

Electronic Investigator Site File Contents Template

Present	File Section	Documentation
<input type="checkbox"/>	Key Study Materials	Sponsor/CRO contact information, Clinical Study Report
<input type="checkbox"/>	Protocol – ICF – IB	Protocol, Informed Consent Form (blank), Investigator Brochure, Marketed Product Material
<input type="checkbox"/>	Manuals & Procedures	Procedure Manual, Decoding Procedure, Sample Case Report Form
<input type="checkbox"/>	Subject Facing Recruiting and consenting	Subject Information Sheet, Advertisement for Subject Recruitment, Informed Consent Form (blank)
<input type="checkbox"/>	Study Conduct	Study Participant Card, Subject Diary (blank), Subject Questionnaire (blank)
<input type="checkbox"/>	Participants Logs	Subject Enrollment Log, Subject Identification Code List, Subject Screening Log, Specimen Tracking, Protocol Deviation
<input type="checkbox"/>	Source	Source
<input type="checkbox"/>	IRB/ IEC Submissions	HREC/IRB/ IEC Submissions, HREC/IRB/ IEC Responses
<input type="checkbox"/>	Compliance and Qualifications	IRB/ IEC Compliance, IRB/ IEC Composition, Reliance Agreement
<input type="checkbox"/>	Reg Authority Submissions	Regulatory Authority Submission, Regulatory Authority Responses
<input type="checkbox"/>	Other Committees	Ancillary Committee Submission and/or responses, RGO & Site Specific Application and/or amendment
<input type="checkbox"/>	Monitoring	Monitoring Visit Confirmation Letter, Monitoring Visit Follow Up Letter, Monitoring Visit Log
<input type="checkbox"/>	PI Oversight	Protocol Signature Page, Acceptance of IB, Acceptance of Marketed Product Materials, Delegation of Authority, 1572 or equivalent

Present	File Section	Documentation
<input type="checkbox"/>	Staff	
<input type="checkbox"/>	Qualifications	CV, Medical License, Training Evidence (non-study specific), Biosketch, Signature & Initials
<input type="checkbox"/>	Financial Disclosures	Financial Disclosure Forms, Conflict of Interest
<input type="checkbox"/>	Study Training	Training Evidence (study-specific), Training Materials
<input type="checkbox"/>	Safety	Adverse Event Report, Expedited Safety Report
<input type="checkbox"/>	IP & Supplies	IP Instructions for Handling IP, Sample Labels, IP Accountability, IP Excursions, IP Destruction, IP & Supply Shipping, Investigator Brochure*, Marketed Product Material*
<input type="checkbox"/>	Lab	Lab Certificate, Lab Normal Ranges, Lab Director Qualifications
<input type="checkbox"/>	Correspondence & Note to File	Correspondence, Note to File, Site Activation
<input type="checkbox"/>	Contracts & Budgets	Budget, Contract, Confidentiality Agreement, Internal Budget, Data Privacy Forms
<input type="checkbox"/>	Feasibility	Feasibility Questionnaire, Protocol Synopsis

*Secondary filing location for this record