Regulatory Binder

- Protocol
    - Initial protocol and ALL amendments
- Informed Consent
    - ALL approved versions
- Form 1572
    - All versions of the 1572 signed and dated
- CVs
    - Demonstrates qualifications of ALL investigator and associate investigators
    - Updated copies, should be signed and dated
- Serious Adverse Events
    - Copies of Reports
    - Documentation of receipt from IRB, Sponsor, FDA, as applicable
- IND Safety Reports
    - Copies of Reports
    - Documentation of receipt from IRB
- IRB Correspondence
    - Regarding Approval process of the protocol, amendments
        - Submissions, stipulations, responses to stipulations
        - Does not need to be entire package
        - Keep enough documentation to provide a trail of the process
    - Regarding continuing review
        - Reminder notices
- IRB Letters
    - IRB approvals
    - Continuing review approvals
- IB (investigator's brochure)
    - All versions of the IB and updates
    - Contains scientific information for investigation product
    - For FDA approved agents, file a copy of the package insert
- Recruitment advertisements/letters
    - With documented IRB and sponsor approvals
- Sponsor Correspondence
    - Pre-study correspondence as appropriate
    - Details processes and procedures for study conduct
    - Phone logs
    - Site visit letters/summaries
- Correspondence
    - Any miscellaneous protocol-related correspondence
- Laboratory Certification

    - All copies of CLIA certifications for all labs submitting subject results for purpose of the study.
    - Need to have valid certifications filed as long as the study is open
- Subject Enrollment/Screening Log
    - Log to document chronological enrollment of subjects
    - Log to document patients who entered pre-trial screening period
    - Should document why potential subjects were not included in the study.
- Delegation Log
    - List of the signatures and initials of ALL persons authorized on the study.
- Site Visit Log
    - Log in which monitors will document their visits
    - Site staff will have a place to initial/verify that monitor was present on specific dates
- Pharmaceutical Information
    - Drug accountability including shipping and dispensing records
    - Sample of labels attached to investigational product containers
- Case Report Forms
    - Approved case report Forms