Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Clinical Trial Sample Analysis in University Laboratories**		
SOP Reference Number:	QUB-RGEI-022	Version Number:	FINAL v 1.0
Revision Date:	18 January 2022	Review Date:	18 January 2025

	Name and Position	**Signature**	**Date**
Author:	Research Governance, Ethics and Integrity Team		
		---	---
Reviewed and approved by:	Chair Research Governance, Ethics and Integrity Committee		
		---	---

This is a controlled document.
When using this document please ensure that the version is the most up to date by checking the Research Governance, Ethics and Integrity Website

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

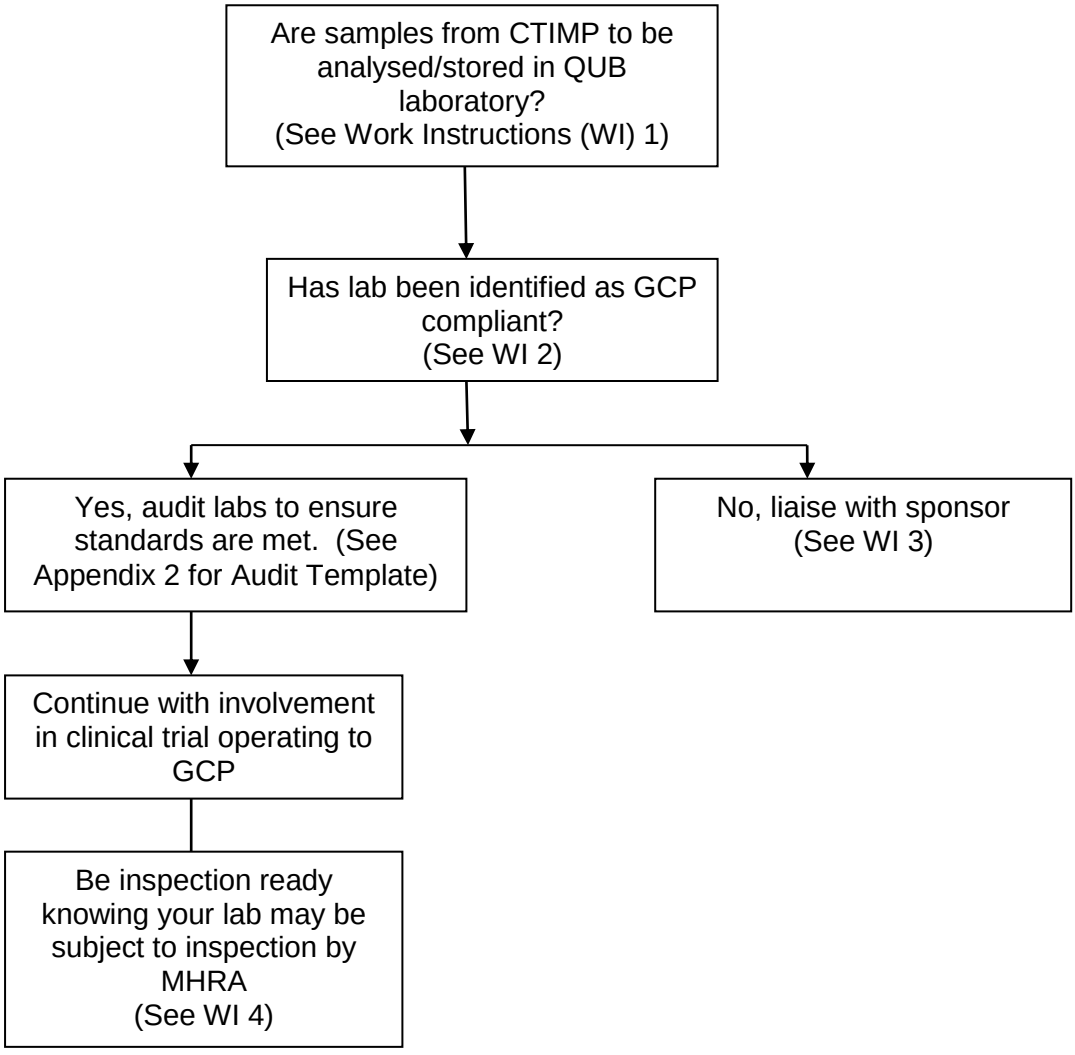
1. Purpose

The quality of data produced from scientific research must be to a high standard, reliable and provide accurate data for reporting. University laboratories undertaking sample analysis for clinical research, in particular, clinical trials must ensure adherence with ICH-GCP (Good Clinical Practice) standards and Good Laboratory Practice (GLP).

2. Scope

This procedure applies to any stage of analytical testing of human samples originating in a CTIMP. This includes the clinical assessment of participants, for example ECG and blood pressure readings.

3. Procedure



4. References

EMA Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (last accessed January 2022)
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/05/WC500127124.pdf

5. Appendices

Work Instruction 1 – Analysing/Storage of Samples from CTIMP
Work Instructions 2 – Is your lab GCP compliant?
Work Instructions 3 – Liaising with Sponsor
Work Instructions 4 – Inspections by MHRA

Appendix 1: Analytical Analysis of Human Samples from Clinical Trials of Investigational Medicinal Product (CTIMP)
Appendix 2: Audit Template

Work Instructions 1 – Analysing/Storage of samples from CTIMP

1. All laboratory analysis detailed within the protocol of a Clinical Trial requires analysis to GCP standards, this includes exploratory end-points.
2. All those involved in analytical laboratory work must be appropriately trained and qualified to perform the roles and responsibilities assigned to them, be this laboratory management, quality assurance, scientific analysis, reporting or archiving.
3. Complete Appendix 1 to ascertain whether the laboratory will be analysing samples from a CTIMP.

Work Instructions 2 - Is your lab GCP compliant?

1. Specific laboratories have been designated as GCP compliant in agreement with the Faculty PVC.
2. Laboratories must have in place the correct Quality Assurance plan underpinned by the necessary standard operating procedures.
3. Laboratories must have the necessary resources i.e. qualified and appropriately trained personnel, suitable facilities and equipment available to provide timely and proper analysis of human specimens.
4. As the Sponsor is the responsible party for the Clinical Trial your laboratory must have established and documented the lines of communication to the Sponsor.
5. You must ensure that the Sponsor has agreed that your laboratory is able to perform its functions to the appropriate standard(s).
6. There must be in place an appropriate contracting document/collaboration agreement to govern the work to be undertaken on behalf of the Sponsor?
7. You must ensure that your laboratory has the necessary maintenance contracts in place for equipment to be used in samples analysis.

Work Instructions 3 – Liaising with Sponsor

1. In the event that your laboratory has not operated to GCP, or had previous sponsor/vendor review you must advise the Sponsor that your laboratory may not be GCP compliant.
2. The planned schedule of work may be conducted in another lab, capacity permitting, to deliver on contract/collaboration agreement.

Work Instructions 4 – Inspections by MHRA

1. The laboratory within which the work is being undertaken is responsible for any inspection by the MHRA.
2. Prior to any inspection the MHRA will expect to see procedures in place – this should be captured in the laboratory's Quality Manual.
3. All documentation required to demonstrate compliance with GCP must be maintained and presented to Inspectors upon request.
4. All staff working on the clinical trial sample analysis must make themselves available for interview when required by MHRA.
5. Address any CAPA (Corrective Action and Preventative Plan) plans created following inspection in a timely manner, keeping the Sponsor apprised as required.

QUEEN'S UNIVERSITY BELFAST

Analytical Analysis of Human Samples from Clinical Trials of Investigational Medicinal Product (CTIMP)

Attention: To be completed and signed by the Chief Investigator/ Lead QUB Researcher

Scope

The analysis of human samples from CTIMPs is regulated by the MHRA. This applies to all processes in the analytical testing of human samples, for example, storage of samples. Please read the following statements and indicate what is relevant to your study.

CTIMPs within the University are audited internally and externally by the MHRA. Failure to comply with regulatory expectations in laboratories may lead to action by the MHRA. It is the lab owner's responsibility to ensure compliance with GCP.

Type of testing involved:

Yes | No	Primary end-point and safety monitoring analysis that requires compliance with cGCP for laboratories
Yes | No	Primary end-point and safety monitoring using 'innovative' biomarkers that requires compliance with cGCP for laboratories
Yes | No	Analysis providing additional information from clinical trial samples that requires compliance with cGCP for laboratories
Yes | No	Testing that does not provide any information on the study IMP but is part of the study protocol requires compliance with cGCP for laboratories.
Yes | No	Other (please provide details):

Guidance sought to date:

Yes | No I have received guidance from the MHRA

Yes | No I have contracted an independent Regulatory / GxP consultant

Yes | No I have contacted the lead Sponsor and asked their advice

Please provide further details if you have already sought guidance:

Please note: This form will remain on file and could be held in archive indefinitely. As the Chief Investigator it is legally your responsibility to ensure that CTIMPs are conducted in accordance with GCP. The MHRA have determined that laboratory analysis of human samples from CTIMPs is an important aspect of GCP.

Chief Investigators/ Lead QUB Researcher's Name (please print):_____

Position held at the University: _____

Date:_____

Audit Checklist

The following categories should be rated for compliance with the legislation.

1 = not compliant, 2 = some aspects of compliance, 3 = compliance in key areas, 4 = compliant with GCP and 5 = exceeds compliance

Requirement	Compliance Level	Notes
Organisation		
Organogram		
Job descriptions		
Capacity planning		
Serious GCP breaches reporting procedure		
Resources		
Communication with the Sponsor		
Personnel		
Training record		
Appropriate GCP training		
Contracts and Agreements		
Contracting policy		
Contracts in place for all active studies		
Practice reflects contracts		
Service contracts in place eg equipment maintenance		
Study Conduct		
Clinical protocol available and controlled		
Work instructions		
Deviation procedures		
Patient safety procedures		

Additional work controls		
Sub-contracting procedure		
Informed Consent, including withdrawal procedure		
Sample receipt and chain of custody		
Transit procedures		
Control of transit conditions		
Control of storage conditions		
Receipt checks and process		
Cataloguing of samples		
Confidentiality		
Sponsor Incident reports		
Back-up cold storage		
Analytical processes		
Method Validation		
Repeat Analysis		
Data recording		
Reporting		
Facilities and Equipment		
Suitable design		
Degree of separation		
Cross-contamination		
Waste disposal procedures		
Equipment maintenance		
Computerised Systems		
Validation package and user testing		
Revalidation		

Control of hardware		
Disaster recovery plan for IT systems		
Source data		
Access control		
Quality Assurance (QA)		
Suitable processes in place		
Frequency and duration of QA checks is appropriate		
Documented checks for essential activities		
Appropriate QA staff		
QA staff training		
Study Audits		
QMS audit		
Audit of computer systems		
'Key' task audit		
Procedural Audit		
CAPA system		
QA reporting process		
Quality Control (QC)		
Checks on specific processes		
QMS		
Contracts and agreements		
Analytical procedures		
Patient issues		
Supply-chain		
Validation, qualification, calibration and maintenance		

Retention of data		
QA and QC functions		
Archival of data and QMS		
Blinding/unblinding		
Clinical kits		

Audit outcome:

After audit and review of the risks using the Risk: Compliance Tool the following determination has been made: (delete as appropriate):

- 'Approved' for the analysis of human samples obtained from a CTIMP.
- Conditionally 'approved' for the analysis of human samples obtained from a CTIMP.
- Deemed not appropriate or requiring substantial measures to increase GCP compliance.

{Further information to be provided}

Auditor 1: **Auditor 2:**

Date: **Date:**