Table of Contents

|  |
| --- |
| **1.0 Feasibility and Start Up** |
| 1.1 Pre-submission |
| 1.2 Site Initiation Visit (eg: SIV slides, letters etc) |
| **2.0 Investigator’s Brochure (IB)** |
| 2.1 Current Approved IB |
| 2.2 Superseded IB(s) |
| 2.3 IB Signature Page(s) / Acknowledgment of Receipt (AoR) |
| **3.0 Protocol and Amendments** |
| 3.1 Current Approved Protocol |
| 3.2 Superseded Protocol(s) |
| 3.3 Protocol Signature Page(s) |
| **4.0 Patient Information Consent Forms (PICFs) and Patient Materials** |
| 4.1 Current HREC / governance Approved PICFs |
| 4.2 Superseded HREC/ governance Approved PICFs |
| 4.3 Master PICFs |
| 4.4 HREC Approved Patient Materials (E.g. QOL, Patient Diary, Study Card, recruitment material) |
| 4.5 Superseded HREC Approved Patient Materials |
| **5.0 Agreements** |
| 5.1 Current Clinical Trial Research Agreement(s) (including amendments and/or addendums) |
| 5.2 Superseded Clinical Trial Research Agreement(s) (including amendments and/or addendums) |
| 5.2 Insurance and/or Indemnity Certificate(s) |
| 5.3 Confidentiality Agreement (If Applicable) |
| 5.4 Study Budget |
| **6.0 HREC and Governance** |
| 6.1 HREC and Governance Submission Documentation |
| 6.2 HREC and Governance Approval Documentation |
| 6.3 HREC and Governance Correspondence (including all queries and responses) |
| 6.4 Protocol Waiver(s) and/or Deviation(s) |
| 6.5 HREC and IRB guidance documents |
| 6.6 HREC Membership List |
| 6.7 Interim, clinical study and Annual Report(s) |
| 6.8 Final Report and Publication(s) |
| **7.0 Regulatory Documents** |
| 7.1 CTN/CTX Form(s) |
| 7.2 Statement of Investigator (FDA 1572) |
| 7.3 Financial Disclosure Forms |
| 7.4 TGA Acknowledgement Letter and Correspondence |
| **8.0 Site Personnel Documentation** |
| 8.1 Curriculum Vitas |
| 8.2 GCP Certificates (including pharmacy and other trial specific personnel) |
| 8.3 Medical Registration Details (AHPRA) |
| 8.4 Delegation Log |
| 8.5 Training Log (including pharmacy and other trial specific personnel) |
| 8.6 Supervision Plan (for teletrials) |
| 8.7 Handling and Shipping of Category B substances Certificates |
| 8.8 CRF Training Certificates |

|  |
| --- |
| **9.0 Laboratory** |
| 9.1 Laboratory Normal Values and Reference Ranges |
| 9.2 Laboratory Accreditation |
| 9.3 Laboratory Manual and Procedures |
| 9.4 Laboratory Certificates (eg: calibration certificates, freezer/fridge temperature logs, sample inventory log) |
| 9.5 Laboratory Correspondence |
| **10.0 Pharmacy** |
| 10.1 Pharmacy Manual |
| 10.2 Pharmacy Records (eg: temperature logs, shipping log, accountability log) |
| **11.0 Monitoring** |
| 11.1 Training Material |
| 11.2 Monitoring Plan |
| 11.3 Monitor/Auditor Visit Log |
| 11.4 Monitoring Visit Reports/Letters |
| 11.5 Data Query Tracker |
| 11.6 Protocol Deviation Log |
| **12.0 Case Report Forms (CRFs)** |
| 12.1 Blank CRF |
| 12.2 Superseded Blank CRFs |
| 12.3 CRF Guidelines |
| 12.4 Completed CRFs (if paper-based) |
| **13.0 Serious Adverse Event (SAE) and Safety Reports** |
| 13.1 Safety Monitoring Plan |
| 13.2 Risk Management Plan |
| 13.3 SAE Reporting Guidelines |
| 13.4 Expedited Safety letters or notifications |
| 13.5 Blank SAE Report Forms |
| 13.6 SAE/Adverse Events of Special Interest (AESI) Log |
| 13.7 SUSARs |
| 13.8 Safety Reports (eg: Annual Safety Report (ASR), Development Safety Update Report DSUR)) |
| **14.0 Study Subjects** |
| 14.1 Subject Logs (eg: Subject Identification Log, Screening and enrolment log) |
| 14.2 Subject Folders Index |
| **15.0 Correspondence** |
| 15.1 Sponsor Correspondence (eg: teleconferences, meeting notes etc) |
| 15.2 Project Newsletters |
| 15.3 Site Correspondence |
| **16.0 Study Templates** |
| 16.1 Recruitment (eg: Pre-screening log) |
| 16.2 Visit Worksheets/Source Documents |
| 16.3 Pharmacy Scripts (if paper-based) |
| **17.0 Contacts** |
| 17.1 Sponsor Contact Details |
| 17.2 Reviewing HREC Contact Details |
| 17.3 Study team/site Contact Details (including pharmacy) |
| **18.0 Other (please specify below)** |
|  |
|  |
|  |
|  |
|  |