**Trial Lab File INDEX**

This lab file index is for a Clinical Trial of an Investigational Medicinal Product sponsored by UCL JRO.

It should be printed and placed in the front of the Lab File for the trial.

If a document is filed in another location add details of this location as a file note.

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| --- | --- |
| **Trial Title:** |  |
| **Sponsor Reference:**  |  |
| **Laboratory Reference:** |  |
| **Named Lab person responsible for this trial:** |  |

|  |
| --- |
| **TRIAL SET UP STAGE:** |
| 1. Lab accreditation (s)
 |
| 1. Method validation report
 |
| 1. Lab reference ranges (if applicable)
 |
| 1. Head of Lab GCP certificate + signed and dated CV
 |
| 1. Staff records:

(Job description, CV, training certificates, SOP training log) |
| 1. List of equipment used for the trial with certificates of maintenance + calibration:

Fridge, freezers, centrifuge, PCR machines… |
| 1. Contracts (or state if filed elsewhere):

fire alarm maintenance, freezer samples recovery pest control… |
| 1. IT validation certificates: computers, software+ IT equipment
 |
| 1. Log/certificates of fridge and freezer alarm testing
 |
| 1. Trial Laboratory Agreement
 |
| 1. Protocol and superseded versions
 |
| 1. Protocol Amendment Assessment – Document if amendments require any change to laboratory procedures or assays.
 |
| 1. Sample shipment procedures / Sample management Plan / Laboratory Manual
 |
| 1. Sample Analytical/Analysis Plan
 |
| 1. Serious breach SOP/location of the serious beach SOP /Document detailing serious breach procedure
 |
| STUDY OPEN |
| 1. GREEN light from the sponsor, to proceed with receiving and analysing the samples
 |
| 1. Storage records (e.g. Temp logs)

(Document demonstrating required storage temperatures were maintained and any temperature excursions evaluated while the samples were shipped to and stored at the laboratory) |
| 1. Log of fridge/ freezer alarm testing
 |
| 1. Delegation Log (who is doing what in the lab on this trial)

signed and dated by the Named lab Person |
| 1. Monitoring + Audit Log where the sponsor’s monitor/auditor will record their visits
 |
| 1. Sample log/tracker
 |
| 1. Sample receipt forms with temperature shipment document
 |
| 1. Analysis records
 |
| 1. Analytical Reports
 |
| 1. Correspondence with Trials Team/Sponsor
 |
| 1. Meetings/conference call meetings
 |
| 1. Documented Deviations/ Violations
 |
| 1. Documented incidents reported to sponsor
 |
| UPON CLOSURE TO RECRUITMENT/AFTER CLOSUREOF THE TRIAL |
| 1. Sponsor email formally closing the study in the lab and requesting archiving
 |
| 1. Sample chain of custody (destruction/longer term storage/ biobanking etc)
 |
| 1. File notes
 |
| 1. Any other documents needed to be able to re-construct the trial.
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