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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 | 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- 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
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\*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
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