**Investigational Medicinal Product (IMP)/ Pharmacy Site File Review Checklist**

The Investigational Medicinal Product (IMP)/ Pharmacy Site 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 IMP/ Pharmacy Site File 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.

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| --- | --- | --- | --- |
| **UCL Sponsor Number:** |  | **Date of Review:** |  |
| **Trial Short Title / Acronym:** |  | **Reason for Review:** | [ ]  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. **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 **Superseded**
 | Superseded Protocol Versions |  |  |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 Superseded
 | Superseded Summary of Drug Arrangements (SODA) / Advanced Therapy Investigational Medicinal Product (ATIMP) Management Plan and associated documents |  |  |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 |  |  |