**Investigational Medicinal Product (IMP)/ Pharmacy Site File INDEX**

The filing of essential documents in the Pharmacy Site File 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 IMP/ Pharmacy Site File.

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 (copy of main site log) |  |
| * 1. **Sponsor Approvals** | Open to Recruitment Letter |  |
| Site Close Out confirmation |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **REGULATORY APPROVALS** | | |
| * 1. **REC** | REC Favourable Opinion Letter |  |
| Amendment Favourable Opinion Letter |
| * 1. **HRA** | HRA Final Assessment/ Approval Letter |  |
| Amendment Approval letters |  |
| * 1. **MHRA** | MHRA Notice of Acceptance Letter (CTA) |  |
| Amendment Approval letters |  |
| * 1. **Site Specific** | Trust Confirmation of Capacity & Capability/ R&D NHS permission letter / Site approval (NHS R&D Management Approval letter for Research) |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PROTOCOL** | | |
| * 1. **Current** | Current Approved Protocol |  |
| * 1. **Superseded** | Superseded Protocol Versions |  |
| * 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 Superseded | Superseded Summary of Drug Arrangements (SODA) / Advanced Therapy Investigational Medicinal Product (ATIMP) Management Plan and associated documents |  |
| * 1. **Safety Document** | | |
| * + 1. Current | Current IMP Safety Information documents (Investigator Brochure (IB), Summary of Product Characteristics (SmPC), Material Safety Data Sheet (MSDS) |  |
| * + 1. Superseded | Superseded version of IMP Safety Information documents (IB, SmPC, MSDS) |  |
| * + 1. nIMP | Safety document for unlicensed non-Investigational Medicinal Product (nIMP) *(if applicable)* |  |
| * 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. **Correspondence** | General correspondence |  |
| 1. **MONITORING** | | |
| * 1. **Site Initiation** | Trial Site Initiation Slides |  |
| Trial Site Initiation Report |  |
| Site Initiation Attendance Log |  |
| * 1. **Monitoring Visits** | Monitoring visit documentation |  |
| Pharmacy Monitoring Visit Log |  |
| * 1. **Site Close Out** | Site Close Out Documentation |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PROCEDURAL DOCUMENTS** | | |
| * 1. **Trial SOPs/ Plans** | | |
| * + 1. Current | Current Relevant SOPs / Plans |  |
| * + 1. Superseded | Superseded SOPs / Plans |  |
| * 1. **Correspondence** | General correspondence |  |