# Florence eBinders Single-Site Template Sections

1. **Consent & HIPAA**—*maintained exclusively by CTSI regulatory specialists*
    a. Current approved ICF
    b. Current approved HIPAA
    c. Previously approved ICF(s) and HIPAA(s)
2. **Delegation of Authority**—*maintained by CTSI regulatory specialists for all study team members listed in ETHOS; study team is responsible for anybody that is required to be listed on the DOA but not in ETHOS*
    a. DOA Log**
3. **FDA Form 1572**—*CTSI regulatory specialists will maintain the Form 1572 for sponsored studies and all FDA paperwork required for IRB submissions; for investigator-held INDs/IDEs, study team will maintain 1572 and FDA submissions*
    a. 1572 (drugs) or Investigator Agreement (devices)
    b. FDA submissions and communications
4. **General Correspondence**—*maintained exclusively by study team*
5. **Investigator Brochure (can be renamed: Package Inserts or Device Manual)**—*maintained exclusively by CTSI regulatory specialists*
    a. IB signature page (drugs)
6. **IRB**—*maintained exclusively by CTSI regulatory specialists*
    *For ceded studies, create separate folders for UMN and the IRB of record within the below sub-folders, as appropriate*
    a. Initial IRB application
        i. *Including FDA determination, if applicable; FDA submissions themselves are stored outside of the regulatory binder*
    b. Continuing review(s)
    c. Modifications
    d. Reports
    e. Other IRB correspondence
    f. IRB Closure
7. **Monitoring & Auditing**—*maintained exclusively by study team*
    a. Monitor reports
    b. Monitor correspondence
    c. Monitor visit log
8. **Laboratory Info**—*CTSI regulatory specialists can file CAP/CLIA and NTF about lab normal ranges; other laboratory documents are maintained by the study team*
    a. CAP/CLIA
    b. NTF regarding lab normal ranges
    c. Test-specific lab workflows
    d. Shipping instructions
9. **Notes to File**—*maintained exclusively by study team*
10. **Other Review Committees**—*maintained exclusively by CTSI regulatory specialists*
11. **Protocol**—*maintained exclusively by CTSI regulatory specialists*
    a. Current approved protocol
    b. Previously approved protocol(s)
    c. Protocol signature page

12. **Safety and Deviations**—*CTSI regulatory specialists can document PI decision regarding whether Medwatch forms require IRB submission and file Medwatch reports; DSMB/monitor reports, AE reporting to sponsors, and submissions to Medwatch are maintained by the study team*
    a. DSMB or medical monitor reports
    b. Local AE reporting
    c. Medwatch submissions
13. **Staff and Investigator Info**—*CTSI regulatory specialists maintain all of this section except for study specific training, which remains the responsibility of the study team*
    a. Protocol Training Log**
    b. Study specific training (e.g. procedures)
    c. CV
    d. Licensure
    e. Certifications
    f. Financial disclosure forms
14. **Subject Materials**—*maintained exclusively by CTSI regulatory specialists*

***Regulatory specialists will set up eLogs, send initial eLog signature requests, and help study teams request access to Florence eBinders. Regulatory specialists will NOT follow up on pending signatures or pending Florence access.*

*Please also note that CTSI regulatory specialists do not maintain any patient binders.*