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| **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 * Delegation of Authority Log—list name, signature, and initials of all personnel who perform study-related procedures |
| 2- Protocol | ProtocolAmendment(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- IRB/IEC Approvals** | * IRB/IEC approval letter (original)) 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 |
| 6- 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 |
| 7- FDA 1572/Regulatory Forms | * Form FDA 1572 and updated forms * Financial disclosure for all principal and sub-investigators * Statement of Compliance from PI for non-IND studies |
| 8- Research Team Qualifications | * 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 * GCP Training |
| 9- 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 |
| 10- 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.

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| 11- Serious Adverse Events | * Master serious adverse event (SAE) reporting form and instructions for completion * Completed subject SAE forms—if filed elsewhere, insert a note in this section indicating where they may be found. * Related correspondence |
| 12- Training | * Site initiation visit (SIV) attendance log * Trial-related training certificates |
| **13 Sponsor Correspondence/Monitoring Reports** | * 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 |