**Multi-Site Trial Master File Checklist**

 **(Interventional and Research Studies)**

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

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|  | **Document** | **Y/N** | **Comments** |
|  | **Administrative** |
|  | Contact list  |  |  |
|  | Version control log |  | *Please list the current version of the protocol, PIS, ICF, GP Letter. Any other patient facing document.* |
|  | File note log |  |  |
|  | **Clinical Trials Units (CTUs) or Clinical Research Organisations (CROs)**  |
|  | Contract(s) between sponsor and CTU/CRO |  |  |
|  | Compliance with Sponsors Standard SOPs |  |  |
|  | **Study Protocol**  |
|  | Current version  |  |  |
|  | Superseded protocol(s) |  |  |
|  | **Participant Information Sheet (s) (PIS)/Informed Consent Form (ICF)(s)/GP Letters/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|  | Superseded submitted PIS(s)  |  | *To be marked as superseded* |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|  | Superseded submitted ICF(s)  |  | *To be marked as superseded* |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|  | Superseded GP letter / Information for participant’s GP |  | *To be marked as superseded* |
|  | Recruitment advertisement(s) |  |  |
|  | Superseded recruitment advertisement(s) |  | *To be marked as superseded* |
|  | Other approved documents as applicable |  |  |

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|  | **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 study 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 documentation |  |  |
|  | **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 filled in.* |
|  | Correspondence  |  |  |
|  | **Health Research Authority (HRA)** |
|  | Initial assessment |  |  |
|  | HRA approval |  |  |
|  | Correspondence  |  |  |

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|  | **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** |
|  | Contract checklist |  | *Final signed contract checklist* |
|  | Funding agreement  |  |  |
|  | Site Agreement |  | If Applicable |
|  | Contract(s) between the sponsor and each third-party vendor  |  | *To include but not limited to:* * *Labs*
* *External Imaging*
* *Couriers*
 |
|  | Confidentiality agreement(s) |  |  |
|  | **Research Team – Staff and Training** |
|  | Delegation log for coordinating team |  | *Delegation log template* |
|  | Signed and dated CVs & Good Clinical Practice (GCP) certificates |  |  |
|  | Study specific training  |  | *Training template 10 of SOP 45 can be used* |
|  | Database training |  | *Evidence of training on database for each staff member should also be filed.* |
|  | **Study Intervention** |
|  | Instructions for use |  |  |
|  | Safety information |  |  |
|  | Intervention management plan |  |  |
|  | Site intervention accountability log |  |  |
|  | Overall intervention accountability and destruction log |  |  |
|  | Administration form |  |  |
|  | Correspondence relating to intervention |  |  |
|  | Other |  |  |
|  | **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 Reaction (SUSAR) reporting forms |  | *Evidence of PI and CI assessment to be filed with form.*  |
|  | Correspondence associated with submission of SUSARs (including Research Ethics Committee (REC) a submission and site information) |  |  |
|  | Completed Pregnancy forms |  |  |
|  | **Participant data** |
|  | Screening Log |  | *Includes all patients considered for the trial, including pre-screen and screen failures* |
|  | Master 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 |  | *To include version and list of changes made* |
|  | 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 the 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 |  |  |
|  | Monitoring visit log  |  |  |
|  | Template Site Initiation Visit (SIV) documentation  |  |  |
|  | 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 |  |  |
|  | EOT declaration form |  |  |
|  | Sponsor agreement |  |  |
|  | Evidence of REC submission |  |  |
|  | REC acknowledgment of receipt of End of Trial (EoT)  |  |  |
|  | Final report  |  |  |
|  | Sponsor approval to submit to submit EoT |  |  |
|  | Evidence of submission to REC  |  |  |
|  | 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***

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|  | **Document** | **Y/N** | **Comment** |
|  | **Administrative**  |
|  | Contact List  |  |  |
|  | **Study Protocol**  |
|  | Current protocol signature pages |  |  |
|  | Superseded protocol signature pages |  |  |
|  | **Site Specific Documents**  |
|  | 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 ARSAC Licence  |  |  |
|  |  **Site approval**  |
|  | Feasibility documentation |  | *To include evidence of site feasibility confirmation* |
|  | Capacity and capability approval |  |  |
|  | Site activation notification  |  |  |
|  | Correspondence  |  |  |
|  | **Finance and contracts** |
|  | Signed site agreement |  |  |
|  | Record of study payments |  |  |

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|  | **Research Team – Staff and Training**  |
|  | Site Delegation Duties Logs |  |  |
|  | Signed & Dated CVs & GCP Certificates  |  |  |
|  | Study specific/SOP training log |  |  |
|  | Out of hours contact test |  |  |
|  | Imaging Transfer test  |  |  |
|  | **Patient data** |
|  | Completed screening logs  |  | *Includes all patients considered for the trial, including pre-screen and screen failures* |
|  | Completed enrolment logs |  | *Only recruited patients.* |
|  | Location of CRFs/Source data  |  | *Completed diary cards/questionnaires* |
|  | **NHS Laboratory** |
|  | Certificate of accreditation  |  |  |
|  | Laboratories Reference Ranges  |  |  |
|  | **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  |  |  |
|  | **35.0 Equipment**  |
|  | Evidence of equipment sent to site  |  |  |
|  | **Monitoring and Audits** |
|  | SIVreport and evidence of actins 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 |  |  |