**Minimum requirements for a proposed laboratory**

This guidance document is to be used when assessing laboratories ability to perform sponsored Medicines and Healthcare products Regulatory Agency (MHRA) regulated studies. These guidelines are considered best laboratory practice for sponsored interventional and research studies.

**Background:**

The MHRA conducts statutory Good Clinical Practice (GCP) inspections in accordance with the UK Statutory Instrument 2004/1031 (the Medicines for Human Use (Clinical Trials) Regulations 2004) and subsequent amendments, and it is the intention of the MHRA GCP Inspectorate to conduct inspections of laboratories that perform the analysis or evaluation of human samples collected as part of a clinical trial. This inspection programme will have a focus on analysis which is conducted in support of primary or secondary endpoint data and objectives or where the analysis is critical to the conduct of the study (e.g., specific genetic mutations associated with eligibility assessments). Routine sample analyses for safety testing e.g., standard panels of tests within clinical chemistry and haematology for example, are not the focus of this inspection programme.

Laboratories generate data that are used to make decisions on the safety and efficacy of medicinal products, and answer endpoints that can change clinical care. Consequently, it is of paramount importance that the data they produce is reliable.

Analyses must be performed in accordance with the clinical protocol, GCP and the laboratory’s internal quality control system.

**Clarifications:**

Laboratories are expected to be GCP compliant when they are conducting the analysis or evaluation of samples from clinical research studies which drive clinical care (e.g., safety and eligibility screening), or which monitor the efficacy of Investigational Medicinal Products (IMP) and therefore impact on the evaluation of study outcomes. The type of analysis performed by the laboratory should be determined before entering into discussion regarding selecting a laboratory. The risk should be assessed depending on the activities being performed, the importance of the activities to the study, and how well established any methodologies are. For example, a laboratory performing the primary endpoint analysis using a novel assay is higher risk than a laboratory storing samples for future research. Both types must be compliant with GCP and the guidance in the Standard Operating Procedure (SOP) but could be applied proportionately to the lower risk activities.

Good Laboratory Practice (GLP) applies to non-clinical studies conducted for the assessment of the safety or efficacy of chemicals (including pharmaceuticals) to man, animals, and the environment. GLP for clinical analysis is not enough as it does not cover patient safety, informed consent, expedited reporting, or handling blinded studies.

Good Clinical Laboratory Practice (GCLP) is similar in many ways to laboratory GCP compliance but is not a standard recognised internationally, or by the MHRA.

UKAS (United Kingdom Accreditation Service) International Organization for Standardization (ISO) 15189 accreditation is not sufficient to show compliance with laboratory GCP requirements.

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| **Preliminary Laboratory requirements**  The laboratory must agree to the following conditions prior to any commencement of work | |
| **Compliance with regulatory requirements** | Ability to comply with GCP, MHRA guidelines |
| **Sponsor procurement assessment** | Ability to provide cost quote and pass the Sponsor procurement assessment |
| **Contract/service level agreement** | Willingness to enter into a written contract/service level agreement |
| **Laboratory capability and capability** | Confirmation that all activities can be completed by the laboratory. |
| **Laboratory equipment and facilities** | Appropriate equipment and facilities to perform activities. |
| **Staff training and competency** | Appropriate staff capability to perform activities. See [SOP 34a Researcher Training](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-34a/) for requirements.  Due to the variety of sample processing, in terms of both purpose and laboratory facilities, the level and style of training will vary, but in all cases must be sufficient for each individual to perform their allocated role. All laboratory staff processing research samples should have study specific and protocol training proportionate to their role. Laboratory leads should attend site initiation meetings or investigator meetings, where appropriate.  UKAS ISO 15189 accredited laboratories that process research samples to the same standard as for clinical care should maintain systems for training that will have been subjected to review by audit and inspection to gain accreditation. There should be no requirement to obtain CV and GCP certificates in this situation unless there is a specific reason to do so. However, where specific requirements for processing research samples exist, these should be subject to documented training. |
| **Quality Management System** | A current quality management system in use or willingness to introduce one. See [SOP 24 Quality Management Systems](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-24-/) for further details |
| **Monitoring, Audits, and Inspections** | Willingness to be monitored, audited, and inspected. See [SOP 22 Audits](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-22/) and [SOP 28 Monitoring](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-28/) for further details |
| **Archiving** | Willingness to archive for Sponsors standard as per stipulated on [SOP 20 Archiving](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-20/) |

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| **Laboratory Documentation – Essential**  The laboratory must provide documentation for the following criteria prior to any commencement of work | |
| **Organisation structure** | To include all laboratory staff noted on the delegation log, roles, and job titles. |
| **User guide** | To include laboratory contact details, opening times, out of hour provisions. |
| **Health and safety** | Document all health and safety criteria and local policy. |
| **Staff training and competency assessment** | In accordance with [SOP 34a Researcher Training](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-34a/). |
| **Facilities** | Detail of all laboratory facilities to include specimen reception, continuity of service processes. |
| **Equipment management** | To include equipment lists, maintenance, calibration, working temperatures and acceptable ranges. |
| **Consumable Management** | To include consumable lists, in use/expiry dates, validation of in-house consumables. |
| **SOPs** | SOPs for all activities to be performed. See [SOP 29 Document control and creating JRMO SOPs](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-29/) for further details. |
| **Method Validation** | Detailing the procedure/method selection process and validation |
| **Document control procedure** | To include version control, effective/expiry dates, document access. See [SOP 29 Document control and creating JRMO SOPs](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-29/). |
| **Computer System Validation** | See [SOP 38b Electronic data management systems for MHRA-regulated studies](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-38b/) and [SOP 38c Computer System Validation for Interventional and Research Studies](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-38c/) for further details |
| **Maintaining Quality** | Quality Control (QC) and Quality Assurance (QA) processes  See for [SOP 24 Quality Management System](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-24-/) for further details |
| **Error reporting** | To include procedures for reporting non-compliances, corrective/preventative action plans, escalation procedures  See [SOP 31 Non-compliance and reporting of serious breaches](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-31/) for further details |
| **Reporting** | To include who will report results, format of report, reporting results to the sponsor, reporting of unexpected results,  Agreement should be reached at the contract stage detailing what data will be transferred to the CI and sponsor and how this will occur. Consideration should be given to:   * How data will be recorded, transferred, and in what format. * Whether the laboratory is expected to analyse, summarise, and create a report to accompany raw data. * What QC checks are required on the data. * When repeat analysis be requested or permitted. * The software with which the data be transferred. * Whether data will be transferred in real time or in batches at predefined time points |
| **Repeat Analysis** | Detailing criteria for when repeat analysis would be considered/necessary. |
| **Sample Storage** | To include the laboratory storage facilities/procedures |
| **Retention of Data** | To include the laboratory retention policy, access to data |

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| **Laboratory Documentation – If applicable**  Where applicable, the laboratory must provide documentation for the following criteria prior to any commencement of work | |
| **Patient/subject safety** | Consider the safety of study patients/subjects should contact with the laboratory be required. |
| **Informed Consent** | Consider Informed Consent procedures should these be applicable to the laboratory. See [SOP 25 Informed Consent](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-25/) for details. |
| **Clinical Kits** | Provide details of preparation and distribution of clinical kits should the laboratory require such use. |
| **Sub-contacting procedure** | If the laboratory requires to subcontract, provide details of procedure, contracts, vendor assessment. |
| **Blinding/unblinding** | Where applicable, detail how the laboratory would unblind/re-blind samples should this be required. |