|  |  |  |
| --- | --- | --- |
| Protocol No | **:** |  |
| **Protocol Title** | **:** |  |
|  |  |  |
| **Principal Investigator** | **:** |  |
| **Site Name** | **:** |  |
|  | | |

| **SECTION** | **CONTENTS** | **Present in ISF**  **(Tick Box)** | **Record NA or if not filed in ISF, state alternative location** |
| --- | --- | --- | --- |
| **1** | **Contact Details** |  |  |
| 1.1 | Contact details of site staff |  |  |
| 1.2 | Contact details of external vendors |  |  |
|  |  |  |  |
| **2** | **Investigator’s Brochure/ Package Insert** |  |  |
| 2.1 | Current Version |  |  |
| 2.2 | All Previous Submitted Versions and Updates |  |  |
|  |  |  |  |
| **3** | **Study Protocol and Amendments** |  |  |
| 3.1 | Current Approved Version |  |  |
| 3.2 | All Previous Approved Versions |  |  |
| 3.3 | Protocol Signature Page(s) |  |  |
|  |  |  |  |
| **4** | **Informed Consent Form and Amendments** |  |  |
| 4.1 | Current Approved Version (including all applicable translations) |  |  |
| 4.2 | All Previous Approved Versions (including all applicable translations) |  |  |
| 4.3 | Translation Certificates (if applicable) |  |  |
| 4.4 | Signed Informed Consent Forms |  |  |
| 4.5 | Signed Informed Consent Tracking Log |  |  |
|  |  |  |  |
| **5** | **Any Other Written Information Provided to Trial participants** |  |  |
| ***5.1*** | ***Patient Card/ Patient Diary/ Questionnaires (if applicable)*** |  |  |
| 5.1.1 | Current Approved Version (including all applicable translations) |  |  |
| 5.1.2 | All Previous Approved Versions (including all applicable translations) |  |  |
| 5.1.3 | Translation Certificates (if applicable) |  |  |
|  |  |  |  |
| **6** | **Advertisement for Trial participant Recruitment** |  |  |
| 6.1 | Current Approved Version (including all applicable translations) |  |  |
| 6.2 | All Previous Approved Versions (including all applicable translations) |  |  |
| 6.3 | Translation Certificates (if applicable) |  |  |
|  |  |  |  |
| **7** | **Case Report Form (CRF)** |  |  |
| 7.1 | Current CRF Version (Blank Sample) |  |  |
| 7.2 | Previous CRF Version (Blank Sample) |  |  |
| 7.3 | CRF Completion Guidelines |  |  |
| 7.4 | Signed, dated and completed CRFs |  |  |
| 7.5 | Documentation of CRF Corrections |  |  |
|  |  |  |  |
| **8** | **Source Documents** |  |  |
|  |  |  |  |
| **9** | **Institutional Review Board (IRB)** |  |  |
| 9.1 | All Submission and Approval Documents e.g.   * Investigator’s Brochure and updates * Protocol and subsequent amendments * ICF and subsequent amendments * Any Other Written Information Provided to Trial participants * Advertisement * CRF (if applicable) |  |  |
| 9.2 | Progress Reports to the IRB |  |  |
| 9.3 | IRB Composition |  |  |
| 9.4 | Notification of Safety Reports to IRB |  |  |
| 9.5 | Notification of Non-compliance to IRB |  |  |
| 9.6 | Correspondences with IRB |  |  |
|  |  |  |  |
| **10** | **Health Sciences Authority (HSA)** |  |  |
| 10.1 | All Submission and Approval Documents e.g.   * Investigator’s Brochure and updates * Protocol and subsequent amendments * ICF and subsequent amendments |  |  |
| 10.2 | Trial Status Reports to HSA |  |  |
| 10.3 | Clinical Research Material (CRM) Notifications |  |  |
| 10.4 | Notification of Expedited Safety Reports to HSA |  |  |
| 10.5 | Notification of Serious Breaches to HSA |  |  |
| 10.6 | Correspondences with HSA |  |  |
|  |  |  |  |
| **11** | **Study Personnel** |  |  |
| 11.1 | Signature Sheet |  |  |
| 11.2 | Curriculum Vitae of All Study Personnel (including CITI / GCP / Medical Licensure, where applicable) |  |  |
| 11.3 | Training Log/ Documentation |  |  |
|  |  |  |  |
| **12** | **Financial Matters** |  |  |
| 12.1 | Signed Confidentiality Agreement |  |  |
| 12.2 | Signed Clinical Trial Agreement |  |  |
| 12.3 | Any Other Relevant Agreement/ Contracts |  |  |
| 12.4 | Insurance Certificate |  |  |
|  |  |  |  |
| **13** | **Trial participant Logs** |  |  |
| 13.1 | Trial participant Screening Log |  |  |
| 13.2 | Trial participant Enrolment Log |  |  |
| 13.3 | Trial participant Identification Log |  |  |
| 13.4 | Trial participant Visit Tracking Log |  |  |
|  |  |  |  |
| **14** | **Investigational Product (IP)** |  |  |
| 14.1 | Instructions for Handling of IP (if not included in protocol or IB) |  |  |
| 14.2 | IP Shipping and Receipt Records (including Certificate (s) of Analysis of IP shipped) |  |  |
| 14.3 | IP Dispensing and Accountability Logs |  |  |
| 14.4 | IP Destruction Documentation |  |  |
| 14.5 | IP Storage Temperature Logs |  |  |
|  |  |  |  |
| **15** | **Randomization** |  |  |
| 15.1 | Decoding Procedures for blinded |  |  |
|  |  |  |  |
| **16** | **Monitoring** |  |  |
| 16.1 | Site Visit Log |  |  |
| 16.2 | Visit Correspondences (e.g. visit confirmation/ follow up letters) |  |  |
|  |  |  |  |
| **17** | **Laboratory** |  |  |
| 17.1 | Normal values / ranges for Medical / Laboratory / Technical procedures and/or Tests included in the protocol |  |  |
| 17.2 | Certification / Accreditation / Established Quality Control / External Quality Assessment / Other Validation for Medical / Laboratory / Technical Procedures / Tests |  |  |
|  |  |  |  |
| **18** | **Biological Samples** |  |  |
| 18.1 | Biological Sample Handling Log |  |  |
| 18.2 | Biological Sample Handling Manual |  |  |
| 18.3 | Biological Samples Shipping Records |  |  |
| 18.4 | Biological Samples Destruction/ Return Records |  |  |
|  |  |  |  |
| **19** | **Safety Reports** |  |  |
| 19.1 | Serious Adverse Event (SAE) Tracking Log |  |  |
| 19.2 | SAE Reports Submitted to Sponsor |  |  |
| 19.3 | Expedited Safety Reports (e.g. CIOMS Reports) |  |  |
|  |  |  |  |
| **20** | **Study Reports/ Publications** |  |  |
| 20.1 | Interim Report/ DSMB Reports |  |  |
| 20.2 | Final Clinical Study Report |  |  |
| 20.3 | Relevant Study Publications/ References |  |  |
|  |  |  |  |
| **21** | **Study Meetings** |  |  |
| 21.1 | Investigator Meeting (e.g. Agenda, Presentations, Attendance List) |  |  |
| 21.2 | Site Initiation Visit (e.g. Agenda, Presentations, Attendance List, Report) |  |  |
| 21.3 | Other Relevant Meeting Documentation |  |  |
|  |  |  |  |
| **22** | **Correspondences** |  |  |
| 22.1 | Relevant Correspondences with Sponsor |  |  |
| 22.2 | Relevant Correspondences with Site Staff |  |  |
| 22.3 | Relevant Correspondences with Central Lab/ Vendors |  |  |
| 22.4 | Any Other Relevant Correspondences |  |  |
|  |  |  |  |
| **23** | **Miscellaneous** |  |  |