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| **Sec.** | **Essential Documents** |
| **1** | **STUDY TEAM** |
|  | Study Team Contact List |
|  | Study Team Signature and Delegation Log |
|  | CVs, Licenses, Financial Disclosures, Applicable Certifications of Key Study Personnel |
|  |  |
|  |  |
| **2** | **PROTOCOL** |
|  | Study protocol + amendments |
|  | IRB Stamped Consent Document and Translations |
|  | IRB Stamped Advertisements |
|  | Investigator Brochure (IB) |
|  | Safety update letters for inclusion in IB |
|  | Sample of Questionnaires / survey forms |
|  | Sample of Diary cards |
|  | Sample of Memory aids for study procedures |
|  | Any other written information given to the patient |
|  | Sample of CRF |
|  |  |
| **3** | **REGULATORY** |
|  | **Committee for Protection of Human Subjects (IRB)** |
|  | IRB Submission Forms (initial, amendments, renewals etc) |
|  | IRB Outcome Letters (Approvals, Acknowledgments etc.) |
|  | IRB Correspondence (or location) |
|  |  |
|  | **Food and Drug Administration** |
|  | Form FDA 1572 for all Key Study Personnel |
|  | Copy of IND / IDE submission |
|  | FDA Correspondence |
|  | Annual Reports |

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| **4** | **PATIENT LOGS** |
|  | Screening log |
|  | Enrollment log |
|  | Subject Visit Schedule Log |
|  | Signed Informed Consent Forms (or location) |
|  |  |
| **5** | **UNANTICIPATED PROBLEMS** |
|  | Copies of AE reports if not included in CRF |
|  | AE log for events in non-site subjects |
|  | AE log for events in site subjects |
|  | Adverse Event reports |
|  | Protocol Deviation Logs |
|  |  |
| **6** | **DRUG / DEVICE ACCOUNTABILITY** |
|  | Package Insert / Prescribing Information |
|  | Drug / Device Receipt (Shipping Records) |
|  | Drug / Device Accountability Log |
|  | Drug Disposal Records |
|  | Sealed unblinding envelopes (or location) |
|  | Individual treatment codes (or location) |
|  | Temperature Logs |
|  |  |
| **7** | **LABORATORY** |
|  | Laboratory Name and Contact Address |
|  | Logistic Arrangements with lab (if local lab is used) |
|  | Lab certifications and normal ranges |
|  | Biological specimen sampling, labeling, storing and shipping procedure |
|  | Biological specimen log |
|  | Shipping records (if central lab is used) |
|  | Temperature Logs |
|  |  |
| **8** | **MONITORING** |
|  | Monitoring log |
|  | Monitoring reports |
|  | Initiation meeting information (sign in sheet, agenda, minutes etc) |
|  | Correspondence |
|  |  |
| **9** | **FINANCIAL DOCUMENTS (may be stored in separate location)** |
|  | Clinical Trial Agreement |
|  | Budget |
|  | Financial expenditure records |
|  | Billing statements |
|  |  |
| **10** | **Other Documents** |
|  | Completed CRF's (location) |
|  | Study Closure Documentation |
|  | Publications, presentations, manuscripts, etc |