**SOP 43 Associated Document 2 – Laboratory Set up checklist**

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| **Set-up requirements** | **Completed and comments** | **Date** |
| Laboratory site file set up and location noted. |  |  |
| Contracts/written agreement in place |  |  |
| Contact details for all appropriate laboratory personnel |  |  |
| Completed delegation log |  |  |
| Study Protocol |  |  |
| Personnel folders to include CV and job description |  |  |
| Training folders for all personnel to include GCP and role specific training |  |  |
| REC/ MHRA/ R&D submissions |  |  |
| REC/MHRA/R&D approval letters |  |  |
| Relevant Laboratory Accreditation Certificates. |  |  |
| Appropriate laboratory protocol to include a list of all SOPs to be used and version control criteria |  |  |
| List of all equipment and facilities to include maintenance, calibration and working temperature details. |  |  |
| Health and Safety Policy |  |  |
| Details of sample audit trail/tracking procedure |  |  |
| Quality Assurance and Quality Control procedures to include validation methods |  |  |
| Computer System/Database details to include relevant CSV and back up procedure. |  |  |
| Computer system access list |  |  |
| Safety data and Data Reporting to include to include procedures for escalation of deviations, potential serious breaches and abnormal results agreed |  |  |