eISF?
- What is the process for document quality review or internal auditing?
- Which documents require approval?

Source Documents

- Which source documents are stored in SiteVault?
- How will source documents be maintained in SiteVault?
- Will source documents be redacted prior to upload to SiteVault? (*Note: Redaction is not recommended, SiteVault is HIPAA-compliant and capable of storing unredacted documents*)

Copy Certification

- What is the process for certifying a copy in SiteVault?
- What is the process for maintaining or destroying paper original once the electronic copy is certified?

Archiving and Record Retention

- What are procedures for archiving in SiteVault?
- When does the archival process begin in SiteVault?
- Are archived documents stored in SiteVault or exported and stored elsewhere?

External Auditing and Monitoring

- How will an auditor obtain access to SiteVault documents?
- Will the auditor login to SiteVault directly?
- What is the process for external monitoring in SiteVault?
- How will the monitor obtain access to SiteVault?

eSignature

- What is the process for collecting eSignatures in SiteVault?

Delegation of Authority (DOA)

- What is the process for creating and maintaining the DOA in SiteVault?
- Is DOA managed electronically or on paper and uploaded to SiteVault?
- How will DOA updates be managed on paper and/or electronically?

Informed Consent

- What is the process for creating the eConsent templates in SiteVault?
- How will eConsent template creation vary if eConsent is site or sponsor-driven?
- How will the IRB access, review, and approve the electronic consent form?
- What is the process for requesting and collecting eConsent?
- Who is responsible for requesting and countersigning eConsent (ex. Site Staff, PI, multiple staff members)?

eRegulatory System Administration and Training

- Is SiteVault administration centralized or decentralized at your organization?
- Who is responsible for creating profiles and provisioning access?
- What roles are available in the system and how do they map to existing staff positions?
- What initial training is required to obtain access?
- What training is required to maintain access (by role)?
- How is training completion confirmed and tracked (by role)?
- What support procedures are in place?
- What downtime procedures are in place?

Training within SiteVault

- On which documents will staff complete training in SiteVault?
- Who is responsible for requesting training completion?
- Who is responsible for ensuring training is completed?