Quality Control Document:

External Laboratory Self-Assessment Questionnaire

# Purpose

This document contains a questionnaire which can be used to assess whether external laboratories which will be used to perform storage, processing, analysis or evaluation of human biomaterial for clinical trials comply with the regulatory requirements and Good Clinical Practice (GCP) in the Laboratory Standard.

This document is designed to be used for Clinical Trials of Investigational Medicinal Products, but can be used as an example for other types of clinical research.

# Instructions

1. Remove this first instruction page.
2. Update the identifier in the header e.g., laboratory name/research group/facility or trial/study ID.
3. Update the footer, retaining the reference information to this quality control document (QCD).
4. Update page 1 of the questionnaire to include the email address to which the laboratory should return the questionnaire and the date it is required to be returned by.
5. Send the questionnaire to the laboratory.
6. Once the completed questionnaire has be returned by the laboratory, send a copy via email to the Clinical Research Compliance Team (CRCT) ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)).
7. If the CI (or delegate) or the CRCT have any queries relating to the information in the questionnaire, clarify these with the laboratory and ensure the questionnaire is updated as appropriate until resolution.
8. When both the CRCT and the CI (or delegate) are satisfied that the answers in the questionnaire indicate that the laboratory has sufficient process in place to work to GCP in the laboratory standard file the finalised questionnaire in the Trial Master File throughout the trial.
9. Archive the questionnaire with the other trial documents when the trial closes; see the *Archiving SOP (UoB-ARC-SOP-001)*.

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-SOP-001 Laboratory Set Up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues
* UoB-CRL-SOP-006 External Laboratory Set-up and Oversight

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (<mailto:crct@contacts.bham.ac.uk>) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

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 sections.

Please note, the red instructional text is provided for guidance. Please remove the rest instructional text once the questionnaire is complete.

# To be completed by the CI/Clinical Trials Unit (CTU) representative

|  |  |
| --- | --- |
| Contact information | |
| Contact name | Please insert contact name to whom the completed questionnaire should be returned (e.g. the CI or a CTU representative) |
| Contact email address |  |
| Date to return | Please insert the date by which the questionnaire needs to be returned by |

# To be completed by vendor laboratory

Please complete this questionnaire and return it along with a copy of your organizational chart and current list of Standard Operating Procedures (SOPs) and Policies to the individual(s) listed in the previous section.

Please complete all sections. If a section is not applicable to your laboratory, please add clarification in the relevant comment section.

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| Laboratory Details | |
| Laboratory Name |  |
| Laboratory Address |  |
| Date questionnaire completed |  |
| Summary of range of clinical and research services provided by the laboratory |  |
| Details of current accreditation scheme, if applicable | Provide information of the status of the accreditation (e.g. active, expired), the applicable standard (e.g. the applicable ISO standard) and the date of the last inspection. |
| Details of audits/inspections in last 5 years, if applicable | Provide details on the dates of the audits/inspections, who conducted the audits/inspections and the applicable standard. |

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| Key Contacts | |
| Laboratory Manager (or equivalent) | Please provide name and contact details |
| Laboratory GCP lead | This will be someone familiar with the specific requirements for processing research samples and an understanding of the general principles of GCP. Please provide name and contact details. |
| Quality Assurance Manager (or equivalent) | Please provide name and contact details |
| Archivist (or equivalent) | This will be the individual responsible for ensuring laboratory records (results, Standard Operating Procedures, contracts etc.) are retained in accordance with laboratory and organizational policies. Please provide name and contact details. |

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| Quality Management System (QMS) | **Yes** | **No** | **Comments** | **UoB use** |
| Does your laboratory have a Quality Management System covering each of the following: |  |  | These processes may be described in Standard Operating Procedures (SOPs) or Policies and may be provided as standard practice for all laboratory activities or may be research specific.  Please provide list any relevant SOPs separate to this questionnaire. |  |
| * 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 |  |  |  |  |
| Are new or modified procedures required to process research samples, in accordance with Good Clinical Practice (GCP) if the processing will differ from existing procedures? |  |  |  |  |
| **Staff Training** | | | | |
| Do all staff maintain a current training record and a job description describing the individual’s role and responsibilities? |  |  |  |  |
| Where the procedure for activities performed on research samples differs from usual practice, does the training record include evidence of training for such procedures? |  |  |  |  |
| 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 (Note: Proportionate GCP training is required for staff processing research samples (see UKCRC guidance) |  |  |  |  |
| * 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) |  |  |  |  |
| **Patient Safety** | | | | |
| Do laboratory reports contain normal range values and identify results outside of normal ranges? |  |  |  |  |
| Is there a process for expedited reporting of urgent and/or atypical results? |  |  | Please list the document/procedure that contains this information or describe the process. |  |

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| **Contracts and Agreements** | | | | | | | | |
| Are parties/contractors/vendors/third parties external to your laboratory used for the processing of research samples (including parties within your own institution? If ‘Yes’ please detail who they are and for what activities they are used in the comments section. |  | |  | | |  |  | |
| Are contracts (with third parties)/agreements (with parties within you own institution) in place for the processing of research samples (between the laboratory and third parties if affecting research samples)? |  | |  | | |  |  | |
| Is there a procedure that outlines the selection and use of external contractors/vendors/third parties that are used for processing of research samples and their approval for use? |  | |  | | | Please list the document/procedure name or describe the process |  | |
| Does each contract/agreement state that samples will be processed in accordance with the study protocol, GCP and the applicable regulations? |  | |  | | |  |  | |
| **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? |  | |  | | |  |  | |
| Is there a procedure for recording and reporting deviations from standard procedures? |  | |  | | | Please list the document/procedure name or describe the process |  | |
| 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 the document/procedure name or describe the process |  | |
| Is there a process for communication with the sponsor/study site to destroy samples if a patient withdraws consent? |  | |  | | | Please list the document/procedure name or describe the process |  | |
| **Sample Shipment, Receipt and Storage** | | | | | | | | |
| Does the sample receipt SOP include procedures for: |  | |  | | | If individual requirements are detailed in other documents rather than in a sample receipt SOP please provide details in the comments section. |  | |
| * 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 |  | |  | | |  |  | |
| **Preparation and distribution of clinical trial kits and sample containers** | | | | | | | | |
| Does the laboratory supply clinical kits/sample containers? If ‘No’ please write N/A in the comments section for the next 4 rows. |  | |  | | |  |  | |
| 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? If ‘Yes’ please detail in the comments section whether this includes both the identification of defects and communication with users. |  | |  | | |  |  | |
| **Method Validation** | | | | | | | | |
| Are assays used in the analysis of research samples validated? If ’No’ please describe what external quality processes are used to validate results (e.g. commercial standards, EQA) in the comments section. |  | |  | | |  |  | |
| **Repeat analysis** | | | | | | | | |
| Is there a SOP that covers repeat analysis in the event of assay failure/atypical results? |  | |  | | |  |  | |
| Do the laboratory’s reporting procedures include the needs for reporting the original and repeat result? |  | |  | | |  |  | |
| Are acceptance criteria defined and in accordance with accepted standard/validated ranges (e.g. defined by kit, commercial standards used to produce standard curve)? If ‘No’ please provide details about how acceptance criteria are determined in the comments section. |  | |  | | |  |  | |
| **Recording and reporting of results** | | | | | | | | |
| Do your existing procedure(s) cover the process for the recording and reporting of results of research samples? |  | |  | | |  |  | |
| Are results reported in the same way and detail as non-research samples? If ‘No’, please detail the specific processes for research sample reporting and how this is defined in the comments section. |  | |  | | |  |  | |
| Does the procedure for recording and reporting of results of research samples include the following: |  | |  | | |  |  | |
| * Processes for expedited reporting of urgent/out of range results |  | |  | | |  |  | |
| * Methods to maintain blinded information |  | |  | | |  |  | |
| Is it possible to track a research sample from receipt, through analysis to reporting, including associated reagents, equipment records (including analyser access and instrument settings) and individual staff records? |  | |  | | |  |  | |
| **Facilities** | | | | | | | | |
| Is access to the laboratory restricted? If ‘Yes’ please add details of who maintains the access rights to the laboratory and how often is it reviewed to the comments section. |  | |  | | |  |  | |
| 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 for ensuring that equipment is fit for the intended use in the individual laboratory setting? |  | |  | | | . |  | |
| **Data handling Procedures and Computer Validation** | | | | | | | | |
| Is access to computers limited by an individual username and password system? If ‘No’ please provide further details in the comments section, e.g. 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? |  | |  | | |  |  | |
| Do processes exist for revalidation following upgrades or maintenance activities? |  | |  | | | Please list the document/procedure name or describe the process |  | |
| Is the data output in an editable format? If ‘Yes’ please detail the process used to ensure data integrity in the comments section. |  | |  | | |  |  | |
| Are databases backed up routinely to prevent loss? If ‘Yes’, 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? |  | |  | | | Please list the document/procedure name or describe the process |  | |
| **Quality Assurance** | | | | | | | | |
| Does your laboratory have an individual responsible for Quality Management (including Quality Control and Quality Assurance)? |  | |  | | |  |  | |
| Does your laboratory have an Internal Audit Plan? |  | |  | | |  |  | |
| Has your laboratory been inspected by a regulatory authority? If ‘Yes’, please provide details in comments section (depending on confidentiality) such as inspection dates, inspecting body and summary of inspection findings. |  | |  | | |  |  | |
| Does your laboratory have a HTA license? |  | |  | | |  |  | |
| Does your laboratory have any other licenses or accreditations? If ‘Yes’ please provide details in the comments section. |  | |  | | |  |  | |
| **Blinding/Unblinding** | | | | | | | | |
| If the laboratory is supplied with the codes necessary to unblind trial samples, is a procedure in place to ensure this information will be stored securely and accessed only by authorised laboratory personnel? | |  | |  | Please list the document/procedure name or describe the process | | |  |
| Is there a procedure detailing action to be taken, by whom, to unblind samples if required? | |  | |  | Please list the document/procedure name or describe the process | | |  |
| **Archiving** | | | | | | | | |
| 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-trial specific data e.g. assay results centrally archived? If ‘Yes’, please detail in the comments section how long these records are retained for. | |  | |  |  | | |  |
| Are non-trial specific data e.g. Equipment validation, maintenance records staff training records, SOP’s etc. centrally archived? If ‘Yes’, please detail in the comments section how long these records are retained for. | |  | |  |  | | |  |
| Does the SOP that covers archiving detail the following: | |  | |  |  | | |  |
| * 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 | |  | |  |  | | |  |

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| **To be completed by a laboratory representative** | |
| **Name:** | **Position:** |
| **Signature:** | **Date:** |

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| **To be completed by the CI/CTU representative**  The completed questionnaire should be reviewed by staff who are familiar with the requirements of laboratories processing research samples, and with the EMA and MHRA guidance. | |
| **Comments:** | |
| **Actions Required:** Where laboratories do not meet the requirements in the questionnaire, the impact on the overall objectives of research conducted should be assessed. This may be in a generic manner covering general research processes. If specific concerns are identified these be addressed via discussion and updates to the questionnaire or additional oversight may be required e.g. a compliance review or audit. | |
| **Reviewed by:** | |
| **Name:** | **Position:** |
| **Signature:** | **Date:** |

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| **To be completed by UoB Clinical Research Compliance Team (CRCT) representative** |
| **Date received by CRCT:** |
| **Reviewed by:** |
| **Comments and recommendations:** |