**Investigator Site 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 Study Protocol** | | |
| 2.1 Current version |  |  |
| 2.2 Superseded protocol(s) |  |  |
| **3.0 Participant Information Sheet (s) (PIS)/Informed Consent Form (ICF)(s)/GP Letters/Diary Cards/Recruitment adverts** | | |
| 3.1 Current approved PIS(s) |  |  |
| 3.2 Superseded submitted PIS(s) |  |  |
| 3.3 Current approved ICF(s) |  |  |
| 3.4 Superseded submitted ICF(s) |  |  |
| 3.5 Current GP letter / Information for participant’s GP |  |  |
| 3.6 Superseded GP letter / Information for participant’s GP |  |  |
| 3.7 Template diary cards |  |  |
| 3.8 Superseded template diary cards |  |  |
| 3.9 Recruitment advertisement(s) |  |  |
| 3.10 Superseded recruitment advertisement(s) |  |  |
| 3.11 Other approved documents as applicable |  |  |
| **4.0 Sponsor** | | |
| 4.1 Confirmation of sponsorship email |  |  |
| 4.2 Conditions of sponsorship |  |  |
| 4.3 Full set of study data |  |  |
| 4.4 Insurance or indemnity certificate(s) |  |  |
| 4.5 Study commencement notification to sponsor |  |  |
| 4.6 Notification of first participant consented to sponsor |  |  |
| 4.7 Correspondence |  |  |
| 4.8 Evidence of registration on a public website |  |  |
| 4.9 Institute (Queen Mary) or Clinical Board (Barts Health) approval |  |  |
| 4.10 Scientific peer review |  |  |
| 4.11 Confirmation of Capacity and Capability (C&C) email |  |  |
| 4.12 Organisation identification document (OID) (or contract, or other agreement with site) |  |  |
| **5.0 MHRA** | | |
| 5.1 Original Competent Authority application (Full submission package and approval) |  |  |
| **6.0 Ethics** | | |
| 6.1 Original ethics application |  |  |
| 6.2 Ethics Annual Progress Report(s) (APRs) and cover letter(s) |  |  |
| 6.3 Correspondence |  |  |
| **7.0 Health Research Authority (HRA)** | | |
| 7.1 Initial assessment |  |  |
| 7.2 HRA approval |  |  |
| 7.3 Correspondence |  |  |
| **8.0 Other Regulatory Approval ( include Full submission , approval and correspondence in each case)** | | |
| 8.1 Administration of Radioactive Substances Advisory Committee (ARSAC) |  |  |
| 8.2 National Offender Management Service (NOMS), Her Majesty's Prison and Probation Service (HMPPS) |  |  |
| 8.3 Confidentiality Advisory Group (CAG) |  |  |
| 8.4 Gene Therapy Advisory Committee (GTAC) |  |  |
| 8.5 Other approvals as applicable |  |  |
| **9.0 Amendments** | | |
| 9.1 Amendment log |  |  |
| 9.2 Non-substantial / minor amendments |  |  |
| 9.3 Substantial / major amendments |  |  |
| **10.0 Finance and contracts** | | |
| 10.1 Site to Sponsor Agreement |  |  |
| **11.0 Research Team – Staff and Training** | | |
| 11.1 Delegation log for Site team |  |  |
| 11.2 Signed and dated CVs & Good Clinical Practice (GCP) certificates |  |  |
| 11.3 Study specific training |  |  |
| **12.0 Medicinal products** | | |
| 12.1 Investigator Brochure (IB) and/or Summary of Product Characteristics (SmPC) (s) |  |  |
| 12.2 Superseded version(s) |  |  |
| 12.3 Pharmacy manual |  |  |
| 12.4 Accountability / dispensing log template |  |  |
| 12.5 Prescription template(s) |  |  |
| 12.6 SOP(s) related to medicinal products and/or their handling |  |  |
| 12.7 Correspondence related to the medicinal products |  |  |
| **13.0 Safety Reporting** | | |
| 13.1 Safety reporting procedures |  |  |
| 13.2 Template reporting forms |  |  |
| 13.3 Safety event reporting log |  |  |
| 13.4 Completed Serious Adverse Event (SAE) reporting forms |  |  |
| 13.5 Completed Suspected Unexpected Serious Adverse Reaction (SUSAR) reporting forms |  |  |
| 13.6 Correspondence associated with submission of SUSARs (including MHRA and Research Ethics Committee (REC) a submission and site information) |  |  |
| 13.7 Completed Pregnancy forms |  |  |
| **14.0 Participant data** | | |
| 14.1 Completed screening logs |  |  |
| 14.2 Completed enrolment logs |  |  |
| 14.3 Location of CRFs/Source data |  |  |
| **15.0 Deviations and breaches** | | |
| 15.1 Deviation log |  |  |
| 15.2 Potential Serious Breaches |  |  |
| 15.3 Correspondence |  |  |
| **16.0 Clinical Trial Sample Management** | | |
| 16.1 Sample management Manual ( including Sample collection, transfer, and storage procedure(s)) |  |  |
| 16.2 Log of all samples |  |  |
| 16.3 Template sample transfer forms |  |  |
| 16.4 Completed sample transfer forms |  |  |
| 16.5 Storage and location of samples |  |  |
| 16.6 Temperature monitoring records if applicable |  |  |
| 16.7 Laboratory’s name, address, and primary contact and tests and analyses being conducted |  | Repeat this line for each local lab or sample prep area being used |
| 16.7.1 Accreditation certificate &  Normal reference ranges |  |  |
| **17.0 Data management** | | |
| 17.1 Template Case Report Forms (CRF) and/or eCRFs, |  |  |
| 17.2 CRF/eCRF approval/sign off form |  |  |
| 17.3 CRF/eCRF completion guidelines or E-CRF user manual and or SOP |  |  |
| 17.4 Completed CRFs (and/or eCRFs) |  |  |
| 17.5 Data queries |  |  |
| **18.0 Randomisation ( if in use)** | | |
| 18.1 Randomisation guide |  |  |
| 18.2 Randomisation printouts if needed |  |  |
| 18.3 Unblinding procedures if applicable |  |  |
| **19.0 Central facilities (repeat & adjust per facility)** | | |
| 19.1 Imaging Manual |  |  |
| 19.2 Imaging transfer log |  |  |
| **20.0 Monitoring, Audits and Inspections.** | | |
| 20.1 Monitoring visit log |  |  |
| 20.2 Site Initiation Visit (SIV) documentation |  |  |
| 20.3 Monitoring Reports correspondence |  |  |
| 20.4 Close out visit report and documentation |  |  |
| 20.5 Audit and Inspection certificates as applicable |  |  |
| **21.0 Close out activities** | | |
| 21.1 EOT declaration form |  |  |
| 21.2 Sponsor agreement to close site |  |  |
| 21.3 REC and MHRA Acknowledgment of receipt of EOT |  |  |
| **22.0 Archiving** | | |
| 22.1 Sponsor permission to archive |  |  |
| 22.2 Archiving details |  |  |
| **23.0 Correspondence** | | |
| 23.1 Any pertinent correspondence not associated with the sections listed above |  |  |