**Single-Site Trial Master 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* |
|  | **Clinical Trials Units (CTUs) or Clinical Research Organisations (CROs)**  |
|  | Contract(s) between sponsor and CTU/CRO |  |  |
|  | 2.2 Compliance with Sponsors Standard Operating Procedures (SOP) |  | Approved compliance statements |
|  | **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|  | Superseded protocol(s) |  | To be marked as superseded |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|  | Superseded submitted PIS(s)  |  | *To be marked as superseded* |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|  | Superseded submitted ICF(s)  |  | *To be marked as superseded* |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|  | Superseded GP letter / Information for participant’s GP |  | *To be marked as superseded* |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|  | Superseded template diary cards |  | *To be marked as superseded* |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|  | Superseded recruitment advertisement(s) |  | *To be marked as superseded* |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** |
|  | Sponsor submission |  | *Submission email and sponsor confirmation of receipt* |
|  | Sponsorship with conditions email |  |  |
|  | 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 |  |  |
|  | Risk Assessment |  |  |
|  | **Medicines and Healthcare products Regulatory Agency (MHRA)** |
|  | Original Competent Authority application  |  | *Full submission package should be filed in this section.* |
|  | Acknowledgement letter |  | *Please write N/A if not applicable* |
|  | Grounds of non-acceptance letter |  | *Please write N/A if not applicable* |
|  | Evidence of re-submissions |  | *Please write N/A if not applicable* |
|  | Approval letter  |  |  |
|  | **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 |  |  |
|  | **Annual Reports** |
|  | Developmental Safety Update Report (DSURs) |  | *Cover Letter**Report**GCP manager approval to submit**Evidence of submission* *MHRA acknowledgement (delivery notification automated email from MHRA)* |
|  | Annual reports to Funders  |  |  |
|  | **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** |
|  | Contract checklist |  | *Final signed contract checklist* |
|  | Funding agreement  |  |  |
|  | Site agreements  |  | *If applicable* |
|  | Contract(s) between the sponsor and each third-party vendor  |  | *To include but not limited to:* * *Labs*
* *Pharmacy*
* *External Imaging*
* *Couriers*
 |
|  | Confidentiality Agreements |  |  |
|  | **Research Team – Staff and Training**  |
|  | Delegation log for coordinating 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* |
|  | Evidence of annual review from CI |  | *CI must review SmPC/IB for each IMP for significant changes and notify team if changes affect the study* |
|  | Medicinal product management plan |  |  |
|  | Pharmacy manual |  |  |
|  | Accountability / dispensing log template  |  |  |
|  | Overall medicinal product accountability log  |  |  |
|  | Handling, shipping, and ordering of medicinal products documents |  | *Please leave note if section is filed in pharmacy file* |
|  | Prescription template(s) |  |  |
|  | Destruction log template / return to sponsor form |  |  |
|  | SOP(s) related to medicinal products and/or their handling |  |  |
|  | Correspondence related to the medicinal products  |  |  |
|  | Storage of medicinal products out of Pharmacy  |  |  |
|  | Out of pharmacy temperature monitoring logs |  |  |
|  | Out of Pharmacy Thermometer details  |  |  |
|  | Out of pharmacy Management of temperature excursions  |  |  |
|  | **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** |
|  | Screening log |  | *Includes all patients considered for the trial, including pre-screen and screen failures* |
|  | Recruitment log  |  | *Includes only recruited patients*  |
|  | **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 |  |  |
|  | Version control log for eCRFs |  | *To include version and list of changes made* |
|  | Data Queries |  |  |
|  | Data Management Plan (DMP) |  |  |
|  | **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 procedure for new participants |  |  |
|  | Unblinding / decoding procedures |  |  |
|  | Out-of-hours procedure test report  |  |  |
|  | Statistical Analysis Plan (SAP) |  |  |
|  | Statistical reports  |  |  |
|  | **Central Laboratories (repeat per laboratory and specify role in study)** |
|  | Laboratory’s name, address, and primary contact |  |  |
|  | Laboratory’s tests and analyses being conducted |  |  |
|  | Accreditation certificate  |  |  |
|  | Normal reference ranges  |  |  |
|  | Laboratory staff training |  |  |
|  | Study specific SOPs  |  |  |
|  | Test results and analyses |  |  |
|  | **Monitoring, Audits and Inspections.** |
|  | Monitoring plan |  |  |
|  | Template Site Initiation Visit (SIV) documentation  |  | *Includes SIV checklist and report*  |
|  | Monitoring visit log  |  |  |
|  | Monitoring documentation for Trial Master File (TMF) and central facilities  |  | *Includes:** *Final monitoring report*
* *Response to summary of findings*
* *Monitor’s feedback*
* *Completed summary of findings table*
* *Confirmation of closure of all findings*
 |
|  | Close out visit documentation for TMF  |  |  |
|  | Audit and Inspection certificates |  | * *Audit reports are not to be filed in the TMF but should be available upon request*
 |
|  | **Committees and Meetings (applicable for every committee)** |
|  | 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 |  | *Note: consumer / public / patient representatives do not need GCP training* |
|  | 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 |  |  |
|  | **Close out activities** |
|  | Confirmation of Data Lock |  |  |
|  | Laboratory activities complete |  |  |
|  | End of Trial (EoT) declaration form |  |  |
|  | Sponsor agreement to submit EOT |  |  |
|  | Evidence of REC and MHRA submission |  |  |
|  | REC and MHRA Acknowledgment of receipt of EoT  |  |  |
|  | Final report (CSR) |  |  |
|  | Sponsor approval to submit CSR  |  |  |
|  | Evidence of submission to REC and MHRA |  |  |
|  | Evidence public website updated with study results |  |  |
|  | **Publications**  |
|  | Publications produced from the study  |  |  |
|  | **Archiving** |
|  | Sponsor permission to archive |  |  |
|  | Archiving details |  |  |
|  | **Correspondence** |
|  | Any pertinent correspondence not associated with the sections listed above |  |  |

**Trial Master File – Investigator Site Section Checklist**

***Please repeat this section X1 per site***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Document** | **Y/N** | **Comments** |
|  | **Administrative** |
|  | Contact List |  |  |
|  | **Study Protocol** |
|  | Current protocol signature pages |  |  |
|  | Superseded protocol signature pages |  |  |
|  | **Site Specific Documentation**  |
|  | Current PIS  |  |  |
|  | Superseded PIS(s)  |  |  |
|  | Current ICF  |  |  |
|  | Superseded ICF  |  |  |
|  | Current Letter/Information for Patient’s GP  |  |  |
|  | Superseded GP Letter/Information for Patient’s GP  |  |  |
|  | Current Recruitment Advertisement(s)  |  |  |
|  | Superseded Recruitment Advertisement(s)  |  |  |
|  | Site Administration of Radioactive Substances Advisory Committee (ARSAC) Licence  |  |  |
|  | **Site Approval** |
|  | 30.1 Feasibility documentation |  | To include evidence of site feasibility confirmation |
|  | 30.2 Capacity and capability approval |  |  |
|  | 30.3 Site activation notification  |  |  |
|  | 30.4 Correspondence  |  |  |
|  | **Finance and Contracts** |
|  | Signed site agreement |  |  |
|  | Record of study payments |  |  |
|  | **Research Team – Staff Training** |
|  | Site Delegation Duties Logs |  |  |
|  | Signed & Dated CVs & GCP Certificates  |  |  |
|  | Study specific/SOP training log |  |  |
|  | Out of hours contact test |  |  |
|  | Imaging Transfer test  |  |  |
|  | **IMP Section**  |
|  | Receipt of IB and/or SmPC(s) updates |  |  |
|  | Sample IMP Accountability log and approved IMP accountability logs |  |  |
|  | Sample Prescription(s) and approval |  |  |
|  | Local Decoding/Unblinding procedures  |  |  |
|  | Documentation of IMP shipments and receipts |  |  |
|  | IMP return/destruction documentation and procedures |  |  |
|  | Temperature deviation information |  |  |
|  | Lead Pharmacist declaration (where applicable) |  |  |
|  | **Pharmacovigilance** |
|  | Receipt of safety notifications to investigators |  |  |
|  | **NHS Laboratory** |
|  | Certificate of accreditation  |  |  |
|  | Laboratories Reference Ranges  |  |  |
|  | **Clinical Trial 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  |  |  |
|  | **Equipment** |
|  | Evidence of equipment sent to site |  |  |
|  | **Monitoring and Audits** |
|  | SIVreport and evidence of actions completed  |  |  |
|  | Monitoringreports including pharmacy |  |  |
|  | Correspondence and evidence of findings closed |  |  |
|  | Close out visit report |  |  |
|  | Site only audit Certificates  |  |  |
|  | **Study Closure** |
|  | Notification of site closure |  |  |
|  | Acknowledgment of receipt of EOT documentation |  |  |
|  | Acknowledgment of receipt of clinical study report |  |  |
|  | Letter confirming permission to archive |  |  |
|  | Details of archive arrangements |  |  |
|  | **Correspondence** |
|  | Any pertinent correspondence not listed in the sections above |  |  |