**Trial Master File Review Checklist**

The Trial Master File review should be completed periodically by the trial team, as per JRO/INV/S02/07 SOP for the Preparation and Maintenance of the Trial Master File (TMF) / and Investigator Site File (ISF) for CTIMPs Sponsored by UCL.

Note: Contents of the TMF may vary depending on trial specifics. Indicate (i.e. NA) where an item is not applicable to the trial and add a reason in the comments column if necessary.

|  |  |  |  |
| --- | --- | --- | --- |
| **UCL Sponsor Number:** |  | **Date of Review:** |  |
| **Trial Short Title / Acronym:** |  | **Reason for Review:** | Trial Initiation  Periodic Review  End of Trial |
| **Name of Reviewer:** |  |

| **SECTION NAME** | **DOCUMENT NAME** | **FILED?**  ***Yes/No/NA*** | **COMMENTS**  ***(including date and version if applicable)*** |
| --- | --- | --- | --- |
| 1. **TRIAL ADMINISTRATION & MANAGEMENT** | | | |
| * 1. **Contact Information** | UCL JRO Trial Contact Sheet |  |  |
| * 1. **Training** | Staff CVs (signed and dated) |  |  |
| Staff Training Records (e.g., GCP Certificates, Protocol and trial specific training) |  |  |
| * 1. **Statistician CV** | Statistician CV |  |  |
| * 1. **Site Contact Information** | Site Contact Information |  |  |
| * 1. **TMF Review** | TMF Review Checklist |  |  |
| * 1. **Central Trial Responsibilities Log** | Central Trial Responsibilities Log |  |  |
| * 1. **Trial Management Plans** | Contract Research Organisation (CRO)/Clinical Trial Unit (CTU)/Sponsor Oversight/ Project Management Plan *(if applicable)* |  |  |
| * 1. **Newsletters** | Newsletters *(if applicable)* |  |  |
| * 1. **Trial Close Out & Archiving** | Confirmation of Trial Close & Archiving Email / Letter |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **UCL SPONSORSHIP** | | | |
| * 1. **Sponsor Letters** | Sponsorship Letter(s) - In principle/ Final |  |  |
| Legal Representative Letter of Engagement *(if applicable)* |  |  |
| Other |  |  |
| * 1. **Insurance** | Insurance Certificate/ Policy |  |  |
| * 1. **Peer Review** | Peer Review *(if applicable)* |  |  |
| * 1. **Conflict of Interest** | Conflict of Interest Management Plan *(if applicable)* |  |  |
| * 1. **Trial Registry Confirmation** | Trial Registration Confirmation (e.g., Clinicaltrials.gov, ISRCTN) |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **AGREEMENTS** | | | |
| * 1. **IMP** | Investigational Medicinal Product (IMP) Supply/ Manufacture/ Import Agreement |  |  |
| Quality and Technical Agreements (i.e., manufacturing/ QP release, packaging, radiolabelling, IMP importation) |  |  |
| Other |  |  |
| * 1. **Laboratory** | Central Laboratory Services Agreement/ Material Transfer Agreement if not with the model Non-Commercial Agreement (mNCA) *(if applicable)* |  |  |
| * 1. **Service Provider** | CTU/ CRO Agreement/ Service Level Agreement *(if applicable)* |  |  |
| * 1. **Randomisation System** | Randomisation/ Code Break System Agreement *(if applicable)* |  |  |
| * 1. **Sponsor-CI Agreement** | Sponsor- Chief Investigator (CI) Agreement |  |  |
| * 1. **Clinical Trial Site Agreement** | Sample model Non-Commercial Agreement (mNCA) |  |  |
| Signed mNCA (including pharmacy/ laboratory and material transfer agreement *if applicable*) |  |  |
| * 1. **Other Agreements** | Confidentiality Agreements *(if applicable)* |  |  |
| Other agreements *(If applicable)* |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **FUNDING AND FINANCE** | | | |
| * 1. **Grant Award** | Funding – Grant Application |  |  |
| Funding – Grant Award Letter/ Agreement |  |  |
| * 1. **Funding Agreement** | Funding Agreement |  |  |
| * 1. **Other Funding** | Other |  |  |
| * 1. **Invoices** | Invoices |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **RESEARCH ETHICS COMMITTEE, HEALTH RESEARCH AUTHORITY & NATIONAL INSTITUTE FOR HEALTH RESEARCH (REC, HRA & NIHR)** | | | |
| * 1. **REC** | | | |
| * + 1. Application | Initial Signed Application, supporting documentation and cover letter to REC |  |  |
| Response to Conditions of Approval *(if applicable)* |  |  |
| * + 1. Approvals | REC / Gene Therapy Advisory Committee (GTAC) Validation Letter, Favourable/ Provisional/ with Conditions Letter |  |  |
| * + 1. Annual Progress Reports | Annual Progress Report to REC and acknowledgement |  |  |
| * + 1. End of Trial to REC | End of Trial Notification to REC and acknowledgement |  |  |
| Final Report Notification and supporting documents |  |  |
| * + 1. Other Notifications | Serious Breach Notifications and acknowledgement *(if applicable)* |  |  |
| Notification of Urgent Safety Measures *(if applicable)* |  |  |
| Other |  |  |
| * + 1. Correspondence | General correspondence |  |  |
| * 1. **HRA** | | | |
| * + 1. Application | Statement of Activities/ Organisation Information Document (OID) |  |  |
| Schedule of Events/ Schedule of Events Cost Attribution Template (SoECAT) |  |  |
| * + 1. Assessment & Approval | HRA Initial Assessment Letter |  |  |
| HRA Final Assessment/ Approval Letter |  |  |
| * + 1. Correspondence | General correspondence |  |  |
| * 1. **NIHR** | | | |
| * + 1. Portfolio Adoption | Portfolio Adoption Confirmation |  |  |
| * + 1. Correspondence | General correspondence |  |  |
| 1. **MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA)** | | | |
| * 1. **CTA Application** | Clinical Trial Authorisation (CTA) Initial signed application and supporting documentation to MHRA (including Cover Letter, Response to Conditions of Approval/ Non-acceptance) |  |  |
| * 1. **Approvals** | MHRA Validation Letter/ Acceptance Letter/ with Conditions Letter/ Grounds for Non-acceptance Letter |  |  |
| * 1. **Other Notifications** | Serious Breach Notifications *(if applicable)* |  |  |
| Notification of Urgent Safety Measures *(if applicable)* |  |  |
| * 1. **End of Trial** | End of Trial Notification to MHRA |  |  |
| Final Report Notification and supporting documents |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **AMENDMENTS** | | | |
| * 1. **Amendment #** | | | |
| * + 1. Submission | Substantial and Non-Substantial Amendments (including where applicable, completed Amendment Tool, cover letter, supporting documents, response to conditions of approval) |  |  |
| * + 1. Approvals | Amendment HRA/ REC/ GTAC/ MHRA Approval Letter(s)/ Substantial and Non-substantial Amendments Favourable Opinion Letter/ with Conditions Letter |  |  |
| Trust R&D NHS Permission Letter / acknowledgement for Trial Amendments |  |  |
| * + 1. Correspondence | General correspondence |  |  |
| 1. **PROTOCOL** | | | |
| * 1. **Current** | Current approved Protocol & signature page |  |  |
| * 1. **Superseded** | Superseded Protocol versions |  |  |
| * 1. **Protocol Development** | Protocol development documentation - draft versions and correspondence |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **PARTICIPANT INFORMATION** | | | |
| * 1. **Participant Information Sheet (PIS) & Informed Consent Form (ICF)** | | | |
| * + 1. Current | Current approved Template Participant Information Sheet (PIS) / Informed Consent Form (ICF) |  |  |
| * + 1. Superseded | Superseded Template Participant Information Sheet (PIS) / Informed Consent Form (ICF) |  |  |
| * 1. **GP Letter** | | | |
| * + 1. Current | Current approved Template GP letter |  |  |
| * + 1. Superseded | Superseded versions of Template GP letters |  |  |
| * 1. **24hrs Contact Card** | 24 hrs contact card *(if applicable)* |  |  |
| * 1. **Questionnaires** | | | |
| * + 1. Current | Current Template Quality of Life Questionnaires (*validated / trial specific if applicable)* |  |  |
| * + 1. Superseded | Superseded versions of Template Quality of Life Questionnaires (*validated / trial specific if applicable)* |  |  |
| * 1. **Patient Diary** | | | |
| * + 1. Current | Current Template Patient Diaries (*if applicable*) |  |  |
| * + 1. Superseded | Superseded versions of Patient Diaries (*if applicable*) |  |  |
| * 1. **Other** | Other (e.g., posters, leaflets) (*if applicable*) |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **INVESTIGATIONAL MEDICINAL PRODUCT (IMP)** | | | |
| * 1. **SODA/ ATIMP Management Plan** | | | |
| * + 1. Current | Current Summary of Drug Arrangements (SODA)/ Advanced Therapy Investigational Medicinal Product (ATIMP) Management Plan and associated documents |  |  |
| * + 1. Superseded | Superseded SODA/ ATIMP Management Plan and associated documents |  |  |
| * 1. **IMPD** | | | |
| * + 1. Current | Current Product Information (Full/ Simplified Investigational Medicinal Product Dossier (IMPD)) |  |  |
| * + 1. Superseded | Superseded Product Information (Full/ Simplified IMPD) |  |  |
| * 1. **Safety Document (IB / SmPC)** | | | |
| * + 1. Current | Current IMP Safety Information document (Investigator Brochure (IB) or Summary of Product Characteristics (SmPC)) |  |  |
| * + 1. Superseded | Superseded version of IMP Safety Information document (IB or SmPC) |  |  |
| * + 1. Review | JRO and CI review of IB/ SmPC updates |  |  |
| * + 1. nIMP | Safety document for unlicensed non-Investigational Medicinal Product (nIMP) *(if applicable)* |  |  |
| * 1. **GMS Approval (if applicable)** | Genomic Medicine Service (GMS) Approval *(if applicable)* |  |  |
| * 1. **IMP Label** | | | |
| * + 1. Current Labelling Form | Current IMP Label Regulatory Approval Form |  |  |
| * + 1. Superseded Labelling Form | Superseded IMP Label Regulatory Approval Form |  |  |
| * + 1. Current Label Artwork | Current Label Artwork |  |  |
| * + 1. Superseded Label Artwork | Superseded Label Artwork |  |  |
| * 1. **QP release** | Certified Qualified Person (QP) Release Statement *(if applicable)* |  |  |
| QP Statement on EU GMP Compliance *(if applicable)* |  |  |
| QP Declaration *(if applicable)* |  |  |
| IMP Certificate of Analysis *(if applicable)* |  |  |
| TSE Certificate *(if applicable)* |  |  |
| * 1. **Recalls** | IMP Recalls *(if applicable)* |  |  |
| * 1. **IMP Accountability Log** | IMP Accountability Log Template *(if applicable)* |  |  |
| * 1. **IMP Destruction & Transfer** | IMP Destruction Log Template *(if applicable)* |  |  |
| * 1. **IMP Temperature Deviations** | Temperature Log Template *(if applicable)* |  |  |
| Temperature Deviation Log Template *(if applicable)* |  |  |
| * 1. **IMP Shipment & Orders** | IMP Shipment Records |  |  |
| IMP Orders |  |  |
| * 1. **IMP Prescription Template** | IMP Prescription Master Template |  |  |
| * 1. **Other** | Other |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **DATA MANAGEMENT** | | | |
| * 1. **Data Protection** | | | |
| * + 1. UCL Data Protection Registration | UCL Data Protection Registration Application Form |  |  |
| Data Protection Impact Assessment (DPIA) *(if applicable)* |  |  |
| UCL Data Protection Registration Confirmation |  |  |
| * + 1. Data Protection Breaches | Data Protection Breach Reports *(if applicable)* |  |  |
| * 1. **CRF** | | | |
| * + 1. Current | Current approved CRF |  |  |
| * + 1. Superseded | Superseded versions of CRF |  |  |
| * + 1. CRF Approval | CRF Sign-off Form – CI and Statistician approval |  |  |
| * 1. **Data Management Plan** | | | |
| * + 1. Current | Current Data Management Plan/ SOP |  |  |
| * + 1. Superseded | Superseded Data Management Plan/ SOP |  |  |
| * 1. **Database / eCRF / Randomisation system** | User manuals |  |  |
| Database validation documentation *(if applicable)* |  |  |
| User Acceptance Testing (UAT) *(if applicable)* |  |  |
| * 1. **Completed CRFs** | Completed CRFs |  |  |
| Completed Diaries *(if applicable)* |  |  |
| Completed Quality of Life Questionnaires *(if applicable)* |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **PHARMACOVIGILANCE** | | | |
| * 1. **SAE Log/ Listings** | | | |
| * + 1. [Trial Site Name] | Completed SAE Recording Logs/ Listings from sites |  |  |
| * 1. **Unblinding (if applicable)** | Documentation of Emergency Un-blinded cases *(if applicable)* |  |  |
| * 1. **DSUR** | | | |
| * + 1. [DSUR#\_Year] | Development Safety Update Report (DSUR) |  |  |
| Submission to MHRA and REC |  |  |
| * 1. **End of trial SAE reconciliation** | Documented reconciliation between JRO SAE list and trial database |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **MONITORING** | | | |
| * 1. **Monitoring Plan** | | | |
| * + 1. Current | Current Monitoring Plan |  |  |
| * + 1. Superseded | Superseded Monitoring Plan |  |  |
| * 1. **Central Coordinating Centre Initiation (if applicable)** | Central Coordinating Centre Initiation Pack |  |  |
| Central Coordinating Centre Initiation Slides |  |  |
| Central Coordinating Centre Initiation Report |  |  |
| Central Coordinating Centre Initiation Attendance Log |  |  |
| * 1. **Central Coordinating Centre Monitoring Visits (if applicable)** | Letter/ Email of Intent to Monitor Central Coordinating Centre |  |  |
| Central Coordinating Centre Monitoring Reports |  |  |
| Central Coordinating Centre Monitoring Visit Log |  |  |
| * 1. **Central Coordinating Centre Close Out (if applicable)** | Central Coordinating Centre Close Out Report |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **STATISTICS** | | | |
| * 1. **Statistical Analysis Plan** | | | |
| * + 1. Current | Current Statistical Analysis Plan |  |  |
| * + 1. Superseded | Superseded Statistical Analysis Plan |  |  |
| * 1. **Randomisation List** | Master Randomisation List *(if applicable)* |  |  |
| * 1. **Analysis** | | | |
| * + 1. Interim | Interim Data Analysis *(if applicable)* |  |  |
| * + 1. Final | Final Data Analysis / End of Trial Report |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **PUBLICATIONS** | | | |
| * 1. **Conferences** | Conference slides/ abstracts |  |  |
| * 1. **Publications** | Related publications/ abstracts |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **TRIAL OVERSIGHT COMMITTEES** | | | |
| * 1. **TMG** | Trial Management Group (TMG) Terms of Reference/Charters |  |  |
| TMG reports/minutes |  |  |
| * 1. **DMC / IDMC** | Data Monitoring Committee/Independent Data Monitoring Committee (DMC)/(IDMC) Terms of Reference/Charters |  |  |
| DMC/IDMC reports/minutes |  |  |
| * 1. **TSC** | Trial Steering Committee (TSC) Terms of Reference/Charters |  |  |
| TSC reports/minutes |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **AUDITS & INSPECTIONS** | | | |
| * 1. **Letters** | Letter of Intent to Audit by Sponsor or External Representative / Audit plan |  |  |
| * 1. **Audit Certificate / Report** | Audit Summary Report |  |  |
| Audit Summary Report for Site (*where applicable to that site*) |  |  |
| Audit Certificate |  |  |
| * 1. **Follow up** | Follow up from Audit |  |  |
| * 1. **Inspections** | Regulatory Inspections documentation |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **CENTRAL LABORATORIES & SAMPLES** | | | |
| * 1. **[Lab Name]** | | | |
| * + 1. Accreditation Certificates | Accreditation Certificates/ Conformity Documentation |  |  |
| * + 1. Sample Analysis Plan | Sample Analysis Plan *(if applicable)* |  |  |
| * + 1. Deviations | Notification of deviations *(if applicable)* |  |  |
| * 1. **Laboratory /Sample Processing Manual** | Laboratory/ Sample Processing Manual |  |  |
| * 1. **Sample Shipment / Receipt** | Sample Shipment / Receipt Documentation |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **PROCEDURAL DOCUMENTS** | | | |
| * 1. **Trial SOPs/ Plans** | | | |
| * + 1. Current | Current Trial Specific SOPs / Plans (e.g., Randomisation Plan, Unblinding Plan, Sample Management Plan, Dose Decision and Dose Escalation Plan) |  |  |
| * + 1. Superseded | Superseded Trial Specific SOPs / Plans |  |  |
| * 1. **JRO SOPs** | JRO SOPs (e.g. SOP for the Recording, Management and Reporting of Adverse Events by Investigators, SOP for the Recording & Reporting of Deviations, Violations, Potential Serious Breaches, Serious Breaches and Urgent Safety Measures) |  |  |
| * 1. **JRO SOP training logs** | JRO SOP training logs |  |  |
| * 1. **Correspondence** | General correspondence |  |  |
| 1. **SITE SPECIFIC DOCUMENTS** | | | |
| * 1. **[Add Site Name]** | | | |
| * + 1. NHS Permissions | Site R&D Confirmation of Capacity & Capability / NHS Permission Letter |  |  |
| * + 1. Open to Recruitment | Open to Recruitment Letter |  |  |
| * + 1. Deviations (Protocol, GCP, SOP) | Completed Log of Deviations, Violations, Potential Serious Breaches, Serious Breaches, Urgent safety measures |  |  |
| * + 1. Delegation Log | Completed Staff Signature and Delegation of Tasks Log |  |  |
| * + 1. Correspondence | General correspondence |  |  |