Self-Assessment Questionnaire to assess regulatory compliance in The Christie Pathology Partnership Laboratories to perform the storage and release of ATMPs (including ATIMPs) on behalf of The Pharmacy Department at The Christie NHS

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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 to assess regulatory compliance of storage and release of ATMPs at The Christie Pathology Partnership for delegated responsibilities by The Christie NHS Foundation Trust Pharmacy Department. Please complete all sections.

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.
HTA Designated Individuals	
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	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.	
Can new or modified procedures required to store and release AMTPs in accordance with Good Clinical Practice and license requirements?			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 for ATMPs?			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.			Proportionate GCP training is required for staff processing research samples (see UKCRC guidance)	

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 storage and release of ATMPs (between the laboratory and associated parties)? - If yes, are external contractors/vendors used for the storage and handling of ATMPs? 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 ATMPs will be managed 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 manage ATIMPs if not stipulated in the protocol or covered in existing SOPs? Are procedures for ATIMPs 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 ATMP receipt SOP include procedures for - Checking ATMP were maintained in appropriate correct transport conditions (if required) - Checking of sample labels - Checking the integrity of ATMP - Chain of custody (record of movement of ATMP from receipt, through analysis, to final storage) - Storage of ATMP 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?				
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.	

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.	

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

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

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:**