**Investigator Site File Checklist**

**For Interventional and Research Studies**

|  |  |
| --- | --- |
| **Study Title:** |  |
| **Chief Investigator:** |  |
| **IRAS number:** |  |
| **Date Created:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Document** | **Y/N** | **Comments** |
|  | **Administrative** |
|  | Contact list  |  | *To include contact details for out of hours study provisions* |
|  | Version control log |  | *Please list the current version of the protocol, PIS, ICF, GP Letter. Any other patient facing document.**Please reference the amendment which included the updated versions.* |
|  | File note log |  | *Deviations should not be logged on file notes. Use the deviation log accordingly* |
|  | **Clinical Trials Units (CTUs) or Clinical Research Organisations (CROs)** |
|  | Contract(s) between sponsor and CTU/CRO |  |  |
|  | Delegation of responsibilities  |  |  |
|  | Compliance with Sponsors SOPs |  |  |
|  | **Study Protocol**  |
|  | Current version  |  |  |
|  | Superseded protocol(s) |  | To be marked as superseded |
|  | **Participant Information Sheet (s) (PIS)/Informed Consent Form(s)(ICF)/GP Letters/Diary Cards/Recruitment adverts** |
|  | Current approved PIS(s) |  |  |
|  | Superseded submitted PIS(s)  |  | *To be marked as superseded* |
|  | Current approved ICF(s)  |  |  |
|  | Superseded submitted ICF(s)  |  | *To be marked as superseded* |
|  | Current GP letter / Information for participant’s GP |  |  |
|  | Superseded GP letter / Information for participant’s GP |  | *To be marked as superseded* |
|  | Recruitment advertisement(s) |  |  |
|  | Superseded recruitment advertisement(s) |  | *To be marked as superseded* |
|  | Other approved documents as applicable |  |  |
|  | **Sponsor** |
|  | Confirmation of sponsorship email |  |  |
|  | Conditions of sponsorship  |  | *This is the sponsor-CI agreement*  |
|  | Full set of approved documents at study start |  | *Study start defined as Confirmation of Sponsorship* |
|  | Insurance or indemnity certificate(s) |  |  |
|  | Confirmation of capacity and capability email |  | *Note: Study cannot start recruitment without this email.* |
|  | Study commencement notification to sponsor |  |  |
|  | Notification of first participant consented to sponsor |  |  |
|  | Correspondence  |  | *Pertinent/decision making correspondence only* |
|  | Evidence of registration on a public website |  |  |
|  | Departmental authorisation  |  | *Acknowledgment of study from Head of Department*  |
|  | Scientific peer review |  |  |
|  | Organisation identification document (OID) (or contract, or other agreement with site) |  |  |
|  | **Ethics**  |
|  | Original ethics application  |  | *Full submission package* *All correspondence (letters of approval or evidence of submission).* |
|  | Correspondence  |  |  |
|  | **Health Research Authority (HRA)** |
|  | Initial assessment |  |  |
|  | HRA approval |  |  |
|  | Correspondence  |  |  |
|  | **Other Regulatory Approval (include Full submission, approval and correspondence in each case)** |
|  | Administration of Radioactive Substances Advisory Committee (ARSAC)  |  |  |
|  | National Offender Management Service (NOMS), Her Majesty's Prison and Probation Service (HMPPS)  |  |  |
|  | Confidentiality Advisory Group (CAG)  |  |  |
|  | Gene Therapy Advisory Committee (GTAC)  |  |  |
|  | Other approvals as applicable |  |  |
|  | **Amendments** |
|  | Amendment log |  | *All versions, previous versions to be marked as superseded* |
|  | Non-substantial/amendments |  | *All full amendment packages including evidence of submission to be filed in chronological order, pre-approval amendments to be filed as part of final sponsorship approval.* *Note: Amendments cannot be submitted or implemented without sponsor authorisation to submit or implement, please file evidence of sponsor authorisation to submit and sponsor implementation of amendment.*  |
|  | Substantial amendments |  |
|  | **Finance and contracts** |
|  | 10.1 Contract checklist |  |  |
|  | 10.2 Funding agreement  |  |  |
|  | 10.3 Contract(s) between the sponsor and each third-party vendor  |  |  |
|  | 10.4 Confidentiality agreement(s) |  |  |
|  | **Research Team – Staff and Training**  |
|  | Delegation log for site team |  | *Delegation log template* |
|  | Signed and dated CVs & Good Clinical Practice certificates |  |  |
|  | Study specific/SOP training  |  | *Training template 10 of SOP 45 can be used* |
|  | Database training  |  | *Evidence of training on database for each staff member should be filed.* |
|  | **Intervention** |
|  | Instructions for use |  |  |
|  | Safety information |  |  |
|  | Intervention management plan |  |  |
|  | Site intervention accountability log |  |  |
|  | Overall intervention accountability and destruction log |  |  |
|  | Administration form |  |  |
|  | Correspondence relating to intervention |  |  |
|  | Other  |  |  |
|  | **Safety Reporting** |
|  | Safety reporting procedures |  |  |
|  | Template reporting forms  |  |  |
|  | Safety Event reporting log  |  | *Needs to be a Master SAE log and evidence that Sites are sending their Site SAE logs periodically – ONLY applicable for Multi-Site Studies.* |
|  | Completed Serious Adverse Event (SAE) reporting forms |  | *Evidence of PI and CI assessment to be filed with form.*  |
|  | Completed Suspected Unexpected Serious Adverse Reactions (SUSAR) reporting forms |  | *Evidence of PI and CI assessment to be filed with form.* |
|  | Correspondence associated with submission of SUSARs (including Research Ethics Committee submission and site information) |  |  |
|  | Completed Pregnancy forms |  |  |
|  | **Participant data** |
|  | Completed Screening log |  | *Includes all patients considered for the trial, including pre-screen and screen failures* |
|  | Completed enrolment logs  |  | *Includes only recruited patients*  |
|  | Location of CRFs./Source data |  |  |
|  | **Study Sample Management** |
|  | Evidence of sample management protocol |  |  |
|  | Log of all samples  |  |  |
|  | Template sample transfer forms |  |  |
|  | Completed sample transfer forms |  |  |
|  | Sample collection, transfer, and storage procedure(s) |  |  |
|  | Sample analysis results  |  |  |
|  | Storage and location of samples  |  |  |
|  | Temperature monitoring records  |  |  |
|  | Laboratory’s name, address, and primary contact and tests and analyses being conducted |  |  |
|  | Accreditation certificate & Normal reference ranges  |  |  |
|  | **Deviations and breaches** |
|  | Deviation log  |  |  |
|  | Potential Serious Breaches  |  |  |
|  | Correspondence |  | *Assessment of potential serious breaches, serious breaches and any other pertinent/decision making emails to be included* |
|  | **Data management**  |
|  | Template Case Report Forms (CRF) and/or eCRFs,  |  |  |
|  | CRF/eCRF approval/sign off form  |  |  |
|  | CRF/eCRF completion guidelines or E-CRF user manual and/or SOP |  |  |
|  | Completed CRFs (and/or eCRFs) |  |  |
|  | Data queries |  |  |
|  | Data management Plan  |  |  |
|  | **Databases** |
|  | Database system details  |  |  |
|  | Database change control / versioning log |  |  |
|  | Sponsors sign off |  |  |
|  | URS (User Requirements Specifications) |  |  |
|  | Database validation / UAT (User Acceptance Testing) |  |  |
|  | Database acceptance / sign off form |  |  |
|  |  Database roles and access list |  |  |
|  | **Statistics** |
|  | Randomisation code generation ( if applicable) |  |  |
|  | Randomisation procedure for new participants |  |  |
|  | Unblinding / decoding procedures |  |  |
|  | Out-of-hours procedure test report  |  |  |
|  | Statistical Analysis Plan (SAP) |  |  |
|  | Statistical Reports |  |  |
|  | **Monitoring, Audits and Inspections** |
|  | Internal and sponsor risk assessment  |  |  |
|  | Monitoring plan |  | *Where Applicable* |
|  | Monitoring visit log  |  | *Where Applicable* |
|  | Template Site Initiation Visit (SIV) documentation  |  |  |
|  | Monitoring documentation for TMF and central facilities  |  | *Where Applicable* |
|  | Close out visit documentation for TMF  |  |  |
|  | Audit and Inspection certificates |  |  |
|  | **Committees and Meetings** |
|  | Trial Management Group (TMG) charter  |  |  |
|  | TMG meeting agendas and minutes |  |  |
|  | Trial Steering Committee (TSC) charter  |  |  |
|  | TSC meeting agendas and minutes |  |  |
|  | Confidentiality agreements/conflict of interests forms for committee member  |  |  |
|  |  CV and evidence of research training for committee members |  |  |
|  | Independent Data Monitoring Committees(IDMC)/ Data Monitoring and Ethics Committee (DMEC) charter  |  |  |
|  | IDMC/DMEC meeting agendas and minutes  |  |  |
|  | Confidentiality agreements/conflict of interests forms for committee member  |  |  |
|  | CV and evidence of research training for committee members |  |  |
|  | Other committees |  |  |
|  | Agendas, presentations, and minutes for investigator meetings |  |  |
| **22** | **Close out activities** |
| 22.1 | Confirmation of Data Lock |  |  |
| 22.2 | Laboratory activities complete |  |  |
| 22.3 | End of Trial (EoT) declaration form |  |  |
| 22.4 | Sponsor agreement |  |  |
| 22.5 | Evidence of REC submission |  |  |
| 22.6 | REC acknowledgment of receipt of EoT  |  |  |
| 22.7 | Final report  |  |  |
| 22.8 | Sponsor approval to submit |  |  |
| 22.9 | Evidence of submission to REC |  |  |
| 22.10 | Evidence public website updated with study results |  |  |
| **23** | **Publications** |
| 23.1 | Publications produced from the study |  |  |
| **24** | **Archiving** |
| 24.1 | Sponsor permission to archive |  |  |
| 24.2 | Archiving details |  |  |
| **25** | **Correspondence** |
| 25.1 | Any pertinent correspondence not associated with the sections listed above |  |  |