**Trial Information**

|  |  |
| --- | --- |
| **Protocol Number:** |  |
| **Trial Site:** |  |
| **Sponsor:**  |  |
| **Principal Investigator:** |  |

The below form is to be completed by assigned monitor at the Site Initiation Visit or the first monitoring visit thereafter. At the beginning of the study the monitor is responsible for ensuring that the Site file is complete, any missing documents must be supplied and filed by Monitor.

| **Sections as they appear in the ISF** | **Documents** | **On File\***(Yes, No, N/A) | **Notes/ Location**  |
| --- | --- | --- | --- |
| **0.0** | **Index**  |  |  |
| **1.0** | **Contacts List** *(including out of hours contact for CRA and Sponsor)* |  |  |
|  |  |  |  |
| **2.0** | **Protocol**  |  |  |
| 2.1 | Current, Approved Protocol *(include investigator signature page)* |  |  |
| 2.2 | Signed Protocol Page |  |  |
| 2.3 | Superseded Protocols/ amendments  |  |  |
|  |  |  |  |
| **3.0** | **Participant Documentation (Local Versions)***All documents must be on appropriate institution letterhead.* |  |  |
| 3.1 | Current Patient Information Sheet and Informed Consent Form (PIL/ICF) on SJH Headed paper |  |  |
| 3.2 | Advertisement and other documents provided to participants |  |  |
| 3.3 | Current, approved GP letter on SJH headed paper |  |  |
| 3.5 | Participant Screening and Enrolment Log (Template) |  |  |
| 3.6 | Participant Identification Log (Template) |  |  |
|  |  |  |  |
| **4.0** | **Research Ethics/ HRCDC Committee**  |  |  |
| 4.1 | Application to ethics/ HRCDC- Where applicable (including supporting documentation) |  |  |
| 4.2 | Ethics/ HRCDC Approval(s) (including amendments) |  |  |
| 4.3 | Correspondence ***(please file chronologically, most recent at the front, and include all email correspondence)*** |  |  |
|  |  |  |  |
| **5.0** | **Regulatory Authorisation** |  |  |
| 5.1 | Application to HPRA (If Applicable) |  |  |
| 5.2 | HPRA amendment submissions (If Applicable) |  |  |
| 5.3 | HPRA Approval(s) (If Applicable) |  |  |
| 5.4 | CTA Application Through CTIS- Part I and II (If Applicable) |  |  |
| 5.5 | ICTA- Ireland Part 1 and II Approval (If Applicable) |  |  |
| 5.6 | ICTA- Amendment Submissions through CTIS (If Applicable) |  |  |
| 5.7 | Correspondence ***(please file chronologically, most recent at the front, and include email correspondence)*** |  |  |
| 5.8 | Developmental Safety Update Report |  |  |
|  |  |  |  |
| **6.0** | **Financial / Legal** |  |  |
| 6.1 | Insurance |  |  |
| 6.2 | Clinical Trial Agreement (CTA) Indemnity Statement |  |  |
| 6.3 | Confidentiality Agreements  |  |  |
|  |  |  |  |
| **7.0** | **Site Study Team** |  |  |
| 7.1 | Delegation of Responsibility and Signature Log (completed and signed off by PI) |  |  |
| 7.2 | Signed and dated CVs and GCP certificates (including superseded versions) |  |  |
| 7.3 | Study Team Training Records |  |  |
|  |  |  |  |
|  **8.0** | **Safety Reporting** |  |  |
| 8.1 | Safety Reporting Procedures |  |  |
| 8.2 | Adverse Events/ Serious Adverse Event (SAE) Forms/ Templates |  |  |
| 8.3 | SAE Report Template and SAE Report Log**\*** |  |  |
| 8.4 | SUSAR Reporting Template/Forms |  |  |
| 8.5 | Safety Updates/ correspondence |  |  |
|  |  |  |
| **9.0** | **Investigational Medicinal Product (IMP)** *(If documents are retained in separate file – please include in ISF prior to archiving)* |  |  |
| 9.1 | Investigator Brochure (IB)/ Summary of Product Characteristics (SPC) with acknowledgement of receipt |  |  |
| 9.2 | Signed IB/ SPC Amendments |  |  |
| 9.3 | Pharmacy Study Specific Procedures  |  |  |
| 9.4 | Sample Labels  |  |  |
| 9.5 | Instructions for Handling IMP |  |  |
| 9.6 | QP release |  |  |
| 9.7 | Correspondence |  |
| 9.8 | Other Forms/Templates |  |  |
| 9.9 | Emergency Unblinding Procedure  |  |  |
|  |  |  |  |
| **10.0** | **Study Management and Monitoring** |  |  |
| 10.1 | Monitoring Visit Log |  |  |
| 10.2 | Site Initiation Meeting Documentation |  |  |
|  |  |  |  |
| **11.0** | **Clinical Laboratory *(If documents are retained in separate file – please include in ISF prior to archiving)*** |  |  |
| 11.1 | Local Certificate(s) of accreditation and C.V. of Laboratory Director (If applicable) |  |  |
| 11.2 | Local Normal Reference Ranges (If applicable) |  |  |
| 11.3 | Laboratory Manual |  |  |
| 11.4 | Sample Labels |  |  |
| 11.5 | Sample Shipment/Receipt Tracking |  |  |
|  |  |  |  |
|  **12.0** | **Case Report Forms and Data Collection Tools\*** |  |  |
| 12.1 | Blank CRF and CRF Completion Guidelines |  |  |
| 12.2 | Participant Questionnaires |  |  |
| 12.3 | Study Specific Report Forms |  |  |
|  |  |  |  |
| **13.0** | **Study Related Supplies and Equipment***For study materials and supplies*  |  |  |
| 13.1 | Contact details for supplies |  |  |
| 13.2 | Completed supplies re-order forms |  |  |
| 13.3 | Other Forms/Templates |  |  |
| 13.4 | Equipment Documentation  |  |  |
|  |  |  |  |

**General Notes**

* Not all sections will be applicable: Mark such sections as “N/A” in the “On File” Column

The below form is to be completed by assigned monitor at the Site Initiation Visit. At the beginning of the study the monitor is responsible for ensuring that the Site file is complete, any missing documents must be supplied and filed by Monitor.

|  |  |
| --- | --- |
| Name of Monitor completing Site file review: |  |
| Signature of Monitor Completing Site File Review: |  |
| Date ISF file review complete: |  |
| Checked By CRF Quality Dept: |  |
| Signature of CRF Quality Dept:  |  |
| Date Checked by CRF Quality Dept: |  |