|  |  |  |
| --- | --- | --- |
| *Delete this introduction accordingly:*  *Purpose of Investigator Site File: An Investigator Site File (ISF) should be established at the beginning of each research study. The ISF contains the minimum list of essential documents that have to be maintained throughout the study.*  *This Table of Contents serves as a reference template for your filing and documentation purpose. You may edit this Table of Contents accordingly to the needs of your study.*  *研究者站点文件目的：应在每个研究项目开始时建立研究者站点文件 (ISF)。 ISF包含在整个研究项目过程中必须保留的基本文件的最低限度清单。* | | |
| 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 (ICF) 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 Study 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 Study 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** | **ACMS 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 Study participants * Advertisement * CRF (if applicable) | ☐ |  |
| 9.2 | Progress Reports to the IRB | ☐ |  |
| 9.3 | Notification of Safety Reports to IRB | ☐ |  |
| 9.4 | Notification of Non-compliance to IRB | ☐ |  |
| 9.5 | Correspondences with IRB | ☐ |  |
|  |  |  |  |
| **10** | **Study Personnel** |  |  |
| 10.1 | Signature Sheet | ☐ |  |
| 10.2 | Curriculum Vitae of All Study Personnel (including CITI / GCP / Medical Licensure, where applicable) | ☐ |  |
| 10.3 | Training Log/ Documentation | ☐ |  |
|  |  |  |  |
| **11** | **Financial Matters** |  |  |
| 11.1 | Signed Confidentiality Agreement | ☐ |  |
| 11.2 | Signed Research Collaboration Agreement | ☐ |  |
| 11.3 | Any Other Relevant Agreement/ Contracts | ☐ |  |
| 11.4 | Insurance Certificate | ☐ |  |
|  |  |  |  |
| **12** | **Study participant Logs** |  |  |
| 12.1 | Study participant Screening Log | ☐ |  |
| 12.2 | Study participant Enrolment Log | ☐ |  |
| 12.3 | Study participant Identification Log | ☐ |  |
| 12.4 | Study participant Visit Tracking Log | ☐ |  |
|  |  |  |  |
| **13** | **Randomization** |  |  |
| 13.1 | Decoding Procedures for blinded | ☐ |  |
|  |  |  |  |
| **14** | **Monitoring** |  |  |
| 14.1 | Site Visit Log | ☐ |  |
| 14.2 | Visit Correspondences (e.g. visit confirmation/ follow up letters) | ☐ |  |
|  |  |  |  |
| **15** | **Safety Reports** |  |  |
| 15.1 | Serious Adverse Event (SAE) Tracking Log | ☐ |  |
| 15.2 | SAE Reports Submitted to Sponsor | ☐ |  |
| 15.3 | Expedited Safety Reports | ☐ |  |
|  |  |  |  |
| **16** | **Study Reports/ Publications** |  |  |
| 16.1 | Interim Report/ DSMB Reports | ☐ |  |
| 16.2 | Final Study Report | ☐ |  |
| 16.3 | Relevant Study Publications/ References | ☐ |  |
|  |  |  |  |
| **17** | **Study Meetings** |  |  |
| 17.1 | Investigator Meeting (e.g. Agenda, Presentations, Attendance List) | ☐ |  |
| 17.2 | Site Initiation Visit (e.g. Agenda, Presentations, Attendance List, Report) | ☐ |  |
| 17.3 | Other Relevant Meeting Documentation | ☐ |  |
|  |  |  |  |
| **18** | **Correspondences** |  |  |
| 18.1 | Relevant Correspondences with Sponsor | ☐ |  |
| 18.2 | Relevant Correspondences with Site Staff | ☐ |  |
| 18.3 | Relevant Correspondences with Vendors | ☐ |  |
| 18.4 | Any Other Relevant Correspondences | ☐ |  |
|  |  |  |  |
| **19** | **Miscellaneous** | ☐ |  |