**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:** |  |

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| **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 Protocol and superseded versions |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. |