Site Regulatory Binder Suggested Sections

Protocol

- Signature Page(s)
- Current Version
- Previous Versions

Agreements (as applicable)

- Clinical Trial Agreement
- Confidentiality Agreements
- Subsite Agreements

Research Ethics Board

- Approvals
- Annual Renewals
- Initial Study Submission and Communication with REB
- Membership Lists

Informed Consent Form

- Current Version
- Previous Versions

Qualifications and Training

- CV
- Medical or Nursing License
- Training (as applicable): GCP, Division 5, TCPS2, Other
- Study Specific Training

Regulatory (if applicable)

- No Objection Letter
- Qualified Investigator Undertaking

Investigator Brochure or Product Monograph

Administrative Logs

- Screening Log
- Enrollment Log
- Temperature Log
- Delegation of Authority Log
- Monitoring Visits
- Investigational Product Accountability Log

Safety

-
- Safety reports - Sponsor (if applicable)
- Safety reports – Local (if applicable)
- Unblinding instructions (if applicable)

eCRF

Correspondence

- Monitoring
- Newsletters
- Sponsor (other)
- Internal correspondence
- Notes to File

Accreditations

- Lab
- Pharmacy

Other