**Regulatory Binder: Table of Contents Template**

| **Tab** | **Title / Description of Document(s)** |
| --- | --- |
| **1** | **Study Contacts** |
|  | * Sponsor and CRO Contact Information including Medical Monitor
* Other site contact information, if applicable
* Site contact information including PI, study coordinator, etc.
 |
| **2** | **IRB Approved Protocol** |
|  | * Include all versions of protocol that have been IRB approved

*(it would be helpful to section off the “archived” versions from the current version in use through a colored-page break or other mechanism)* |
| **3** | **Informed Consent/Assent/Authorization Documents** |
|  | Informed Consent/Assent/Authorization Tracking Log* Include all versions of Informed Consent / Assent / Authorization that have been IRB approved

 *(it would be helpful to section off the “archived” versions from the current version in use through a colored-page break or other mechanism)* |
| **4** | **Investigational Product Information & Safety** |
|  | * Investigator's Brochure (IB) and addenda, including all safety updates

*(could be maintained in a separate binder if needed for space)* |
| **5** | **Study Personnel Documentation** |
|  | * Delegation of Authority Log
* PI and Sub-Investigator CV's and Licenses, Study Specific Financial Disclosures *(CV’s and Licenses may be housed centrally within a department and referred to here as available upon request)*
* Human Subjects Protection and HIPAA Training Certificates (*may be housed centrally within a department and referred to here as available upon request)*
* Protocol Training Documentation (Initial and Ongoing training with amendments or other updates)
 |
| **6** | **IRB Correspondence** |
|  | * all submissions with approval correspondence and accompanying documents
* IRB Roster and FWA
 |
| **7** | **Laboratory Documentation** |
|  | * Certification(s)
* Normal reference ranges
* Specimen Logs
* Central Laboratory Shipping Documentation (packing lists, shipping labels, etc.)
 |
| **8** | **Clinical Equipment Documentation** |
|  | * Equipment / Maintenance records
* Calibration Logs
* Inspection Reports
* Permits / Licensure
 |
| **9** | **Study Conduct** |
|  | * Screening & Enrollment Logs
* Subject ID Code Log
* Master Protocol Deviation Log (if applicable)
* Subject Withdrawal / Early Termination Log (if applicable)
* Documentation of PI Oversight (team meeting sign-ins / agendas, etc.)
 |
| **10** | **Communication and Correspondence** |
|  | * CRFs (all versions)
* Sponsor / CRO Correspondence
* Site Visit / Monitoring Log
* Monitoring Reports
* DSMB/DSMC Reports *(or if no formal DSMB/DSMC, documentation of review by entity assigned to monitor safety by Data Safety Monitoring Plan; documentation should include what was reviewed, when it was reviewed, and the recommendation for the trial's continuation or discontinuation)*
 |
| **11** | **FDA Related Documentation (if applicable)** |
|  | * Form 1572 (initial and updates)

**IF IU PI is responsible for IND / IDE:*** IND/IDE Application and FDA Approval
* IND/IDE Amendments or Supplemental Applications
* Annual (or Progress) Reports
* Adverse event / Device event (adverse device effects, whether anticipated or not) reports
* Other FDA correspondence
* Final Report and Withdrawal of IND/IDE
 |
| **12** | **Investigational Product Records (if applicable)** |
|  | * Labeling information
* Shipping (Receipt and Return) Records
* Inventory and Storage Records (including temperature logs if applicable)
* Dispensation and Disposition (Destruction) Records
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