Imperial College London

Research Governance
and Integrity Team

NHS
Imperial College Healthcare
NHS Trust

Vendor Laboratory Questionnaire for CTIMPs

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 processing and analysing research samples. Please complete all relevant sections.

Please return to the QA R Team at your earliest convenience

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.

Organisation and Personnel	Yes	No	Comments	JRO 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)	

Patient Safety	Yes	No		Office use
Have you filed a risk assessment of this trial from a GCP perspective. I.e. in terms of impact of the results on patient safety and data validation of the trial Is this trial classified as high risk as per that assessment?				
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	

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 ***DELETE THIS SECTION IF NOT APPLICABLE***				
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?				
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? If unscheduled analysis or evaluation is required for urgent clinical reasons, for example, as a result of adverse events and this is not stipulated in clinical trial protocol, the work instruction or the contract, documented policy detailing how they this type of situation would be addressed?			Please provide details of how acceptance criteria are determined (e.g. defined by kit, commercial standards used to produce standard curve).	

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, reagents 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 processed 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.	
Do you keep in the trial's lab file a log of fridge/freezer alarm testing?				

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?				
If the data is recorded, modified, corrected and stored electronically, is an audit trail also being maintained electronically?				
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.	
Do you have a trial of Log of protocol amendments and revision history				
Do you have serious breach SOP, spelling out what a reportable 'serious breach' is as per the UK legislation underpinning clinical trials.				

Do you hold a log of incidents reported to the sponsor?				
Do you hold a trial's deviation/violation log?				
Do you file in the trial lab's file a delegation log to trace "who is doing what on the trial"?				

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?				
How long are records, including all source data related to analyses, retained for?				
Are non-trial specific data e.g. Equipment/method validation, maintenance records staff training records, SOP's etc. centrally archived? How long are these records retained?				
Is there a dedicated facility/area for the archiving of records?				
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:
Index of the lab file which will be used to collect all the essentials documents and allow to re-construct the analysis
Organisational Chart
Current SOP and Policy Document List

Completed by:

Name:	**Position:**
Signature:	**Date:**

RGIT Use Only	
Comments:	
Actions/Escalation Required: Where laboratories do not meet the requirements in the questionnaire, the RGIT should assess the impact on the overall objectives of research conducted. This may be in a generic manner 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:**