**Sample - REGULATORY BINDER INDEX**

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| 1. Protocol | * Study Protocol * Protocol Amendments   ***Device/Drug Study Additional Information***   * Instructions for Use (all versions) * Non-disclosure agreement * Investigator Brochure (all versions) * FDA Form 1571/1572 IDE Documentation (if applicable) * Protocol Signature Page(s) for each version of the protocol |
| 2. Study Personnel | * Curricula Vitae (For all team members – within last three years) keep all versions during study * Financial Disclosures/Agreements/Conflict of Interest Statements * Other Investigator Qualifications, certifications, training and credentials * Licensure (all clinical studies) * Principal Investigator/Site Liability Insurance Certificate (all clinical studies)   ***Device/Drug Study Additional Information***   * Medical Licenses (must keep copies of license from begin to end of study) * Financial Disclosures and Agreements specific to device or drug. |
| 3. Approved Consent and Assent forms & HIPPA Authorization(s) | * All IRB Approved Consent Forms (a blank copy of original & all subsequent versions) * All IRB Approved Assent Forms (a blank copy of original and all subsequent versions) * All IRB Approved Parental Consent Form (a blank copy of original and all subsequent versions) * All IRB Approved HIPPA Authorizations (a blank copy of original and all subsequent versions) |
| 4. IRB Approvals | * IRB Approvals for Study (including letters of submission) * IRB Approvals for Continuing Review, and Protocol Changes, consent form changes, notifications of Adverse Events, Serious Adverse Events or Unanticipated Events * IRB Approved advertisements and recruitment materials * IRB Membership information * IRB Correspondence * IRB Statement of the Investigator Agreement (signed and dated) * Final IRB reports and/or acknowledgements   ***Device/Drug Study Additional Information***   * IND Safety reports and associated letters |
| 5. Laboratory | * Lab Certificates (CAP, CLIA and Washington State Licensure) * Lab reference ranges/Normal Ranges (of all labs being performed) * Lab Director CV/License (if applicable) |
| 6. Study Logs | * Screening Log(s) * Site Delegation of Duties and Signature Form * Master Subject Enrollment Log(s) * Training Log(s) (training certificates, training attendance logs)[e.g. CITI Biomedical Researcher Training Certificate] * Site Monitoring Visit Log (if applicable) |
| 7. Correspondence | * Communication Log * Correspondence between site, sponsor etc. (include letters, memos, written documentation of telephone conversations, faxes and electronic communication like email) * Participant Correspondence |
| 8. Adverse Events | * Event Logs – Adverse events, serious adverse events, unanticipated events * Completed Adverse/Serious Adverse Event Forms * Blank Adverse/Serious Adverse Event Forms |
| 9. Device or Drug Accountability/  Inventory | **Device/Drug Studies**   * Device or Drug Accountability Logs * Shipment Receipts and Packing Invoices * Refrigeration Monitoring Log (for products requiring refrigeration) * Study Supply Forms * Records of disposition and/or return of unused or damaged study drug or devices. |
| 10. Deviations / Violations: | * Deviation Log * Deviation and Violation Reporting |
| 11. Notes to File | * Copy of all notes to file. The original should be kept in the subject’s research record. |
| 12. Conflict of Interest | * Documentation of declared Conflict of Interest Statements * Plan to eliminate possibility of bias or eliminate the conflict |
| 13. Miscellaneous | * Case Report Forms * Participant Materials (such as dear participant letters or educational pamphlets) * Any site specific information such as administrative support letters for the study |

***Note: We recommend that a separate binder be made and maintained for Budgets and contracts. (Include compensation to subjects, billing information, contracts with the sponsor)***

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