Veeva SiteVault

Study eBinder Quick Reference Card

09 Dec 2024
SiteVault Version 24R3

Main Folder	Subfolders	Document Types
Key Study Materials	Protocol - ICF - IB	Protocol, Informed Consent Form (blank), Investigator Brochure, IB Summary of Changes, Marketed Product Material, Protocol Clarification, Protocol Summary of Changes
	Manuals & Procedures	Procedure Manual, Decoding Procedures, Sample Case Report Form, Recruitment Plan
	Filed to Main Folder	Sponsor/CRO Contact Information, Clinical Study Report, Site Contact Details Source Template (blank)
Participant Facing	Recruiting & Consenting	Informed Consent Form (blank), Participant Information Sheet, Advertisement for Recruitment
	Study Conduct	Study Participation Card, Diary (blank), Participant Questionnaire (blank), Participant Materials - Other
Participants	Logs	Participant Screening Log, Participant Enrollment Log, Participant ID Code List, Protocol Deviations, Specimen Tracking, Participant Adverse Event Log, Participant Decoding Event
	Source	Source Data Agreement, Informed Consent Form (signed), Source
	Filed to Main Folder	Completed CRFs
IRB/IEC	Submissions	IRB/IEC Submission, IRB/IEC Response
	Compliance & Qualifications	IRB/IEC Compliance, IRB/IEC Composition, Reliance Agreement
Reg Authority Submission	(no subfolders)	Reg Authority Submission, Regulatory Authority Response
Other Committees	(no subfolders)	Ancillary Committee Submission, Ancillary Committee Response
Monitoring	(no subfolders)	Monitoring Visit Confirmation Letter, Monitoring Visit Follow Up Letter, Monitoring Visit Log
PI Oversight	(no subfolders)	Acceptance of IB, Acceptance of Marketed Product Material, Protocol Signature Page, Delegation of Authority, 1572 or Equivalent, System User Access
Staff	Qualifications	CV, Biosketch, Medical License, Training Evidence (non-study-specific), Signature & Initials
	Financial Disclosure	Conflict of Interest, Financial Disclosure Form
Study Training	(no subfolders)	Training Material, Training Evidence (study-specific)
Safety	(no subfolders)	Participant Adverse Event Log, Adverse Event Report, Expedited Safety Report
IP & Supplies	(no subfolders)	Investigator Brochure, Marketed Product Material, IP Accountability, IP Destruction, IP Excursions, IP Instructions for Handling, IP Sample Label, IP & Supply Shipping, Equipment Log, IP Quality Complaint, IP Relabeling
Lab	(no subfolders)	Lab Certification, Lab Normal Ranges, Lab Director Qualifications
Correspondence & Notes	(no subfolders)	Site Activation, Correspondence, Note to File
Contracts & Budgets	(no subfolders)	Budget, Internal Budget, Confidentiality Agreement, Contract, Data Privacy, Invoice, Insurance
Feasibility	(no subfolders)	Feasibility Questionnaire, Protocol Synopsis