|  |  |  |
| --- | --- | --- |
| INVESTIGATOR SITE FILE | | |
| **Protocol Number** | **:** |  |
| **Site Number** | **:** |  |
|  |  |  |
| **Principal Investigator** | **:** |  |

| **SECTION** | **DOCUMENTATION** | **PRESENT** | **COMMENT** |
| --- | --- | --- | --- |
| **1** | **Contact Details** |  |  |
| 1.1 | Contact list of study personnel |  |  |
|  |  |  |  |
| **2** | **Investigator’s Brochure/ Product Information** |  |  |
| 2.1 | Current Version |  |  |
| 2.2 | All Previous Submitted Versions |  |  |
|  |  |  |  |
| **3** | **Protocol** |  |  |
| 3.1 | Current Approved Version |  |  |
| 3.2 | All Previous Approved Versions |  |  |
| 3.3 | Protocol Signature Page(s) |  |  |
|  |  |  |  |
| **4** | **Participant Information & Consent Form (PICF)** |  |  |
| 4.1 | Current Approved Version(s) |  |  |
| 4.2 | All Previous Approved Versions |  |  |
| 4.3 | Signed Informed Consent Forms |  |  |
| 4.4 | Signed Informed Consent Tracking Log |  |  |
|  |  |  |  |
| **5** | **Participant Tools** |  |  |
|  | ***Patient Card/ Patient Diary/ Questionnaires (if applicable)*** |  |  |
| 5.1 | Current Approved Version (including all applicable translations) |  |  |
| 5.2 | All Previous Approved Versions (including all applicable translations) |  |  |
|  |  |  |  |
| **6** | **Advertisements** |  |  |
| 6.1 | Current Approved Version |  |  |
| 6.2 | All Previous Approved Versions |  |  |
|  |  |  |  |
| **7** | **Case Report Form (CRF)** |  |  |
| 7.1 | Current CRF Version (Blank) |  |  |
| 7.2 | Previous CRF Version (Blank) |  |  |
| 7.3 | CRF Completion Guidelines |  |  |
| 7.4 | Signed, dated and completed CRFs |  |  |
|  |  |  |  |
| **9** | **Ethics** |  |  |
| 9.1 | Initial Submission |  |  |
| 9.2 | Amendments |  |  |
| 9.3 | Progress Reports |  |  |
| 9.4 | Ethics Composition |  |  |
| 9.5 | Notification of Safety Reports |  |  |
| 9.6 | Notification of Non-compliance / Protocol Deviations |  |  |
| 9.7 | Correspondence |  |  |
|  |  |  |  |
| **10** | **Governance** |  |  |
| 10.1 | Site Authorisation Letter |  |  |
| 10.2 | Post Authorisation Submission/Authorisation Letters |  |  |
|  |  |  |  |
| **10** | **Regulatory Documents** |  |  |
| 10.1 | CTN or CTX |  |  |
| 10.2 | TGA Acknowledgment Letter |  |  |
| 10.3 | Correspondence |  |  |
|  |  |  |  |
| **11** | **Study Personnel** |  |  |
| 11.1 | Delegation Log |  |  |
| 11.2 | Curriculum Vitae (including GCP, Medical License, DCSI ) |  |  |
| 11.3 | Training Log/ Documentation |  |  |
|  |  |  |  |
| **12** | **Agreements** |  |  |
| 12.1 | Signed Confidentiality Agreement |  |  |
| 12.2 | Signed Clinical Trial Agreement |  |  |
| 12.3 | Other Relevant Agreement/ Contracts |  |  |
| 12.4 | Insurance Certificate |  |  |
| 12.5 | Indemnity |  |  |
| **13** | **Participant Logs** |  |  |
| 13.1 | Participant Screening Log |  |  |
| 13.2 | Participant Enrolment Log |  |  |
| 13.3 | Participant Identification Log |  |  |
|  |  |  |  |
| **14** | **Investigational Product (IP)** |  |  |
| 14.1 | Instructions for Handling of IP (if not included in protocol) |  |  |
| 14.2 | IP Shipping and Receipt Records |  |  |
| 14.3 | IP Dispensing and Accountability Logs |  |  |
| 14.4 | IP Destruction Log |  |  |
| 14.5 | IP Storage & Temperature Logs |  |  |
| 14.6 | Decoding and Un-blinding Procedure |  |  |
| 14.7 | Sample of Label(s) attached to IP Container(s) |  |  |
|  |  |  |  |
| **15** | **Randomisation** |  |  |
| 15.1 | Instructions |  |  |
| 15.2 | Un-blinding procedure |  |  |
|  |  |  |  |
| **16** | **Monitoring** |  |  |
| 16.1 | Site Visit Log |  |  |
| 16.2 | Correspondence |  |  |
|  |  |  |  |
| **17** | **Audit** |  |  |
| 17.1 | Report |  |  |
| 17.2 | Correspondences (e.g. visit confirmation/ follow up letters) |  |  |
|  |  |  |  |
| **18** | **Laboratory** |  |  |
| 18.1 | Normal ranges |  |  |
| 18.2 | Certification / Accreditation (NATA) |  |  |
|  |  |  |  |
| **19** | **Biological Samples** |  |  |
| 19.1 | Biological Sample Storage/Destruction Log |  |  |
| 19.2 | Biological Samples Shipping Records |  |  |
| 19.3 | Laboratory Manual & Certification |  |  |
| 19.4 | Shipping Materials |  |  |
| **20** | **Safety Reports** |  |  |
| 20.1 | Serious Adverse Event (SAE) Tracking Log |  |  |
| 20.2 | SAE Reports Submitted to Sponsor |  |  |
| 20.3 | Safety Reports |  |  |
|  |  |  |  |
| **21** | **Study Reports/ Publications** |  |  |
| 21.1 | Interim Report/ DSMB Reports |  |  |
| 21.2 | Final Clinical Study Report |  |  |
| 21.3 | Relevant Study Publications/ References |  |  |
|  |  |  |  |
| **22** | **Study Meetings** |  |  |
| 22.1 | Site Initiation Visit (e.g. Agenda, Presentations, Attendance List, Report) |  |  |
| 22.2 | Other Relevant Meeting Documentation |  |  |
|  |  |  |  |
| **23** | **Correspondence** |  |  |
| 23.1 | Correspondence with sponsor (if applicable) |  |  |
| 23.2 | Correspondence with site(s) |  |  |
| 23.3 | Newsletters |  |  |
|  |  |  |  |