**Investigator Site File INDEX**

The filing of essential documents in the Investigator Site File (ISF) should be done in accordance with JRO/INV/S02 SOP for the Preparation and Maintenance of the Trial Master File (TMF) / Investigator Site File (ISF) for CTIMPs Sponsored by UCL.

This index should be printed and placed in the front of the ISF.

Once a document has been filed, add ‘YES’ in the ‘FILED?’ column. Where the document is not applicable for the trial add ‘N/A’. If a document is filed in another location add details of this location.

| **SECTION NAME** | **DOCUMENT NAME** | **FILED?**  **(YES or N/A)** |
| --- | --- | --- |
| 1. **TRIAL ADMINISTRATION & MANAGEMENT** | | |
| * 1. **Contact Information** | UCL JRO Trial Contact Sheet |  |
| * 1. **Delegation Log** | Staff Signature and Delegation of Tasks Log |  |
| * 1. **Training** | Staff CVs (signed and dated) |  |
| Staff Training Records (e.g., GCP Certificates, Protocol and trial specific training) |  |
| * 1. **ISF Review** | ISF Review Checklist |  |
| * 1. **Meetings** | Meeting Agendas/ Minutes |  |
| * 1. **Newsletters** | Newsletters *(if applicable)* |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **UCL SPONSORSHIP** | | |
| * 1. **Insurance** | Insurance Certificate / Policy |  |
| * 1. **Approvals** | Open to Recruitment Letter |  |
| Site Closedown Letter |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **AGREEMENTS** | | |
| * 1. **Clinical Trial Site Agreement** | Model Non -Commercial Agreement (mNCA) |  |
| * 1. **Other Agreements** | Other Agreements *(if applicable)* |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **RESEARCH ETHICS COMMITTEE, HEALTH RESEARCH AUTHORITY & NATIONAL INSTITUTE FOR HEALTH RESEARCH (REC, HRA & NIHR)** | | |
| * 1. **REC** | | |
| * + 1. Approvals | REC/ GTAC Favourable Opinion Letter |  |
| * + 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. **Approvals** | MHRA Notice of Acceptance Letter - Clinical Trial Authorisation (CTA) |  |
| * 1. **Other Notifications** | Serious Breach notifications *(if applicable)* |  |
| Notification of Urgent Safety Measures *(if applicable)* |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **SITE SPECIFIC APPROVALS** | | |
| * 1. **Site Approval** | Trust Confirmation of Capacity & Capability/ R&D NHS permission letter / Site approval (NHS R&D Management Approval letter for Research) |  |
| * 1. **End of trial** | Trust R&D notification of end of trial |  |
| * 1. **Other approvals** | ARSAC Documentation *(if applicable)* |  |
| Genetic Modification Safety Committee Approval *(for Gene Therapy Trials only)* |  |
| Other Site-Specific Approvals |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **AMENDMENTS** | | |
| * 1. **Amendment #** | | |
| * + 1. Approvals | HRA/ REC/ GTAC/ MHRA Amendment 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 |  |
| * 1. **Superseded** | Superseded Protocol versions |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PARTICIPANT INFORMATION** | | |
| * 1. **Participant Information Sheet (PIS) & Informed Consent Form (ICF)** | | |
| * + 1. Current | Current approved Participant Information Sheet (PIS) / Informed Consent Form (ICF) (on Trust headed paper) |  |
| * + 1. Superseded | Superseded Participant Information Sheet (PIS) / Informed Consent Form (ICF) (on Trust headed paper) |  |
| * + 1. Signed Consent Forms | Signed Informed Consent Forms (*original copies*) |  |
| * 1. **GP Letter** | | |
| * + 1. Current | Current GP Letter (on Trust headed paper) |  |
| * + 1. Superseded | Superseded GP letter (on Trust headed paper) |  |
| * 1. **24hrs contact** | 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 |  |
| **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. nIMP | Safety document for unlicensed non-Investigational Medicinal Product (nIMP) *(if applicable)* |  |
| * 1. **IMP Prescription Template** | Trial Specific IMP Prescription Template |  |
| * 1. **Other** | Other IMP Specific Forms / SOPs |  |
| * 1. **Correspondence** | General correspondence |  |
| ***\*For trials not using a separate PHARMACY FILE please file the following IMP documents in the ISF\**** | | |
| * 1. **Packaging and Labelling** | Approved MHRA Label Text *(if applicable)* |  |
| * 1. **QP Release** | QP Certificate *(if applicable)* |  |
| * 1. **IMP Accountability Log** | IMP Accountability Log Template (if applicable) |  |
| * 1. **IMP Destruction** | Destruction Log |  |
| Destruction certificates *(if applicable)* |  |
| * 1. **Storage** | Temperature Logs (or location if held elsewhere) |  |
| Notification of Temperature Deviation Template |  |
| Sponsor notification / confirmations of Temperature Deviations |  |
| Thermometer calibration / service certification / File note (or location if held elsewhere) |  |
| * 1. **Dispensing** | Local Dispensing Guidelines |  |
| Master Prescription |  |
| Completed Prescriptions |  |
| * 1. **Randomisation / Unblinding** | Randomisation Notification / Confirmation *(if applicable)* |  |
| Emergency Contact details for unblinding *(if applicable)* |  |
| * 1. **Recalls** | IMP Recalls |  |
| 1. **DATA MANAGEMENT** | | |
| * 1. **CRF** | | |
| * + 1. Current | Current Approved CRF |  |
| * + 1. Superseded | Superseded versions of CRF |  |
| * + 1. CRF Instructions | CRF Completion Instructions *(if applicable)* |  |
| * 1. **Data Queries** | Data Query Documentation (e.g., forms, logs etc.) *(if applicable)* |  |
| * 1. **Deviations (Protocol, GCP, SOP)** | Log of Deviations, Violations, Potential Serious Breaches, Serious Breaches, Urgent safety measures |  |
| * 1. **Completed CRFs** | Completed CRFs |  |
| Completed Diaries *(if applicable)* |  |
| Completed Quality of Life Questionnaires *(if applicable)* |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **SCREENING & RECRUITMENT** | | |
| * 1. **Logs** | Subject Identification and Code List |  |
| Subject Screening Log |  |
| Subject Enrolment, Withdrawal and Completion Log |  |
| Subject Randomisation Log *(if applicable)* |  |
| Subject Randomisation System Emails / Notifications *(if applicable)* |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PHARMACOVIGILANCE** | | |
| * 1. **Trial Adapted Templates** | | |
| * + 1. Current | Current trial adapted Serious Adverse Event (SAE) Reporting Form Template |  |
| Current trial adapted Pregnancy Reporting Form Template |  |
| Current trial adapted Serious Adverse Event (SAE) Recording Log Template *(if applicable)* |  |
| * + 1. Superseded | Superseded trial adapted Serious Adverse Event (SAE) Reporting Form Template |  |
| Superseded trial adapted Pregnancy Reporting Form Template |  |
| Superseded trial adapted Serious Adverse Event (SAE) Recording Log Template *(if applicable)* |  |
| * 1. **SAE Log** | Completed SAE Recording Log *(if applicable)* |  |
| * 1. **SAEs** | | |
| * + 1. [Trial Participant ID#\_SAE term] | Completed SAE Reporting Forms and correspondence |  |
| Completed Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting Forms and submission documents from Sponsor |  |
| * 1. **Pregnancy** | | |
| * + 1. [Trial Participant ID#] | Completed Pregnancy Reporting Forms and correspondence |  |
| * 1. **Other Safety Information** | Notification of Safety Information to Investigators (e.g., SUSAR reports from other sites) |  |
| * 1. **Unblinding (if applicable)** | Documentation of Emergency Un-blinded cases |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **MONITORING & AUDIT** | | |
| * 1. **Site Initiation** | Trial Site Initiation Slides |  |
| Trial Site Initiation Report |  |
| Site Initiation Attendance Log |  |
| * 1. **Monitoring Visits** | Sponsor Monitoring Reports / Summary Letters / Follow-up |  |
| Trial Monitoring Visit Log |  |
| * 1. **UK Regulation Compliance Forms (Part 2) (if applicable)** | Completed UK Compliance Forms |  |
| CI’s review of PI UK Compliance Reports |  |
| JRO review of CI/PI UK Compliance Reports |  |
| * 1. **Site Close Out** | Close Out Report / Close out Compliance Form and associated documents |  |
| Declaration of Site Close Down Form *(if applicable)* |  |
| Confirmation of Site Close Out Email / Letter |  |
| * 1. **Source Document List** | Source Document List |  |
| * 1. **Audits** | Audit Summary Report for Site |  |
| * 1. **Inspections** | Regulatory Inspections documentation |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **LABORATORIES / SAMPLES** | | |
| * 1. **Local Labs** | | |
| * + 1. Accreditation Certificates | Local Laboratory Certification/Accreditation |  |
| * + 1. Ranges | Local Laboratory Normal Ranges |  |
| * 1. **Laboratory /Sample Processing Manual** | Laboratory /Sample Processing Manual |  |
| * 1. **Samples** | Record of retained samples |  |
| Sample Shipment Records |  |
| * 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. **Local procedures / SOPs** | Local procedures / SOPs |  |
| * 1. **Correspondence** | General correspondence |  |