

Main Folder	Subfolders	Document Types
<b>Key Study Materials</b>	Protocol - ICF - IB	Protocol, Informed Consent Form (blank), Investigator Brochure, 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
<b>Participant Facing</b>	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
<b>Participants</b>	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
<b>IRB/IEC</b>	Submissions	IRB/IEC Submission, IRB/IEC Response
	Compliance & Qualifications	IRB/IEC Compliance, IRB/IEC Composition, Reliance Agreement
<b>Reg Authority Submission</b>	(no subfolders)	Reg Authority Submission, Regulatory Authority Response
<b>Other Committees</b>	(no subfolders)	Ancillary Committee Submission, Ancillary Committee Response
<b>Monitoring</b>	(no subfolders)	Monitoring Visit Confirmation Letter, Monitoring Visit Follow Up Letter, Monitoring Visit Log
<b>PI Oversight</b>	(no subfolders)	Acceptance of IB, Acceptance of Marketed Product Material, Protocol Signature Page, Delegation of Authority, 1572 or Equivalent, System User Access
<b>Staff</b>	Qualifications	CV, Biosketch, Medical License, Training Evidence (non-study-specific), Signature & Initials
	Financial Disclosure	Conflict of Interest, Financial Disclosure Form
<b>Study Training</b>	(no subfolders)	Training Material, Training Evidence (study-specific)
<b>Safety</b>	(no subfolders)	Participant Adverse Event Log, Adverse Event Report, Expedited Safety Report
<b>IP &amp; Supplies</b>	(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
<b>Lab</b>	(no subfolders)	Lab Certification, Lab Normal Ranges, Lab Director Qualifications
<b>Correspondence &amp; Notes</b>	(no subfolders)	Site Activation, Correspondence, Note to File
<b>Contracts &amp; Budgets</b>	(no subfolders)	Budget, Internal Budget, Confidentiality Agreement, Contract, Data Privacy, Invoice, Insurance
<b>Feasibility</b>	(no subfolders)	Feasibility Questionnaire, Protocol Synopsis