|  |  |  |  |
| --- | --- | --- | --- |
| **Section** | **Document** | **Can be filed outside main ISF? If so, where?** | **Requires 21 CFR Part 11 compliant signature?** |
| ***1*** | ***Subject Information*** | | |
|  | Screening Log |  |  |
|  | Enrollment Log |  |  |
|  | Subject ID Code List | Coordinator records |  |
| ***2*** | ***Protocol Documentation*** | | |
|  | Protocol Documents, including Amendments | Filed electronically |  |
|  | Protocol Signature Page(s) |  | Yes |
|  | Protocol Deviation(s) |  |  |
| ***3*** | ***Investigator Brochure (IB)*** | | |
|  | IB or package insert(s) | Filed electronically |  |
|  | Acknowledgment of Receipt (AoR) |  | Yes |
| ***4*** | ***Case Report Forms (CRFs)*** | *Filed electronically/coordinator’s records* | |
|  | Blank CRFs |  |  |
|  | Completed/Signed/Dated CRFs |  |  |
|  | Documentation of CRF corrections |  |  |
| ***5*** | ***Source Documents*** | *Filed electronically/coordinator’s records* | |
| ***6*** | ***Financial Documentation*** | *Filed electronically – must be separate from ISF* | |
|  | Confidentiality Agreement (CDA) |  |  |
|  | Clinical Trial Agreement (CTA) |  |  |
| ***7*** | ***Institution Review Board (IRB) Documentation*** | *Filed in separate regulatory binder* | |
|  | Initial Submission |  |  |
|  | Amendments |  |  |
|  | Continuing Review |  |  |
|  | IRB approval letters |  |  |
|  | IRB approved Informed Consent Forms (ICFs) |  |  |
|  | IRB approved Assent Forms |  |  |
|  | IRB roster(s) |  |  |
|  | IRB Correspondence |  |  |
| ***8*** | ***Subject Materials*** | | |
|  | Signed ICFs/Assent Forms | Subject chart | Yes |
|  | Advertisements/Recruitment Materials | Filed electronically |  |
|  | Subject-Facing Materials (i.e., questionnaires) | Filed electronically |  |
| ***9*** | ***Investigator/Staff Credentials*** | | |
|  | Delegation of Authority Log |  | Yes |
|  | Protocol-specific Training Log |  | Yes |
|  | FDA form 1572(s) |  | Yes |
|  | Financial Disclosure Forms |  | Yes |
|  | Curriculum Vitae, signed & dated every 2 years |  | Yes |
|  | Medical licenses |  |  |
|  | ICH GCP training certificates |  |  |
| ***10*** | ***Laboratory Documents*** | | |
|  | CAP/CLIA/licenses |  |  |
|  | Reference Ranges |  |  |
|  | Specimen Logs |  |  |
|  | Freezer Temperature Logs |  |  |
|  | Shipping Logs |  |  |
| ***11*** | ***Pharmacy Documentation*** | *Filed in Research Pharmacy* | |
|  | Instructions for Handling |  |  |
|  | Investigational Product (IP) Accountability Logs |  |  |
|  | Shipping Records |  |  |
|  | Temperature Logs |  |  |
|  | Decoding Procedures for Blinded Trials |  |  |
|  | IP Destruction Logs |  |  |
| ***12*** | ***Monitoring*** | | |
|  | Site Visit Log |  | Yes |
|  | Clinical Quality Management Plan (CQMP) |  |  |
|  | Site Selection Visit (SSV)/Site Qualification Visit (SQV) confirmation letter and follow up letter |  |  |
|  | Site Initiation Visit (SIV) confirmation letter and follow up letter/report |  |  |
|  | Interim Monitoring Visit (IMV) confirmation letters and follow up letters/reports |  |  |
|  | Closeout Visit (COV) confirmation letter and follow up letter |  |  |
| ***13*** | ***Relevant Correspondence*** | | |
|  | Newsletters |  |  |
|  | Meeting Notes |  |  |
|  | Phone Calls |  |  |
|  | FDA correspondence, if applicable |  |  |
| ***14*** | ***Serious Adverse Event (SAE) Reporting/IND Safety Reports/SUSARs*** | | |
| ***15*** | ***Final Clinical Study Report*** | | |