***Electronic Regulatory Binder (i.e., Dropbox) Example for Single Site Studies:***

(The following documents (all versions) filed in this regulatory e-binder)

## Study Team Contact list

## IRB Approvals

* IRB approval letters
* IRB annual renewal applications (continuing review)
* IRB-approved recruitment materials and advertisements
* IRB-approved surveys/questionnaires
* IRB-approved blank Case Report Forms
* IRB-approved additional supporting documents uploaded to section 44.1

## Amendments

* IRB-approved amendments and IRB approval letters

## ORIOS

* IRB ORIOs applications and IRB approval letters
* Protocol Deviation Log

## Adverse Events

* Study Specific AE Reporting Plan
* IRB AEs/SAEs applications and IRB approval letters
* Adverse Events (AE) Log

## Informed Consent Documents

* IRB-approved Informed Consents (make sure you upload the IRB approved consent with the IRB stamp on it)

## Protocols

* Institutional Review Board (IRB)-approved protocols (signed protocol page)

## IRB Documentation

* IRB Roster (s)

## Investigator and Staff Qualification Documentation (list by staff or keep in separate folders, study team preference)

* CVs
* Licenses
* Financial Disclosures
* Human Subjects Trainings (PEERRS or other)
* PEERRS Responsible Conduct of Research and Scholarship (RCRS) Trainings
* GCP Trainings (CITI or other)
* Any other certifications that are relevant to the study (e.g., Laboratory training BLS0125w for studies that have the study team process biological samples, etc.)

## Clinical Research and Study Training (add all trainings related to study)

* + Protocol Training Log
  + Database Training Log
  + Randomization tool training

## Delegation of Authority Log

* Delegation of Authority Log

## Study Communication (study correspondence)

* Notes to File
* All other trial related records/correspondence

## Screening/Enrollment Log (these are sometimes kept as one document)

* Screening Log
* Enrollment Log
* Subject Identification Code list (which may need to be kept separately)

## Signed Consent Documents (may be kept in a separate binder)

## Unanticipated Problem Log

## Clinical Site Monitoring Visits and other Audits or Inspections

* Site visit log (monitoring log)
* Site visit reports
* Site visit correspondence (e.g., confirmation letters and follow up letters)
* Monitoring Plan
* ORCR audit
* FDA inspection

## Data and Safety Monitoring Documents

* Study reports generated for Independent Safety Monitor(s)
* Minutes from Independent Safety Monitor(s) meeting(s)
* Recommendations and correspondence from the Independent Safety Monitor(s)
* DSMB Charter
* DSMB summary letter to IRB
* DSMB/Medical Monitor applications

## Sponsor Correspondence (Progress Reports)

## Manual of Procedures (MOP)

## Lab Certifications and accountability

* CAP
* CLIA
* Laboratory Normal ranges
* Record/Accountability of biological samples (retained/shipped)
* Temperature logs for freezer/refrigerator biological samples are kept

## FDA forms

* 1571 or 1572 (IND)
* Investigator agreements (IDE)

## Investigational Product (IP)

* Investigator brochures
* Package Insert/Instruction for Use
* Unblinding procedures
* Product accountability records

*Found in the Research Pharmacy (RP) if using or with site team if not at RP*.

* Accountability records (receipt of the IP, who the IP was dispensed to, return of any IP and destruction of returned IP)
* Invoices from receipt of IP
* Storage, dispensing, destruction guidelines
* Temperature log for where the IP is kept (you only need this if the protocol says that the IP is to be kept at a certain temperature)
* Investigational Product Chain of Custody Logs
* Sample label
* Shipping records
* Certificate of Analysis (drug studies only)
* Master Randomization list
* Records of Final IP Destruction or Return

## Database

* Data Management Plan
* eCRF data entry guidelines
* Reports
* CRFs

## Meeting Summaries, Agendas, Minutes