

Regulatory File Organization in CRIO

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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

Policy Manual



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

Policy Manual

