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| Regulatory File Organization in CRIO |
| Approval Date: 11DEC2021  Revision Date: NA   1. Standard Format (all CRIO filing is Alphabetical or Numerical) Found in CRIO eRegulatory. The organization or site may slightly alter depending on study needs but should initially be set up as follows. Additional folders or sub-folders can be added if the below folders do not capture a specific document appropriately. 2. Be wary of creating too many sub-folders. CRIO has a search function that allows us to find documents easily so creating an eRegulatory system with too many folders just leads to an overly complicated system.   **Study Specific Binder**  Central Lab   * Correspondence * Lab Director CV/Lab Certification/Accreditation * Manual/Normal Values * Supply Requests/Deliveries   Correspondence   * General Correspondence/Emails * Newsletters/Study-wide Memos   Institutional Review Board   * Approval Letters * Approvals * Approved Advertisements * Correspondence * Informed Consent   Investigator Brochure   * Brochure * IB Signature Page * IND Safety Reports * Serious Adverse Events   IP Accountability   * Blinding and Unblinding Procedures * IP Log * Pharmacy Manual * Shipping Documents   Monitoring   * Monitoring Confirmation and Follow-up Letters * Monitoring Log * Site Initiation Documentation   Other   * eCRF Completion Guidelines * Note to File/CAPAs * Protocol Deviations   Protocol   * Protocol and Amendments * Protocol Signature Page   Site Staff Details   * 1572 * Financial Disclosure Forms   Study Contacts  Study Specific Training  Vendor Manuals  **Site Specific Binder**  Calibration Logs  CLIA Certificate  Exodus Temperature Log   * Ambient * Freezer * Refrigerator   ICR Temperature Logs   * Ambient * Freezer * Refrigerator |
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