**Investigator Site File Checklist**

**(CTIMP & ATIMP 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* |
|  | **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|  | Superseded protocol(s) |  | To be marked as superseded |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|  | Superseded submitted PIS(s) |  | *To be marked as superseded* |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|  | Superseded submitted ICF(s) |  | *To be marked as superseded* |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|  | Superseded GP letter / Information for participant’s GP |  | *To be marked as superseded* |
|  | Template diary cards |  |  |
|  | Superseded template diary cards |  | *To be marked as superseded* |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|  | Superseded recruitment advertisement(s) |  | *To be marked as superseded* |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.* |
|  | 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) |  |  |
|  | **Medicines and Healthcare products Regulatory Agency (MHRA)** | | |
|  | Original Competent Authority application |  | *Full submission package should be filed in this section.* |
|  | **Ethics** | | |
|  | Original ethics application |  | *Full submission package*  *All correspondence (letters of approval or evidence of submission).*  *Note: If document set is filed in the MHRA section, duplicate printing is not required, please leave a note on this checklist to indicate which section the full submission package is filed in.* |
|  | 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** | | |
|  | Site to sponsor agreement |  | *Final signed version* |
|  | **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.* |
|  | **Medicinal products** | | |
|  | Investigator Brochure (IB) and/or Summary of Product Characteristics (SmPC) |  |  |
|  | Superseded version(s) |  | *Must be marked as superseded* |
|  | Pharmacy manual |  |  |
|  | Accountability / dispensing log template |  |  |
|  | Prescription template(s) |  |  |
|  | SOP(s) related to medicinal products and/or their handling |  |  |
|  | Correspondence related to the medicinal products |  |  |
|  | **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 MHRA and 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 |  |  |
|  | **Clinical Trial Sample Management** | | |
|  | Sample management Manual ( including Sample collection, transfer, and storage procedure(s)) |  |  |
|  | 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 |  |  |
|  | 16.7 Laboratory’s name, address, and primary contact and tests and analyses being conducted |  |  |
|  | 16.7.1 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 |  |  |
|  | **Randomisation (if in use)** | | |
|  | Randomisation guide |  |  |
|  | Randomisation printouts if needed |  |  |
|  | Unblinding procedures if applicable |  |  |
|  | **Central facilities** | | |
|  | Imaging Manual |  |  |
|  | Imaging transfer log |  |  |
|  | **Monitoring, Audits and Inspections.** | | |
|  | Monitoring visit log |  |  |
|  | Site Initiation Visit (SIV) documentation |  |  |
|  | Monitoring Reports correspondence |  | *Includes findings resolution (completed Summary of Findings Table)* |
|  | Close out visit report and documentation |  |  |
|  | Audit and Inspection certificates as applicable |  |  |
|  | **Close out activities** | | |
|  | End of Trial (EoT) declaration form |  |  |
|  | Sponsor agreement to close site |  |  |
|  | REC and MHRA Acknowledgment of receipt of EoT |  |  |
|  | **Archiving** | | |
|  | Sponsor permission to archive |  |  |
|  | Archiving details |  |  |
|  | **Correspondence** | | |
|  | Any pertinent correspondence not associated with the sections listed above |  |  |