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| **Study title:** | |
| **REC ref:** | **CTIMP: Yes No** *(delete as appropriate)* |
| **Sponsor ref:** | **EudraCT ref:** |
| **Chief Investigator(CI)/Principal Investigator(PI):** | **Laboratory Project Manager:** |
| *Name, address, email* | *Name, address, email* |

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| **Laboratory Accreditation, Certification or licence details:** |
| **ISO 17025:2005 ISO 15189:2012/CPA ISO 9001:2008/ISO 9001:2015 GLP GMP** *(delete as appropriate)*  **If none of the above apply please detail how the Quality Management System is applied below:** |

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| **The terms of informed consent permit analysis of the study samples in accordance with this document in the laboratory? Yes No** *(delete as appropriate)* |

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| **Have laboratory staff involved in processing samples from the study received the appropriate training to complete the analysis? Yes No** *(delete as appropriate)* |
| **Has a Study Delegation log (TMP-QA-13) been completed? Yes No** *(delete as appropriate)* |

**Study samples and laboratory analysis to be undertaken**

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| **Description of Samples** | *eg Whole blood, biopsy etc* |
| **Quantity of Samples** | **Number of patients :**  **Number of visits :**  **Total number of samples:**  *Please note: In the event of a change in the Study protocol which requires an increase in the number of participants, or change in number of samples collected from each participant, an amendment to this Analytical Protocol will be required following the necessary amendment to the Study protocol and any other required amendments to trial documentation / approvals.* |
| **Informed Consent** | **The CI/PI is responsible for ensuring written informed consent is obtained from participants prior to sample transfer to laboratory.** |
| **Sample labelling requirements** | *eg Study Samples will be labelled in the format: study name, participant reference, date, sample type.*  *The CI/PI is responsible for ensuring all patient identifiable information is removed prior to sample transfer to laboratory. However, in the event the laboratory staff receive samples with patient identifiable information, they shall notify the CI/PI, and remove or obscure these details before proceeding with testing.* |
| **Transport of samples to the Laboratory** | *eg Samples will be transported directly to the laboratory by the study research team. Sample receipt shall be recorded by the Laboratory staff.* |
| **Analyses to be Undertaken** | *eg Full blood count, liver function test etc*  *The Laboratory Project Manager is responsible for ensuring methods are validated, and internal quality controls are used for all study analyses. The Laboratory Project Manager shall provide normal ranges, for the analyses performed, to the CI/PI.* |
| **Analytical Method (as detailed in Laboratory SOPs)** | **Laboratory SOPs:**  *(number, title and version)* |
| **Laboratory equipment to be used** | ***Equipment name and unique identifier***  *The Laboratory Project Manager is responsible for ensuring all critical laboratory equipment used to process study samples have current safety, maintenance and calibration records.* |
| **Storage requirements of Study Samples** | *eg Samples will be stored at 2-8C in fridge #2 within the laboratory*  *The Laboratory Project Manager is responsible for ensuring the integrity of samples. The Laboratory Project Manager shall notify the CI/PI in the event of a temperature excursion to agree the appropriate action to be taken.* |
| **Study Sample destruction/returns** | *eg Study Samples shall be destroyed at the request of the CI/PI either at completion of the study or due to patient withdrawal from the study. The Laboratory Manager shall ensure appropriate sample reconciliation and disposal records are completed.* |
| **Timescale for Analysis** | ***From:*** *(insert date)* ***To:*** *(insert date)* |
| **Data handling** | **The Laboratory Project Manager is responsible for ensuring all applicable instrument-based analytical computer software is validated. All data copied, or transcribed, from the original source into a spreadsheet, or report, shall be reviewed by a second member of staff for accuracy. The Laboratory Project Manager is responsible for storage and archiving of source data.** |
| **Result Reporting Requirements** | *eg The Laboratory shall issue results electronically in a spreadsheet format to the CI/PI on completion of analysis of each batch of samples or at the end of the study. The results shall be identified using the same labelling nomenclature as described above under sample labelling requirements. Any unexpected results, which may impact patient safety, shall be reported immediately to the PI/CI. Any out of range results, incidental findings, or laboratory investigations, which may not impact patient safety, shall be reported to PI on a regular basis.* |
| **Deviation handling** | **The Laboratory Project Manager is responsible for ensuring all sample analysis or Analytical Protocol deviations are recorded and reported immediately to the CI/PI.** |
| Analytical Protocol Amendments | Any changes to the Analytical Protocol must be agreed in writing between all signatories to this Analytical Protocol prior to implementation. |
| **Archiving** | **NB. Refer to archiving SOP/study protocol for requirements** |
| **Conditions of blinding and unblinding** | **NB for a blinded study the results may unblind the participants. In this case results shall not be reported until the final study analysis, unless the results impact on patient safety**. |
| **Costs** | ***List analytical costs for study****.* |

**Chief Investigator**

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| *Print name* | *Signature* | *Date* |

**Laboratory Project Manager**

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| *Print name* | *Signature* | *Date* |