|  |  |  |
| --- | --- | --- |
| 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** | [ ]  |  |