**Delegation, Personnel Training, and Qualifications**

* **Curriculum Vitaes (CVs)**
* **Clinical Licenses**
* **Delegation of Authority (DoA) Log**
* **Training Documentation**

**Protocol**

* **IRB Approved Protocol (all versions)**

**Consent Forms**

* **IRB Approved Consent Forms (All versions)**

**Institutional Review Board (IRB) Submission Documents**

* **IRB Federal Wide Assurance (FWA)**
* **IRB Submissions and Approval Letters**
* **IRB Correspondence**

**Recruitment and/or Subject Materials**

* **Recruitment Materials**
* **Subject Materials**

**Study Communication**

* **Study Correspondence**

**Subject Logs**

* **Screening/Recruitment Log**
* **Enrollment Log**

**External Serious Adverse Events (SAEs)/Unanticipated Problems (UAPs)**

* **External SAEs/UAPs**

**Data Safety Monitoring Board (DSMB) Plan and Reports (if applicable)**

* **DSMB Documents and Reports**

**Laboratory (if applicable)**

* **Lab Certificates**
* **Lab Director’s CV and License**
* **Lab Reference Ranges**
* **Specimen Tracking Log**

**Support Services Letters of Support (LOS) (if applicable)**

* **Letters of Support**