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| **INVESTIGATOR SITE FILE** | | |
|
|  | **Section** | **Comments** |
| **1** | **Coordinating Centre Contact Details** |  |
| **2** | **Protocol** |  |
| **2.1** | Protocol |  |
| **2.2** | Protocol Amendment(s) |  |
| **2.3** | Documentation of protocol changes from previous versions | Summary of changes documents |
| **3** | **Ethics/Governance Approvals & Communication** |  |
| **3.1** | Ethics submission(s) & approval letter(s) |  |
| **3.2** | Annual & final reports to ethics |  |
| **3.3** | Ethics membership list | File here if not included on approval letters |
| **3.4** | Other relevant correspondence with Ethics |  |
| **4** | **Consent Forms** |  |
| **4.1** | Signed Informed Consent Form(s) | File originals here or a note-to-file stating location |
| **4.2** | Current Information Sheets and Consent Forms (Master and Site Specific blank copies) |  |
| **4.3** | Superseded Information Sheets and Consent Forms (Master and Site Specific blank copies) |  |
| **5** | **Safety Reporting (AE, SAE, SUSAR)** |  |
| **5.1** | Site safety reports & related correspondence to Ethics |  |
| **5.2** | Sponsor reports to investigator | Reports from Coordinating Centre |
| **6** | **Regulatory & Agreements** |  |
| **6.1** | Certificate(s) of Insurance |  |
| **6.2** | Clinical Trial Agreement |  |
| **6.3** | HMSC | Not required |
| **6.4** | CTRI |  |
| **7** | **Case Report Form (CRF) & Study Manuals** |  |
| **7.1** | Blank CRF | Current and superseded versions |
| **7.2** | Data Completion Manual | Current and superseded versions |
| **7.3** | Operations Manual | Current and superseded versions |
| **7.4** | Website User Guide | Current and superseded versions |
| **8** | **Subject Logs & Related Documents** |  |
| **8.1** | Patient Screening Log | To be filed here at end of study |
| **8.2** | Patient Enrolment Log | To be filed here at end of study |
| **8.3** | Randomisation Reports | To be filed here at end of study |
| **9** | **Investigators & Study Staff** |  |
| **9.1** | Curriculum Vitae & GCP certificates | Principal Investigator, Associate Investigator(s) & RC(s) |
| **9.2** | Site Signature & Delegation Log |  |
| **9.3** | Training Certificates/Logs (as applicable) | Database, start-up meeting attendance etc. |
| **10** | **Laboratory** |  |
| **10.1** | Local Laboratory Normal Ranges |  |
| **10.2** | Local Laboratory Accreditation Certificate (including updates) |  |
| **11** | **Finance** |  |
| **11.1** | Study Payments |  |
| **11.2** | Financial correspondence |  |
| **12** | **Investigational Product and other study supplies** |  |
| **12.1** | Investigational Product Shipment Forms (as applicable) | not applicable |
| **12.2** | Site Accountability Records (Study Drug Reconciliation Log) | SEE Unblinded Trial Folder |
| **12.3** | Instructions for handling Investigational Product | SEE Unblinded Trial Folder |
| **12.4** | Investigational Product Destruction | SEE Unblinded Trial Folder |
| **12.5** | Temperature Logs (as applicable) | SEE Unblinded Trial Folder |
| **13** | **Monitoring Visit (virtual) Reports and Correspondence** |  |
| **13.1** | Site Visit and visit (including virtual visits) Log |  |
| **13.2** | Site Initiation Report & Activation Checklist |  |
| **13.3** | Monitoring Visit (virtual) Reports and Correspondence |  |
| **13.4** | Close-out Visit (virtual) Report and Correspondence |  |
| **14** | **Correspondence** |  |
| **14.1** | Letters, fax & emails |  |
| **14.2** | Telephone Logs |  |
| **14.3** | Note to Files |  |
| **14.4** | Newsletters |  |
| **15** | **Study Tools** |  |
| **16** | **Study Publications/Final Report** |  |
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