**Pharmacy Site File Checklist**

|  |  |
| --- | --- |
| **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 SOPs |  |  |
| **3.0 Study Protocol**  |
| 3.1 Current version  |  |  |
| 3.2 Superseded protocol(s) |  |  |
| **4.0 Participant Information Sheet (s) (PIS)/Informed Consent Form (ICF)(s)/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| 4.2 Superseded submitted PIS(s)  |  |  |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| 4.4 Superseded submitted ICF(s)  |  |  |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| 4.6 Superseded GP letter / Information for participant’s GP  |  |  |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| 4.8 Superseded template diary cards |  |  |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| 4.10 Superseded recruitment advertisement(s) |  |  |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 |  |  |
| 5.13 Confirmation of Capacity and Capability (C&C) email  |  |  |
| 5.14 Organisation identification document (OID) (or contract, or other agreement with site) |  |  |
| **6.0 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 (GCP) certificates |  |  |
| 12.3 Study specific training  |  |  |
| **13.0 Investigational Medicinal Product (IMP)** |
| 13.1 Pharmacy Approval |  |  |
| 13.2 Investigator Brochure (IB) and/or Summary of product characteristics (SmPC) and updates, including acknowledgement of receipt |  |  |
| 13.3 Pharmacy Manual |  |  |
| 13.4 Sample & Completed IMP Accountability/Dispensing logs |  |  |
| 13.5 Sample & Completed Prescription(s) |  |  |
| 13.6 Study Specific Dispensing procedures |  |  |
| 13.7 Records of IMP destruction/return to sponsor |  |  |
| 13.8 Decoding/Unblinding procedures (where applicable) |  |  |
| 13.9 IMP documentation for ordering and receipt |  |  |
| 13.10 Qualified Person (QP) release certificates for all IMP batches |  |  |
| 13.11 Certificates of Analysis for all IMP batches |  |  |
| 13.12 Sample IMP label including record of relabelling (if applicable) |  |  |
| 13.13 QP Third Party Declaration - for IMPs manufactured outside of the EU (where applicable) |  |  |
| 13.14 Transmissible Spongiform Encephalopathies (TSE) statement/certificate (if applicable) |  |  |
| 13.15 Temperature storage records including records of all deviations |  |  |
| 13.16 Calibration and service records |  |  |
| **14.0 Participant data** |
| 14.1 Participant Identification Log  |  |  |
| **15.0 Deviations and breaches** |
| 15.1 Overall deviation log  |  |  |
| 15.2 Potential Serious Breaches  |  |  |
| 15.3 Correspondence |  |  |
| **16.0 Monitoring, Audits and Inspections.** |
| 16.1 Internal and sponsor risk assessment  |  |  |
| 16.2 Monitoring plan |  |  |
| 16.3 Monitoring visit log  |  |  |
| 16.4 Template Site Initiation Visit (SIV) documentation  |  |  |
| 16.5 Monitoring documentation for TMF and central facilities  |  |  |
| 16.6 Close out visit documentation for TMF  |  |  |
| 16.7 Audit and Inspection certificates |  |  |
| **17.0 Correspondence** |
| 17.1 Any pertinent correspondence not associated with the sections listed above |  |  |