**Joint Research Management Office**

***Laboratory Set up Monitoring Form***

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| 1. **GENERAL INFORMATION**
 |
| **Study Title:**  |
| **Study IRAS number:**  |
| **CI:**  |
| **Site:**  | **Laboratory name and address:** |
| **PI:**  | **Date of visit:**  |
| **Name of study monitor:**  | **Type of visit :** |
| **Laboratory staff meeting the monitor:**  | **Summary of activites:**  |
| **Laboratory Manager/Lead name:**  | **Monitoring visit number** *(if applicable)***:**  |
| **Laboratory type:** [ ] Central Laboratory [ ]  Local Laboratory | **Next scheduled visit:**  |
| **Summary of the Visit:** |
| *Please detail what work the laboratory will be performing including if this is towards a study endpoint, or for safety or Diagnostic purposes ( cross check this with the section on contracts and agreements)* |

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| **LABORATORY SITE FILE** | **Yes** | **No** | **Comments and details**  |
| Has Laboratory Site File been set up for this study? | [ ]  | [ ]  |  |
| Is the file located in secure location? | [ ]  | [ ]  |  |
| Does the site file contain all relevant sections? | [ ]  | [ ]  | *Please refer to Laboratory Site File checklist* |
| **REC/ MHRA/HRA** | **Yes** | **No** |  |
| REC Initial approval letters | [ ]  | [ ]  |  |
| Amendments approval/acknowledgements | [ ]  | [ ]  |

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|  | Date | Present |
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| A#2 |  |  |

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| MHRA Initial approval letters | [ ]  | [ ]  |  |
| Amendments approval/acknowledgements | [ ]  | [ ]  |

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|  | Date | Present |
| A#1 |  |  |
| A#2 |  |  |

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| HRA initial approval letters | [ ]  | [ ]  |  |
| Amendments approval/acknowledgements | [ ]  | [ ]  |

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| A#2 |  |  |

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| **Contracts and Agreements** | **Yes** | **No** | **Comments and details** |
| Is there a contact/service level agreement in place between the sponsor and laboratory? | [ ]  | [ ]  |  |
| Has this agreement been periodically reviewed? | [ ]  | [ ]  |  |
| Is there a contract/service level agreement in place with any referral laboratory used for this study? | [ ]  | [ ]  |  |
| **Laboratory organisation**  | **Yes** | **No** | **Comments and details** |
| Does the laboratory have a current organisation chart? | [ ]  | [ ]  | *This is to include established roles and job descriptions.* |
| Does the laboratory have a service user guide? | [ ]  | [ ]  | *To include lab location, services, opening hours, out of hours provisions* |
| **Study conduct** | **Yes** | **No** |  |
| Does the laboratory have a current clinical trial protocol for this study? | [ ]  | [ ]  |  |
| Is there an index available of current SOPs and evidence of superseded versions? | [ ]  | [ ]  | *See SOP 43 Laboratories for details of what is needed* |
| Is there an amendments/deviation log present | [ ]  | [ ]  |  |
| **Sample labelling, receipt, storage and chain of custody:** | **Yes** | **No** | **Comments and details** |
| Does to laboratory have a sample collection and handling policy?If yes, does this policy meet the requirements for this study? | [ ]  | [ ]  | *Consider: transport, temperature, receipt personnel, date stamping,*  |
| Does the laboratory have sufficient written procedures to perform the test required in this study? |  |  | List relevant SOPs |
| **Request for additional work** | **Yes** | **No** | **Comments and details** |
| Does the laboratory have a policy to deal with unscheduled analysis of samples? (Should an urgent clinical event occur) | [ ]  | [ ]  |  |
| Does the laboratory have a policy for reporting unexpected results?  | [ ]  | [ ]  |  |
| **Method validation** | **Yes** | **No** | **Comments and details** |
| Is there evidence that tests have been verified and validated for intended use prior to introduction? | [ ]  | [ ]  | *Consider control material, acceptance/rejection criteria* |
| Does the laboratory have guidelines for repeat testing where needed? | [ ]  | [ ]  |  |
| **Reporting** | **Yes** | **No** | **Comments and details** |
| Does the laboratory have a policy on how tests are reported/analysed? | [ ]  | [ ]  |  |
| **Personnel** | **Yes** | **No** | **Comments and details** |
| Is there evidence of appropriate qualifications, staff training and education? | [ ]  | [ ]  | *To include completed staff training records, GCP certificate, specific role training* |
| How does the laboratory assess staff competency?  | [ ]  | [ ]  | *Detail how staff are deemed competent to perform the tests required.*  |
| **Equipment Maintenance, Reagents and consumables** | **Yes** | **No** | **Comments and details** |
| Are maintenance certificates available for all equipment used in this study? | [ ]  | [ ]  |  |
| Where relevant, are calibration certificates available? | [ ]  | [ ]  | *Consider thermometers, pipettes* |
| Does the laboratory have an in-house maintenance schedule? | [ ]  | [ ]  | *Housekeeping list or schedule* |
| Are all reagents and consumables stored and labelled? | [ ]  | [ ]  | *Consider received, date, opened date, expiry date, storage* |
| Does the department have a Health and Safety policy? | [ ]  | [ ]  |  |
| Is appropriate waste disposal available? | [ ]  | [ ]  |  |
| Emergency procedures policies & signage clearly displayed? | [ ]  | [ ]  |  |
| **Computer systems and data recording** | **Yes** | **No** | **Comments and details** |
| Are there computer systems involved in the laboratories work on this study? | [ ]  | [ ]  | *If yes specify:* |
| Is there evidence of computer system/database validation prior to use in this study? | [ ]  | [ ]  |  |
| How is the recording of data monitored? | [ ]  | [ ]  |  |
| What is the laboratories backup policy? | [ ]  | [ ]  |  |
| **Facilities** | **Yes** | **No** | **Comments and details** |
| Are the facilities suitable to perform the test required in this study | [ ]  | [ ]  | *Consider facility security, space, environmental factors* |
| **Quality Assurance and Control** | **Yes** | **No** | **Comments and details** |
| Does the laboratory have a designated QA lead? | [ ]  | [ ]  | *Please specify:* |
| Is there an established Quality Assurance Policy? | [ ]  | [ ]  |  |
| Is there an ongoing internal audit schedule? | [ ]  | [ ]  | *Consider – if there is evidence this is being adhered to.* |
| What internal quality control checks are in place? | [ ]  | [ ]  |  |
| How does the laboratory manage document control? | [ ]  | [ ]  |  |
| Does the laboratory conform to any external quality assurance schemes, which are relevant to this study? | [ ]  | [ ]  |  |
| How are internal quality control failures reported? | [ ]  | [ ]  |  |
| What is the system for reporting and logging Non-compliances with in the lab? | [ ]  | [ ]  |  |
| Have there been and non-compliances for related to this study samples. | [ ]  | [ ]  |  |
| **Blinding/Unblinding**  | **Yes** | **No** |  |
| Does the laboratory have a procedure or policy for working with on blinded studies? | [ ]  | [ ]  | *Specify if study involves blinding or not.* |
| **Retention of data** | **Yes** | **No** |  |
| Does the laboratory have a retention and archiving policy? | [ ]  | [ ]  |  |
| **Preparation and distributing of clinical kits** | **Yes** | **No** |  |
|  Will the laboratory be creating and distributing Lab sampling Kits?  | [ ]  | [ ]  | *If yes specify purpose* e.g.:-Assembly instructions-QC checks of assembled kits-Kit shipment records-Kit inventory |
| Are appropriate procedures in place to cover this work?  | [ ]  | [ ]  |  |
| **General Monitoring activities** | **Yes** | **No** |  |
| Any resistance or delay in scheduling the monitoring visit? | [ ]  | [ ]  |  |
| Was all documentation requested made available? | [ ]  | [ ]  |  |
| Did study staff have adequate time for the monitoring visit? | [ ]  | [ ]  |  |
| Was a suitable area set aside for monitoring? | [ ]  | [ ]  |  |
| Was there enough time at site to perform required monitoring? | [ ]  | [ ]  |  |
| Was the monitoring log signed? | [ ]  | [ ]  | *Please ensure it is updated* |
| Previous monitoring activities filed. | [ ]  | [ ]  |  |
| Email, letter and telephone records | [ ]  | [ ]  |  |
| Site initiation meeting report and minutes | [ ]  | [ ]  |  |

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| **SUMMARY OF FINDINGS AND ACTIONS**  |
| **No** | **Finding type (please see key for details)** | **Summary of finding** | **Corrective action and person carrying out this action** | **Severity****(Critical, Major, Other)** | **Proposed timeline to resolve** | **Date action completed** **(if not completed state this)** |
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**Key for Findings type:**

1. Essential documents
	1. Study
	2. Approvals
2. Vendors / contracts / subcontractor/ finance
3. Informed consent procedures
4. Inclusion and exclusion criteria
5. IMP and non-IMP
6. Training + Staffing
7. Deviation Study procedures
8. Pharmacovigilance
9. Randomisation and cohort allocation / un-blinding
10. Data Management (Source data + CRF)
11. Study equipment
12. Computer Systems
13. Deviations to GCP / Regulations

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| **SIGNATURES AND REVIEW** |
| Completed by: |
| Study Monitor  | **Name:** **Email:**  | Date:  | Signature |
| Reviewed by  |
| Research Governance and GCP Manager | **Name:** **Email:**  | Date  | Signature |