**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 |