**Single-Site Trial Master File Checklist**

 **(CTIMP & ATIMP Studies)**

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

|  |  |  |
| --- | --- | --- |
| **Document** | **Y/N** | **Comments** |
| **1.0 Administrative** |
| 1.1 Contact list  |  |  |
| 1.2 Version control log |  |  |
| 1.3 File note log |  |  |
| **2.0 Clinical Trials Units (CTUs) or Clinical Research Organisations (CROs)**  |
| 2.1 Contract(s) between sponsor and CTU/CRO |  |  |
| 2.2 Delegation of responsibilities  |  |  |
| 2.3 Compliance with Sponsors Standard Operating Procedures (SOP) |  |  |
| **3.0 Study Protocol**  |
| 3.1 Current version  |  |  |
| 3.2 Superseded protocol(s) |  |  |
| **4.0 Participant Information Sheet (s) (PIS)/Informed Consent Form(s)(ICF)/GP Letters/Diary Cards/Recruitment adverts** |
| 4.1 Current approved PIS(s) |  |  |
| 4.2 Superseded submitted PIS(s)  |  |  |
| 4.3 Current approved ICF(s)  |  |  |
| 4.4 Superseded submitted ICF(s)  |  |  |
| 4.5 Current GP letter / Information for participant’s GP |  |  |
| 4.6 Superseded GP letter / Information for participant’s GP |  |  |
| 4.7 Template diary cards |  |  |
| 4.8 Superseded template diary cards |  |  |
| 4.9 Recruitment advertisement(s) |  |  |
| 4.10 Superseded recruitment advertisement(s) |  |  |
| 4.11 Other approved documents as applicable |  |  |
| **5.0 Sponsor** |
| 5.1 Sponsor submission |  |  |
| 5.2 Sponsorship with conditions letter |  |  |
| 5.3 Confirmation of sponsorship email |  |  |
| 5.4 Conditions of sponsorship  |  |  |
| 5.5 Full set of study data  |  |  |
| 5.6 Insurance or indemnity certificate(s) |  |  |
| 5.7 Study commencement notification to sponsor |  |  |
| 5.8 Notification of first participant consented to sponsor |  |  |
| 5.9 Correspondence  |  |  |
| 5.10 Evidence of registration on a public website |  |  |
| 5.11 Institute (Queen Mary) or Clinical Board (Barts Health) approval |  |  |
| 5.12 Scientific peer review |  |  |
| **6.0 Medicines and Healthcare products Regulatory Agency (MHRA)** |
| 6.1 Original Competent Authority application (Full submission package and approval) |  |  |
| **7.0 Ethics**  |
| 7.1 Original ethics application  |  |  |
| 7.2 Ethics Annual Progress Report(s) (APRs) and cover letter(s) |  |  |
| 7.3 Correspondence  |  |  |
| **8.0 Health Research Authority (HRA)** |
| 8.1 Initial assessment |  |  |
| 8.2 HRA approval |  |  |
| 8.3 Correspondence  |  |  |
| **9.0 Other Regulatory Approval ( include Full submission , approval and correspondence in each case)** |
| 9.1 Administration of Radioactive Substances Advisory Committee (ARSAC)  |  |  |
| 9.2 National Offender Management Service (NOMS), Her Majesty's Prison and Probation Service (HMPPS)  |  |  |
| 9.3 Confidentiality Advisory Group (CAG)  |  |  |
| 9.4 Gene Therapy Advisory Committee (GTAC)  |  |  |
| 9.5 Other approvals as applicable |  |  |
| **10.0 Amendments** |
| 10.1 Amendment log |  |  |
| 10.2 Non-substantial / minor amendments |  |  |
| 10.3 Substantial / major amendments |  |  |
| **11.0 Finance and contracts** |
| 11.1 Contract checklist |  |  |
| 11.2 Funding agreement  |  |  |
| 11.3 Contract(s) between the sponsor and each third-party vendor  |  |  |
| 11.4 Confidentiality agreement(s) |  |  |
| **12.0 Research Team – Staff and Training**  |
| 12.1 Delegation log for coordinating team |  |  |
| 12.2 Signed and dated CVs & Good Clinical Practice certificates |  |  |
| 12.3 Study specific training  |  |  |
| **13.0 Medicinal products** |
| 13.1 Investigator Brochure (IB) and/or Summary of Product Characteristics (SmPC) |  |  |
| 13.2 Superseded version(s) |  |  |
| 13.3 Medicinal product management plan |  |  |
| 13.4 Pharmacy manual |  |  |
| 13.5 Accountability / dispensing log template  |  |  |
| 13.6 Overall medicinal product accountability log  |  |  |
| 13.7 Handling, shipping, and ordering of medicinal products documents |  |  |
| 13.8 Prescription template(s) |  |  |
| 13.9 Destruction log template / return to sponsor form |  |  |
| 13.10 SOP(s) related to medicinal products and/or their handling |  |  |
| 13.11 Correspondence related to the medicinal products  |  |  |
| 13.12 Storage of medicinal products out of Pharmacy  |  |  |
| 13.13 Out of pharmacy temperature monitoring logs |  |  |
| 13.14 Out of Pharmacy Thermometer details  |  |  |
| 13.15 Out of pharmacy Management of temperature excursions  |  |  |
| **14.0 Safety Reporting** |
| 14.1 Safety reporting procedures |  |  |
| 14.2 Template reporting forms  |  |  |
| 14.3 Safety Event reporting log  |  |  |
| 14.4 Completed Serious Adverse Event (SAE) reporting forms |  |  |
| 14.5 Completed Suspected Unexpected Serious Adverse Reactions (SUSAR) reporting forms |  |  |
| 14.6 Correspondence associated with submission of SUSARs (including MHRA and Research Ethics Committee submission and site information) |  |  |
| 14.7 Completed Pregnancy forms |  |  |
| **15.0 Participant data** |
| 15.1 Master Recruitment log  |  |  |
| **16.0 Clinical Trial Sample Management** |
| 16.1 Evidence of sample management protocol |  |  |
| 16.2 Log of all samples  |  |  |
| 16.3 Template sample transfer forms |  |  |
| 16.4 Completed sample transfer forms |  |  |
| 16.5 Sample collection, transfer, and storage procedure(s) |  |  |
| 16.6 Sample analysis results  |  |  |
| 16.7 Storage and location of samples  |  |  |
| 16.8 Temperature monitoring records  |  |  |
| **17.0 Deviations and breaches** |
| 17.1 Overall deviation log  |  |  |
| 17.2 Potential Serious Breaches  |  |  |
| 17.3 Correspondence |  |  |
| **18.0 Data management**  |
| 18.1 Template Case Report Forms (CRF) and/or eCRFs,  |  |  |
| 18.2 CRF/eCRF approval/sign off form  |  |  |
| 18.3 CRF/eCRF completion guidelines |  |  |
| 18.4 Completed CRFs (and/or eCRFs) |  |  |
| 18.5 Data queries |  |  |
| 18.6 Data Management Plan (DMP) |  |  |
| **19.0 Databases** |
| 19.1 Database system details  |  |  |
| 19.2 Database change control / versioning log |  |  |
| 19.3 Sponsors sign off |  |  |
| 19.4 URS (User Requirements Specifications)  |  |  |
| 19.5 Database validation / UAT (User Acceptance Testing) |  |  |
| 19.6 Database acceptance / sign off form |  |  |
| 19.7 Database roles and access list |  |  |
| **20.0 Statistics** |
| 20.1 Randomisation code generation ( if applicable) |  |  |
| 20.2 Randomisation procedure for new participants |  |  |
| 20.3 Unblinding / decoding procedures |  |  |
| 20.4 Out-of-hours procedure test report  |  |  |
| 20.5 Statistical Analysis Plan (SAP) |  |  |
| 20.6 Statistical reports  |  |  |
| **21.0 Central Laboratories (repeat per laboratory)** |
| 21.1 Laboratory’s name, address, and primary contact |  |  |
| 21.2 Laboratory’s tests and analyses being conducted |  |  |
| 21.3 Accreditation certificate  |  |  |
| 21.4 Normal reference ranges  |  |  |
| 21.5 Laboratory staff training |  |  |
| 21.6 Study specific SOPs  |  |  |
| 21.7 Test results and analyses |  |  |
| **22.0 Monitoring, Audits and Inspections.** |
| 22.1 Internal and sponsor risk assessment  |  |  |
| 22.2 Monitoring plan |  |  |
| 22.3 Monitoring visit log  |  |  |
| 22.4 Template Site Initiation Visit (SIV) documentation  |  |  |
| 22.5 Monitoring documentation for Trial Master File (TMF) and central facilities  |  |  |
| 22.6 Close out visit documentation for TMF  |  |  |
| 22.7 Audit and Inspection certificates |  |  |
| **23.0 Committees and Meetings**  |
| 23.1 Trial Management Group (TMG) charter  |  |  |
| 23.2 TMG meeting agendas and minutes |  |  |
| 23.3 Trial Steering Committee (TSC) charter  |  |  |
| 23.4 TSC meeting agendas and minutes |  |  |
| 23.5 Confidentiality agreements/conflict of interests forms for committee member  |  |  |
| 23.6 CV and evidence of research training for committee members |  |  |
| 23.7 Independent Data Monitoring Committees(IDMC)/ Data Monitoring and Ethics Committee (DMEC) charter  |  |  |
| 23.8 IDMC/DMEC meeting agendas and minutes  |  |  |
| 23.9 Confidentiality agreements/conflict of interests forms for committee member  |  |  |
| 23.10 CV and evidence of research training for committee members |  |  |
| 23.11 Other committees |  |  |
| 23.12 Agendas, presentations, and minutes for investigator meetings |  |  |
| **24.0 Close out activities** |
| 24.1 Confirmation of Data Lock |  |  |
| 24.2 Laboratory activities complete |  |  |
| 24.3 End of Trial (EoT) declaration form |  |  |
| 24.4 Sponsor agreement |  |  |
| 24.5 Evidence of REC and MHRA submission |  |  |
| 24.6 REC and MHRA Acknowledgment of receipt of EoT  |  |  |
| 24.7 Final report  |  |  |
| 24.8 Sponsor approval to submit |  |  |
| 24.9 Evidence of submission to REC and MHRA |  |  |
| 24.10 Evidence public website updated with study results |  |  |
| **25.0 Publications**  |
| 25.1 Publications produced from the study  |  |  |
| **26.0 Archiving** |
| 26.1 Sponsor permission to archive |  |  |
| 26.2 Archiving details |  |  |
| **27.0 Correspondence** |
| 27.1 Any pertinent correspondence not associated with the sections listed above |  |  |