This is an example template to be filed within the Investigator Site File and updated as applicable to the study for which it is being utilised. It is not an exhaustive list and all sections may not be applicable to certain types of studies.

Please note that an Investigator Site file may comprise of one or a number of files including for example pharmacy research folders.

The template may be used on its own or together with the Sponsor example file list. Where prompted please update sections as required including the study title, Investigator and Study Coordinator details.

Where utilised, the template must be completed by a member of the team delegated the task of Site File maintenance in indelible ink, changes made by hand must be clear. Instructive text may be removed on completion.

|  |  |
| --- | --- |
| **INVESTIGATOR SITE FILE CHECKLIST**

|  |
| --- |
| **Study title:** Click here to enter text.**.****Protocol number:** Click here to enter text.**CI:** Click here to enter text.**PI:** Click here to enter text.**Study Co-ordinator:** Click here to enter text. |

 |
| Administrative |
| Site File Index |  |  |  |
| Contact List *(Contact details for site staff and coordinating centre)* |  |  |  |
| Version Control Log  |  |  |  |
| Study Protocol  |
| Current Approved Version (Signed by PI), including acknowledgement of receipt |  |  |  |
| Superseded versions of Approved Protocol(s) |  |  |  |
| Master Copy study documents including instructions (as applicable) |
| Patient Information Sheet (PIS) |
| Current Approved PIS Template  |  |  |  |
| Superseded Approved PIS(s) Templates |  |  |  |
| Informed Consent Form (ICF) |
| Current Approved ICF Template |  |  |  |
| Superseded Approved ICF Template |  |  |  |
| Case Report forms (CRF) |
| Current approved CRFs  |  |  |  |
| Superseded approved versions of CRFs |  |  |  |
| Instructions for completion of CRFs or database entry (as applicable) |  |  |  |
| GP Letter |
| Current Approved Letter/Information for Patient’s GP |  |  |  |
| Superseded Approved GP Letter/Information for Patient’s GP |  |  |  |
| Sample Diary Cards *(if applicable)* |
| Current Approved Sample Diary Cards |  |  |  |
| Superseded Approved Sample Diary Cards |  |  |  |
| Other Ethics Approved Information Given to Patients  |
| *<Other ethically approved information given to patients>* |  |  |  |
| REGULATORY (REC, MHRA) |
| IRAS Application |  |  |  |
| HRA Approval Letter |  |  |  |
| Notice of Acceptance Letter (CTA) |  |  |  |
| Log of all the Amendments submitted to MHRA and REC |  |  |  |
| Amendment Approval Letter(s) |  |  |  |
| Notice of Substantial Amendments |  |  |  |
| Annual Progress Reports |  |  |  |
| Data Safety Update Report (DSUR) & Cover letter |  |  |  |
| ARSAC/IRMER Licence (if applicable) |  |  |  |
| Original ARSAC/IRMER submission and approval |  |  |  |
| Updates to ARSAC/IRMER and approvals |  |  |  |
| Related Correspondence |  |  |  |
| Sponsor / Research & Development |
| Sponsor |
| Letter of confirmation of Sponsorship |  |  |  |
| Insurance and Indemnity Certificate(s) |  |  |  |
| Data protection form and registration confirmation |  |  |  |
| Research and Development |
| R&D NHS Permission Letter/ Trust Authorization Letter (CI and Sponsor to hold approvals for each site if multi-site) |  |  |  |
| R&D approvals for Amendments |  |  |  |
| Local Speciality Approvals (SAC, GMSC) |  |  |  |
| Completed Feasibility questionnaire |  |  |  |
| R&D Annual Reports |  |  |  |
| Other R&D forms (Data Transfer, Treatment continuation) |  |  |  |
| Contracts and Agreements |
| Finance |
| Funding Agreements: Grant Applications/ Grant award letters/ Financial Disclosure Letter |  |  |  |
| Material Transfer Agreements (if applicable) |  |  |  |
| Contract(s)/Agreement(s) |
| Contracts (e.g. signed Site Agreement) |  |  |  |
| Confidentiality Agreement(s) |  |  |  |
| PI Agreement |  |  |  |
| Completed and signed FDA 1572 form (if applicable) |  |  |  |
| Other Agreement(s) |  |  |  |
| Research Team – Staff and Training  |
| Delegation Duties Log for Site Team |  |  |  |
| Signed & Dated CVs & GCP Certificates for Site Team |  |  |  |
| Study-specific training records |  |  |  |
| Research Honorary contracts (if applicable) |  |  |  |
| Pharmacy/IMP documents |
| Investigator Brochure and / or SmPC(s) and updates |  |  |  |
| Pharmacy Manual  |  |  |  |
| Temperature monitoring Log |  |  |  |
| Prescription(s) Template and labels |  |  |  |
| Decoding/Unblinding procedures (where applicable) |  |  |  |
| IMP documentation for handling, shipping, ordering, SOPs. |  |  |  |
| IMP accountability logs |  |  |  |
| Pharmacy signature log |  |  |  |
| Related Correspondence |  |  |  |
| Pharmacovigilance |
| Template SAE/SUSAR Form & Reporting Procedures including superseded version(s) |  |  |  |
| Safety Reporting Log and Completed SAE/SUSAR forms (including acknowledgement of receipt by Sponsor) |  |  |  |
| Patient data |
| Patient enrolment |
| Randomisation or enrollment procedure/instructions |  |  |  |
| Subject Identification Log |  |  |  |
| Screening and Recruitment Log  |  |  |  |
| Completed Patient Consent Forms |  |  |  |
| Copies of Letters sent to GP |  |  |  |
| Study Data |
| Completed CRFs /eCRFs (indicate location if held elsewhere) |  |  |  |
| Documentation of CRF corrections and data queries |  |  |  |
| *<Other completed data collection forms e.g. QoL questionnaires as applicable>* |  |  |  |
| <Other study specific data collection forms and procedures e.g. imaging> |
| <insert details> |  |  |  |
| Data management  |
| Case Report Forms |
| Sample Case Report Form(s) / eCRFs  |  |  |  |
| Superseded Case Report Form(s) /eCRFs |  |  |  |
| *<Other data collection form templates e.g. QoL questionnaires as applicable>* |  |  |  |
| Deviations and Potential Serious Breaches |  |  |  |
| Log of Deviations and potential breaches |  |  |  |
| SOP for the Recording and Reporting deviations and serious breaches  |  |  |  |
| LABORATORY And Samples handling |
| Clinical Trial Samples |  |  |  |
| Record of retained samples |  |  |  |
| Sample transfer form template and guidance documents |  |  |  |
| Completed sample transfer forms |  |  |  |
| Labs |  |  |  |
| Local Labs Normal Ranges |  |  |  |
| Certificate of accreditation  |  |  |  |
| Central Laboratories Normal Reference Ranges  |  |  |  |
| Calibration Records of devices used |  |  |  |
| Monitoring, Audits And inspections |  |  |  |
|  Monitoring  |
| SIVdocumentation: presentation, letter, report, attendance log and updates |  |  |  |
| Monitoringdocumentation: letter, report, attendance log and updates |  |  |  |
| PI self-monitoring and CI review (if Applicable) |  |  |  |
| Audit /Inspection  |  |  |  |
| R&D audit reports and responses |  |  |  |
| MHRA Inspection findings and responses |  |  |  |
| Sponsor audit  |  |  |  |
| End Of Study |
| End of study Declarations to the REC/MHRA/R&D |  |  |  |
| Final Reports |  |  |  |
| Archive Plan including location and archivist details |  |  |  |
| Committees and Meetings |
| Investigator Meetings or other meetings as appropriate |
| Agenda, Presentations, Minutes |  |  |  |
| CORRESPONDENCE (filed in chronological order) |
| General Correspondence  |  |  |  |
| Newsletters |  |  |  |