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 (e.g. IDS, CRU)*
    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, separate folders for UMN and the IRB of record are created within the below sub-folders, as appropriate*
    - *Filing will include "as-submitted" documents, IRB communications, and approvals related to each type of submission*

    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/External Updates
    d. Reportable New Info (RNI) & Acknowledgements
    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/lab manuals
    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

Florence eBinders Single-Site Template Sections

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 (*reports that require IRB submission will be filed by the regulatory specialists in the IRB/RNI folder as noted about*)
    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. Other staff qualifications and Central Binder maintenance are maintained by the study team and/or their departmental Florence SuperUser.*
    a. Protocol Training Log**
    b. Study specific training (e.g. procedures)
    c. PI/Co-I qualifications
        i. CV
        ii. Licensure
        iii. Certifications (e.g. GCP)
        iv. Signature page
    d. Other staff qualifications
        i. CV
        ii. Licensure (if applicable)
        iii. Certifications (e.g. GCP)
        iv. Signature page
        v. Other required trainings (e.g. Medidata or IATA/HMS trainings)
    e. Financial disclosure forms
    f. UMN CITI/HIPAA training (saved as snapshots from ETHOS training tab)
14. **Subject Materials**—*maintained exclusively by CTSI regulatory specialists*
    a. IRB-approved Participant-facing materials
    b. IRB-approved Recruitment materials

All files will be named according to the CTSI RegSpec Naming Conventions
***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.*

Any manuals or other instruction documents required to be filed by a Sponsor (e.g. IRT manuals, eCCG/EDC manuals, CRFs, Study Reference Manuals, Imaging Manuals, etc.) will require the study team to create a folder for Staff Materials and file accordingly. Pharmacy documents will also be maintained by the study team, as needed.

Please note the following exceptions:

- *CTSI regulatory specialists do not maintain regulatory binders for studies that we are not also supporting at the IRB level.*
- *CTSI regulatory specialists do not maintain any patient binders.*
- *CTSI regulatory specialists do not maintain drafts or work-in-progress documents in Florence.*