EXAMPLE

Regulatory Binder Table of Contents

Please file the following behind each of the corresponding tabs.

1- Study Logs	• Master Subject Log—list all subjects screened, regardless of their enrollment status • Randomization, screening and enrollment reports • Enrollment confirmation faxes • Site Visit Log—signatures of monitors, auditors, all other personnel performing a site visit • Clinical Trials Responsibility Log—list name, signature, and initials of all personnel who perform study-related procedures
2- Protocol	• Protocol • Amendment(s) • Signature page(s) for the protocol and any amendments
3- Investigator Drug Brochure	• Investigator drug brochure and signed receipt form • IND Safety Reports
4- Informed Consent	• IRB approved versions of consent forms (blank forms) • Signed informed consent forms (if filed elsewhere, please provide memo stating the location of the signed forms)
5- Competent Authority Regulatory Approval Documentation	• Initial notification/approval (not applicable for US and Canada) • Ongoing notification/approval (not applicable for US and Canada) • Interim/annual reports (not applicable for US and Canada) • Signed agreement between Investigator/Regulatory Authority (not applicable for US and Canada) • Other regulatory related documents (not applicable for US and Canada)
6- IRB/IEC Approvals	• IRB/IEC approval letter (original) or Research Ethic Board Attestation (Canada) for protocol, for consent form(s) and any amendments identified by protocol number and/or title and date of approval • Patient recruitment advertisement approvals and corresponding IRB/EC letter(s) • IRB/IEC membership information and/or general assurance number
7- IRB/IEC Communication	• IRB/IEC correspondence—letters of submission and approval notices • IRB/IEC notification of and responses to serious adverse events at your institution • Documentation of submission of safety reports to IRB/IEC and IRB/IEC responses • Progress reports and annual IRB/IEC renewals • Close out/final report notice
8- FDA 1572/Regulatory Forms	• Form FDA 1572 and updated forms • Financial disclosure for all principal and sub-investigators
9- Curricula Vitae (CV)	• Curricula vitae for all principal and sub-investigators and site staff • Medical licensure number, medical specialty, and board certification number (if applicable) for all principal and sub-investigators
10- Drug Accountability*	• Study-agent accountability logs • Study-agent order forms • Study-agent shipment records • Disposition and/or return of unused or damaged study kit records
11- Laboratory	• Laboratory accreditation/certification for all laboratories listed on the Form FDA 1572 • Lab normal ranges for all tests performed in study

*Maintain drug accountability in the pharmacy manual over the course of the trial; at trial completion, file all records here or place a note stating the location of the forms.

EXAMPLE

Regulatory Binder Table of Contents

12- Serious Adverse Events	• Master serious adverse event (SAE) reporting form and instructions for completion • Completed patient SAE forms—if filed elsewhere, insert a note in this section indicating where they may be found. • Related correspondence
13- Training	• Site initiation visit (SIV) attendance log • Trial-related training certificates
14- Trial Agreements	• Signed Clinical Trial Agreement (If Clinical Trial Agreement is filed elsewhere, insert a note in this section indicating where the contract is located) • Signed Confidentiality Disclosure Agreement (If CDA is filed elsewhere, insert a note in this section indicating where the CDA is located)
15- Regulatory Inspections/Audits	• Correspondence relating to inspections and audits
16. Guidelines	• ICH Guidelines • Declaration of Helsinki • Country specific regulations/guidelines (where applicable)
17. Country-Specific Documents	• REB attestation (CA) or equivalent • Qualified Investigator Undertaking • Clinical Trial Site Information Form
18. Correspondence	• Study related communication (letters, memorandums, written documentation of telephone conversations, facsimiles, newsletters, and copies of electronic correspondence) between the site and sponsor, coordinating center, contract research organization, etc. • Monitoring report copies