**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)
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| 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
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| 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)
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| 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)
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| 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.
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| 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.
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| 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
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***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)***

 L\OSA\Mgmt\Forms.Templates\Research\Sample Regulatory Binder Index May 2017