**Joint Research Management Office *Laboratory –Ongoing 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 (i.e. visit no., COV):** |
| **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)* | |
| **Summary discussion with laboratory manager** | |
| Specify details / significant changes in process or staff / concerns etc. | |

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| **2. PREVIOUS VISIT FINDINGS STATUS** | | | | | | |
| **Have all previous visit findings been resolved?**  **Yes  No  If NO detail outstanding findings below:** | | | | | | |
|  | **Finding type (please see key for details)** | **Summary of findings** | **Corrective action and person carrying out this action** | **Severity (Critical, Major, Other)** | **Proposed timeline to resolve** | **Date action completed** |
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| **LABORATORY SITE FILE** | **Yes** | **No** | **Comments and details** |
| Is the laboratory Site File present, in a good condition and up to date? |  |  |  |
| Is the file located in secure location? |  |  |  |
| Laboratory work | **Yes** | **No** | **Comments and details** |
| Is there a sample log accessible? |  |  | *Specific total number (and type) of samples now held:*  *Received since last visit :* |
| Perform a 5% location spot check of total samples held |  |  | *Please confirm which samples checked and result.* |
| Has any analysis been performed? |  |  | *Please specify what analysis and details of numbers involved* |
| Sample storage | **Yes** | **No** | **Comments and details** |
| Review of temperature log |  |  | *For all areas involved summaries:*  *Was a temp log available? Have there been any excursions? Have all excursions been reported and actioned?* |
| **REC/ MHRA/HRA** | **Yes** | **No** |  |
| Document s present as per set up monitoring report? |  |  |  |
| **Contracts and Agreements** | **Yes** | **No** | **Comments and details** |
| Is there a contact/service level agreement in place between the sponsor and laboratory? |  |  | *Check date and period covered is still valid* |
| Has this agreement been periodically reviewed? |  |  | *Consider: have any amendments been made?* |
| Is there a contract/service level agreement in place with any referral laboratory used for this study? |  |  |  |
| **Laboratory organisation** | **Yes** | **No** | **Comments and details** |
| Has the organisation chart and service user guide been updated? |  |  | *This is to include established roles and job descriptions.*  *Is this up to date?* |
| **Study conduct** | **Yes** | **No** |  |
| Does the laboratory have a current clinical study protocol for this study? |  |  |  |
| Is there an amendments/deviation log present and up to date |  |  |  |
| **Policies and procedures** | **Yes** | **No** | **Comments and details** |
| Is there an index available of current SOPs and evidence of superseded versions? |  |  |  |
| Are all SOPs and procedures in date? |  |  | *List relevant out of date SOPs and policies* |
| **Personnel** | **Yes** | **No** | **Comments and details** |
| Is the delegation log up to date, with relevant documentation present for staff? |  |  | *To include completed staff training records, GCP certificate, specific role training* |
| **Equipment Maintenance, Reagents and consumables** | **Yes** | **No** | **Comments and details** |
| Are maintenance certificates available for all equipment used in this study? |  |  |  |
| Is the in-house maintenance schedule being adhered to? |  |  | *Housekeeping list or schedule* |
| Are all reagents and consumables stored and labelled? |  |  | *Consider received, date, opened date, expiry date, storage* |
| **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:* |
| Has there been any updates to Computer software? |  |  | *If yes specify and detail validation/ review that has been conducted* |
| Is there evidence of Backups being verified? |  |  |  |
| Quality Assurance | Yes | No | *Comments and details* |
| Is the internal audit schedule and internal quality control checks schedule being adhered to? |  |  |  |
| Have there been any non-compliances for related to this study samples. |  |  | *Please specify:* |
| **Blinding/Unblinding** | **Yes** | **No** | **If study is not blinded this is n/a please delete** |
| Have there been any unplanned unblinding situation that have occurred? |  |  | *Specify* |
| **Retention of data** | **Yes** | **No** |  |
| Does the laboratory have a retention and archiving policy? |  |  |  |
| **Preparation and distributing of clinical kits** | **Yes** | **No** | If applicable |
| Number of kits created and distributed? |  |  | *If yes, specify number and confirm appropriate paper work in place. Consider :*  -*Assembly instructions*  *-QC checks of assembled kits*  *-Kit shipment records*  *-Kit inventory* |
| **End of study activities** | Yes | No | For all visits other than COV mark as N/A |
| REC End of trial notification and acknowledgement |  |  |  |
| MHRA End of trial notification and acknowledgement |  |  |  |
| Has all analysis been completed? |  |  |  |
| Have all samples been destroyed or transferred to a Tissue bank? |  |  | *Please specify* |
| Is Sample log up to date with end of trial activities? |  |  |  |
| Have report been created? |  |  |  |
| Is evidence of report creation and QC available |  |  |  |
| Has the report been submitted to the CI and accepted? |  |  |  |
| **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 |  |  |  |
| Previous monitoring visit report findings |  |  |  |

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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 |