AUSTRALIAN ICH GCP (Including Teletrials) SOP 70 Appendix 2 Example Study Master File Index

1. **Contact List**
2. **Project Documents incl. IP and safety**
   - 2.1 Investigator Brochure
   - 2.2 Safety Updates (reports, expedited safety letters/notifications, etc.)
   - 2.3 Protocol
   - 2.4 CRF (blank)
   - 2.5 CRF completion guidelines
   - 2.6 IP Shipping records (refer to Pharmacy Folder/Records)
   - 2.7 Accountability records (refer to Pharmacy Folder/Records)
3. **Contracts**
   - 3.1 Site Agreements (CTRA, Indemnities, Confidentiality Agreements, Staff personal information consent, etc.)
4. **Regulatory Authority Documents**
   - 4.1 Regulatory Agreements (e.g. FDA 1572)
   - 4.2 Financial Disclosure Forms (FDFs)
   - 4.3 Other Regulatory Documents (CTX, CTN, etc.)
5. **Ethics Committee (EC) / Institutional Review Board (IRB)**
   - 5.1 Initial Submissions/Approval
   - 5.2 Other Submissions/Approval
   - 5.3 Composition and Registration
   - 5.4 EC and IRB guidance documents
   - 5.5 Clinical Study Report
   - 5.6 Correspondence
6. **Site Staff Qualification**
   - 6.1 Curricula Vita and Medical Licences
   - 6.2 Training (GCP, study specific, vendor specific)
   - 6.3 Delegation of Authority log
   - 6.4 Supervision Plan
7. **Subject Documents**
   - 7.1 Blank informed Consent Forms (signed forms in patient files)
   - 7.2 Screening Log
   - 7.3 Enrolment Log
   - 7.4 Subject Identification Log
   - 7.5 Other (subject diaries, emergency card, recruitment material, etc.)
8. **Safety Documents**
   - 8.1 Safety Monitoring Plan
   - 8.2 Risk Management Plan
   - 8.3 Serious Adverse Events Log
   - 8.4 Serious Adverse Events Form(s)
   - 8.5 SUSARs
   - 8.6 Safety Reports

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9. Laboratory

9.1 Central and Local Lab Accreditation/Certification (NATA, CLIA)
9.2 Central and Local Lab normal ranges
9.3 Central Lab Manual/Instructions
9.4 Other (calibration certification, freezer logs, pathology records/shipment) – refer to Pathology records

10. Monitoring

10.1 Site visits (incl. initial)/Monitoring Visits/Sponsor Visits
10.2 Data query tracking
10.3 Protocol deviation log
10.4 Audit (correspondence, reports, follow up letters, etc.)
10.5 Monitoring Plan

11. Correspondence

11.1 General with Sponsor, CRO, teleconference, meeting notes