

**Self-Assessment Questionnaire for assessing regulatory compliance in laboratories that perform the storage and analysis or evaluation of research samples**


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Please complete this questionnaire and return it to CTU contact email address.

The questions are derived from guidance provided by the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA). The questionnaire has been designed for laboratories with different roles in the processing and analysis of research samples. Please complete all relevant sections.

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| **Laboratory Details** |
| Laboratory Name |  |
| Laboratory Address |  |
| Summary of range of clinical and research services provided by the laboratory |  |
| Details of current accreditation scheme (status, standards, date of last inspection) if present |
| Please identify and add contact details for the following personnel: |
| Laboratory Manager or equivalent |  |
| Laboratory GCP lead | Someone familiar with the specific requirements for processing research samples and an understanding of the general principles of GCP. |
| QA Manager or equivalent |  |
| Archivist or equivalent | Someone responsible for ensuring laboratory records (results, SOPs, contracts etc.) are retained in accordance with laboratory and organizational policies. |

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| **Organisation and Personnel** | **Yes** | **No** | **Comments** | **Office use** |
| Does your laboratory have a quality management system covering each of the following:* Document control and retention
* Sample processing and analysis
* Facilities and equipment
* Data Acquisition, Review and Approval
* Data Transfer
* Computer System Validation
* Method Validation
* Personnel records and training
* Quality Control
* Quality Assurance
 |  |  | These processes may be described in SOPs or policies and may be provided as standard practice for all laboratory activities or may be research specific. Please list any relevant SOPs. |  |
| Are new or modified procedures required to process research samples, in accordance with Good Clinical Practice? |  |  | Where processing of new research samples differs from existing procedures, are new/updated procedures produced? |  |
| Do all staff maintain a current training record and a job description describing the individual’s role and responsibilities? |  |  |  |  |
| Does the training record include evidence of training for those activities performed on research samples? |  |  | Where the research procedure differs from usual practice. |  |
| Does the SOP/Policy document for training cover the following?* Documentation of training on laboratory equipment use
* Documentation of training on research specific processes
* General research training requirements including GCP
* Assessment and documentation of staff review and development
* Procedures to re-validate staff training after a certain time period? If Yes please record the frequency of revalidation in the comments section.
* Competency assessment to perform the required assay (if required)
 |  |  | Proportionate GCP training is required for staff processing research samples (see UKCRC guidance) |  |

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| **Patient Safety**  | **Yes** | **No** |  | **Office use** |
| Do laboratory reports contain normal range values and identify results outside of normal ranges? |  |  |  |  |
| Is there a process for expedited reporting of urgent results? |  |  | Urgent and atypical results may affect study conduct, therefore systems should be in place to allow for expedited reporting if required. Please list the procedure that contains this information. |  |
| **Contracts and Agreements** |  |  |  |  |
| Are contracts/agreements in place for the processing of research samples (between the laboratory and third parties if affecting research samples)? * If yes, are external contractors/vendors used for the processing of research samples? If so describe for what activities
* Are external contractors/vendors qualified/approved for use?
* Is there a procedure that outlines the selection and use of external contractors/vendors?
* Does each contract state that samples will be processed in accordance with the study protocol, GCP and the applicable regulations?
 |  |  | Though formal contracts may not be required for parties within the same host organisation, details of laboratory requirements for processing research samples should be agreed. Agreements with third parties should be formalised. |  |
| **Study conduct** |  |  |  |  |
| Do you use study specific laboratory manuals to process research samples if not stipulated in the protocol or covered in existing SOPs?Are procedures for research samples reviewed for each clinical protocol to ensure they meet the individual protocol requirements? |  |  | When sample processing for a new protocol is requested, is consideration given to whether existing processes are adequate to meet the requirements of the new protocol? |  |
| Is there a procedure for recording and reporting deviations from standard procedures?  |  |  | Please list procedure name/index |  |
| Is there a procedure in place to ensure effective and timely communication with the sponsor/study site regarding any serious deviations from the clinical protocol or contract/agreement? |  |  | Please list procedure name/index or describe process |  |
| Is there a process for communication with the sponsor/study site to destroy samples if a patient withdraws consent? |  |  | Please list procedure name/index |  |

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| **Sample Shipment, Receipt and Storage** | **Yes** | **No** | **Comments** | **Office use** |
| Does the sample receipt SOP include procedures for * Checking samples were maintained in appropriate correct transport conditions (if required)
* Checking of sample labels
* Checking the integrity of samples
* Chain of custody (record of movement of sample from receipt, through analysis, to final storage)
* Storage of samples prior to analysis
* Receipt of patient identifiers
 |  |  | These sample receipt activities are defined in the guidance for research samples. If not all of these requirements are met, please list those that are included in the SOP or if individual requirements are detailed in other documents |  |
| **Preparation and distribution of clinical trial kits and sample containers** |  |  |  |  |
| Does the laboratory supply clinical kits/sample containers?* If yes, are there dedicated areas for the preparation and/or receipt and storage of clinical trial kits?
* Are records kept of component batch numbers
* Are QC checks performed on kits before they are shipped e.g. check expiry dates, volume of additives, label generation completeness of kit)
* Is there a recall procedure if kits are found to be defective? Does this include both the identification of defects and communication with users?
 |  |  |  |  |
| **Method Validation** |  |  |  |  |
| Are assays used in the analysis of research samples validated?If assays are not validated, are external quality processes used to validate results (e.g. commercial standards, EQA) |  |  |  |  |
| **Repeat analysis** |  |  |  |  |
| Is there a SOP that covers repeat analysis in the event of assay failure/atypical results? Are acceptance criteria defined and in accordance with accepted standard/validated ranges?Does this SOP include procedures for reporting the original and repeat result? |  |  | Please provide details of how acceptance criteria are determined (e.g. defined by kit, commercial standards used to produce standard curve). |  |

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| **Recording and reporting of results** | **Yes** | **No** | **Comments** | **Office use** |
| Do your existing procedure(s) cover the process for the recording and reporting of results of research samples?Is there an audit trail of assay conduct including analyser access (should be user specific), instrument settings, reagent logs etc. |  |  | Are results reported in the same way and detail as non-research samples? If not, are specific processes for the research sample reporting defined?It should be possible to track a research sample from receipt, through analysis to reporting, including associated reagents, equipment records and individual staff records. |  |
| Does the procedure include processes for expedited reporting of urgent/out of range results and methods to maintain blinded information? |  |  |  |  |
| **Facilities** |  |  |  |  |
| Is access to the laboratory restricted?* If yes add to the comments who maintains the access rights to the laboratory and how often is it reviewed?
 |  |  |  |  |
| Does the Laboratory have a disaster recovery plan that covers all areas of the facility including sample storage, computer systems and equipment? |  |  |  |  |
| **Equipment**  |  |  |  |  |
| Are there SOPs detailing equipment use, maintenance and calibration? |  |  |  |  |
| Is there an equipment register? |  |  |  |  |
| Is there a written equipment qualification/validation program? |  |  | Process for ensuring that equipment is fit for the intended use in the individual laboratory setting. |  |

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| **Data handling Procedures and Computer Validation** | **Yes** | **No** | **Comments** | **Office use** |
| Is access to computers limited by an individual username and password system? Please record as comment if shared log-ins or generic user profiles are used?  |  |  |  |  |
| Are analyser software and the laboratory IT system subject to appropriate local validation in accordance with manufacturers’ recommendations? |  |  |  |  |
| What processes exist for revalidation following upgrades or maintenance activities? |  |  |  |  |
| Is the data output in an editable format?* If yes add to the comments section the process used to ensure data integrity.
 |  |  |  |  |
| Are databases backed up routinely to prevent loss? |  |  | Please record the frequency of back up and whether this is on or off site  |  |
| Is there an SOP to document data capture, data storage and data transfer? |  |  |  |  |
| **Quality Assurance** |  |  |  |  |
| Does your laboratory have an individual responsible for Quality Management? Do these responsibilities include * Quality Control
* Quality Assurance
 |  |  |  |  |
| Does your laboratory have an Internal Audit Plan? |  |  |  |  |
| Have you been inspected by a regulatory authority? (please give details in comments section (depending on confidentiality) such as inspection dates, inspecting body and summary of inspection findings. |  |  |  |  |
| Do you have a HTA license and/or other accreditations? (please give details in comments section). |  |  | Please list any other licenses or compliance programs that the laboratory holds. |  |

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| **Blinding/Unblinding** | **Yes** | **No** | **Comments** | **Office use** |
| If laboratories are supplied with the codes necessary to unblind trial samples, will this information be stored securely and accessed only by authorised laboratory personnel?Is there a procedure detailing action to be taken, by whom, to unblind samples if required? |  |  |  |  |
| **Retention of data** |  |  |  |  |
| Is there clear definition for each study of which records will be provided to the sponsor and which will be retained by the laboratory?Is there a dedicated facility/area for the archiving of records?Are non-trial specific data e.g. Equipment validation, maintenance records staff training records, SOP’s etc. centrally archived?How long are these records retained? |  |  |  |  |
| How long are records retained for? |  |  |  |  |
| Is there a SOP that details * retention time of records
* procedures for removal of material from the archive
* return of material to the archive
* electronic archiving (including applicable correspondence)
* access to archived records
* maintenance / retention of previous software versions
 |  |  |  |  |

**Please attach the following**

Organisational Chart

Current SOP and Policy Document List

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| **Completed by:** |
| **Name:**  | **Position:**  |
| **Signature:** | **Date:** |

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|  **CTU Use Only**  |
| **Comments:** CTUs should review the completed questionnaire with staff who are familiar with the requirements of laboratories processing research samples, and with the EMA and MHRA guidance. |
| **Actions Required:** Where laboratories do not meet the requirements in the questionnaire, the CTU should assess the impact on the overall objectives of research conducted. This may be in a generic manger covering general research processes. If specific concerns are identified these may form the target of repeat questionnaire (per study) or additional oversight. |
| **Checked by:** |
| **Name:**  | **Position:**  |
| **Signature:** | **Date:** |