|  |
| --- |
| **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protocol with signatures *(Held in the paper file)*Clinical Study Report**2.1 File Notes****2.2 Correspondence****2.3 Superseded Documents** |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Site initiation Visit Documents****3.3 Finance****3.4 Details of protocol non-compliance****3.5 Correspondence****3.6 Superseded Documents** |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*(Held in the paper file)***4.2 Signed Informed consent forms** *(Held in the paper file)***4.3 Correspondence****4.4 Superseded Documents** |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**5.3 Evidence of Original MHRA Regulatory Approval****5.4 Amendments Documentation****5.5 Correspondence****5.6 Superseded Documents**  |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from Sponsor****6.4 Instructions for randomisation, unblinding and code breaking****6.5 Correspondence****6.6 Superseded Documents** |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 CapacitySponsor 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: