



SOP Needs Assessment Checklist

Which of your current SOPs need revision?

If your site has implemented SiteVault features, some of these current SOPs at your site will be needed to be revised:

- Regulatory Management/Maintenance**
Are you storing your regulatory documents on SiteVault?
- Source Documentation**
Are you storing and managing source documentation on SiteVault?
- Essential Documentation**
Are you creating and maintaining required original and revised essential documents?
- Business Continuity Plan**
Do you have a plan for business operations in the event of staff change, emergency, or disaster?
- Monitoring Visits**
Have you had remote monitoring visits via SiteVault?
- Signatures**
Have you been using the SiteVault eSignature feature?
- Site Responsibilities**
Are you using SiteVault user access/roles and responsibilities?
- Training Records**
Are you using SiteVault to train staff on study protocols?
- Data Management**
Do you use SiteVault for CRF management, data entry, or data security?

What completely new SOPs will you need to adopt SiteVault?

Are you using any of these SiteVault-specific features?

- Source/Remote Monitoring**
- Electronic Investigator Site File**
- User Management and Training**
- SiteVault Training**
- SiteVault System Administrator**
- Certified Copy**
- eDOA**
- eSignature**