|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SITE FILE INDEX REPORT TEMPLATE** | | | | | | | | |
| **P0 No.** | P0XXXX | | | | **Study Title:** | |  | |
| **PI** |  | | | | **Monitor(s)** | |  | |
| **Site Name** |  | | | | **Site ID** | |  | |
| **Date of Visit** |  | | | | **Site Staff**  **Present** | |  | |
| **RECRUITMENT STATUS** | | | | | | | | |
| **No. patients**  **screened:** | | | | **No. patients**  **consented:** | | **No. participants**  **randomised:** | | **Recruitment**  **Target:** |
|  | | | | | | | | |
| **SECTION** | | | ***Version Control Log*** | | | | | |
| **Comments** | | |  | | | | | |
| **Action required** | | |  | | | | | |
| **CTC/CTA comment** | | |  | | | | | |
| **SECTION** | | ***1.0 site file structure and Index check*** | | | | | | |
| **comments** | |  | | | | | | |
| **Action required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***2.0 Trial Specific Documentation*** | | | | | | |
| **ITEM** | | Current approved protocol with signatures *(Held in the paper file)*  Clinical Study Report  **2.1 File Notes**  **2.2 Correspondence**  **2.3 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***3.0 Site Documentation*** | | | | | | |
| **ITEM** | | Site Delegation Log *(Held in the paper file)*  **3.1 Localised (site specific) Documents**  **3.2 Study Staff Training Documentation** *(held in the paper file)*  **3.2.1 CVs and GCPs certificates**  **3.2.2** **Training log**  **3.2.3 Site initiation Visit Documents**  **3.3 Finance**  **3.4 Details of protocol non-compliance**  **3.5 Correspondence**  **3.6 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***4.0 Recruitment*** | | | | | | |
| **ITEM** | | **4.1 Screening/-enrolment log** *(Held in the paper file)*  **4.2 Signed Informed consent forms** *(Held in the paper file)*  **4.3 Correspondence**  **4.4 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***5.0 Evidence of Ethics/HRA and Regulatory approvals*** | | | | | | |
| **ITEM** | | **5.1 Evidence of Original Ethics Approval**  **5.2 Evidence of Original HRA Approval**  **5.3 Evidence of Original MHRA Regulatory Approval**  **5.4 Amendments Documentation**  **5.5 Correspondence**  **5.6 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***6.0 Safety*** | | | | | | |
| **ITEM** | | Blank/template SAE form  **6.1 Adverse event reports**  **6.2 SAE reports**  **6.3 Safety information notifications from Sponsor**  **6.4 Instructions for randomisation, unblinding and code breaking**  **6.5 Correspondence**  **6.6 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***7.0 Governance*** | | | | | | |
| **ITEM** | | Site confirmation of Capability and Capacity  Sponsor Green Light  **7.1 Regulatory Checklists**  **7.2 Local Information Pack**  **7.3 Site agreement**  **7.3.1 Superseded Documents**  **7.4 Correspondence**  **7.5 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***8.0 Data Management*** | | | | | | |
| **ITEM** | | **8.1 Blank case report forms (CRFs)**  **8.2 Completed CRFs + data collection instruments**  **8.3 Data amendment forms**  **8.4 Data queries**  **8.5 Correspondence**  **8.6 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***9.0 Monitoring*** | | | | | | |
| **ITEM** | | Site Visit Log *(Held in the paper file)*  Close out report  **9.1 Monitoring Reports**  **9.2Audit Reports 9.3 Remote Monitoring Documents**  **9.4 Correspondence**  **9.5 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***10.0 Pharmacy*** | | | | | | |
| **ITEM** | | **10.1 IMP Handling Manual**  **10.2 Copies of prescriptions**  **10.3 Correspondence**  **10.4 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***11.0 Pharmacovigilance*** | | | | | | |
| **ITEM** | | Investigators Brochure (IB) and /or Summary of Product Characteristics (SmPC) and updates  **11.1. RSI (Reference Safety Information)**  **11.2. Correspondence**  **11.3. Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***12.0 Meetings*** | | | | | | |
| **ITEM** | | **12.1. Team meetings**  **12.2. Correspondence**  **12.3 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***13.0 Laboratory*** | | | | | | |
| **ITEM** | | **13.1 Laboratory Manual/Instructions**  **13.2 Sample Collection Worksheets**  **13.3 Sample Labels**  **13.4 Sample Storage Log**  **13.5 Sample Shipment/Receipt Tracking**  **13.6 Storage Condition Monitoring**  **13.7 Sample Destruction and/or use for future research**  **13.8 Local Certificates and Accreditation**  **13.9 Lab Reference Ranges**  **13.10 Correspondence**  **13.11 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA Comment** | |  | | | | | | |
| **SECTION** | | ***14.0 Investigational Device*** | | | | | | |
| **ITEM** | | **14.1 Certificates**  **14.2 Service/PAT Testing Log**  **14.3 Device Manual/Instructions**  **14.4 Delivery/Return of Devices Log**  **14.5 Correspondence**  **14.6 Superseded Documents** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |
| **SECTION** | | ***15.0 Equipment*** | | | | | | |
| **ITEM** | | **15.1 Calibration records** | | | | | | |
| **Comments** | |  | | | | | | |
| **Action Required** | |  | | | | | | |
| **CTC/CTA comment** | |  | | | | | | |

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| **SUMMARY OF ACTION POINTS – please state who is to action and by when** |
|  |

Monitor’s Name:

Monitor’s Signature:

Date:

Principle Investigator’s Name:

Principal Investigator’s Signature:

Date: