Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Preparing and Hosting External Inspections

SOP002

Author	**Date of Approval**
Karen Jennings-Wilding	15th July 2026
Approved on behalf of ratifying committee	**Date of Approval**
Professor Tony Marson (Vice-Chair of Clinical Research Regulatory Oversight Committee)	14th July 2026

Document Control

Issue Date	15/07/2026
Effective Date	15th July 2026
Review Date	15th July 2028
This document is controlled using Ideagen Quality Management and is made available on the University of Liverpool Clinical Research Governance website. The web version of this document is the only version that is maintained. This document is uncontrolled when printed and as such, may not necessarily contain the latest updates and amendments.	

Document History can be viewed on Ideagen Quality Management

Review Process Prior to Sign Off

Name of Committee	**Date**
Joint Research Office Sponsorship Committee (Version 1)	12th May 2015
SPARK Sponsorship Committee (Version 4)	14th April 2022
Clinical Research Regulatory Oversight Committee (v5)	Email review 18th July 2024

Name of Committee	Date
Chair of Clinical Research Regulatory Oversight Committee (v6)	14th July 2026

Contents

1. Introduction 3
2. Scope of Procedure 3
3. Who 4
4. When 4
5. Notification of a regulatory inspection 4
6. The Preparation Required Ahead of an Inspection or Audit 5
7. General Good Housekeeping Prior to Visit 6
8. The Inspection 7
9. Remote and Hybrid Inspections 7
10. Interview Principles 8
11. Close out Meeting 8
12. Post Inspection Follow Up 9
13. Roles and Responsibilities 9
14. Abbreviations 9
15. Associated Documents and References 10
16. Training and Resources 10
17. Monitoring and Audit 10

1. Introduction

The Medicines and Healthcare Products Regulatory Agency (MHRA) inspect Clinical Trials of Investigational Medicinal Products (CTIMPs) conducted by both commercial and non-commercial organisations. Good Clinical Practice (GCP) Inspectors assess whether organisation sponsoring and/or conducting CTIMPs have systems in place to meet the requirements of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. A regulatory inspection is performed to assess compliance with guidelines and regulations and to assure the Competent Authority of the validity of the study data, and to ensure the rights and protection of subjects are not jeopardised. This is done through verifying adherence to the protocol and other study related documents such as Standard Operating Procedures (SOPs) in addition to adherence to GCP and the regulatory requirements for clinical trials.

The University of Liverpool (University) expects the MHRA to conduct routine GCP regulatory inspections of the University as a Sponsoring organisation or of the Liverpool Clinical Trials Centre (LCTC) as a Clinical Trials Unit (CTU). The MHRA may also inspect GCP Laboratory facilities, and other departments undertaking CTIMP related work. The University may also be subject to other regulatory inspections from bodies such as International Competent Authorities and the Human Tissue Authority.

2. Scope of Procedure

The purpose of this SOP is to describe the processes to be followed upon notification of inspection from the MHRA or other regulatory authority. It is noted that this SOP relates to the University being subject to inspection as a Sponsoring Organisation only and departmental SOPs may apply at other times.

The University is required to have procedures in place for conducting trials in accordance with GCP and the Clinical Trial Regulations. The list below outlines some (but not all) of the areas, which would be subject to regulatory inspection;

- Staff training and credentials;
- Departmental structures and roles (e.g. organisational charts, contracts and agreements, delegation log);
- Knowledge of the trial(s) and quality systems in all support departments;
- Systems and facilities used for the purpose of clinical trials (e.g. computer systems, equipment, SOPs);
- Evidence of conduct of the trial(s) in accordance with the protocol, including informed consent, reporting of adverse events/reactions as per protocol (and Trust Incident reporting policy); un-blinding procedures; and IMP storage and disposal;
- Adequate trial documentation and archiving of trial documentation (including any electronic records/files).

3. Who

This SOP relates to all University staff members involved in the management and conduct of CTIMPs. This includes Chief Investigators, Trial Coordinators, Research Fellows, support staff and Professional Services staff.

4. When

This SOP should be referred to when notification of an MHRA or other regulatory inspection is received.

5. Notification of a regulatory inspection

When notified of an MHRA inspection of the University of a Sponsoring organisation the Head of Clinical Operations, Technology, Infrastructure and Environment Directorate will nominate the Senior Clinical Research Governance Manager to initiate and coordinate preparations. This will be done in collaboration with the Clinical Research Governance Team, and other individuals or departments as required.

The Senior Clinical Research Governance Manager will notify the appropriate departments that will be required to assist with the inspection preparations, and which may be subject to scrutiny during the inspection. Notification of regulatory inspection will be provided to the Executive Pro Vice Chancellor, Faculty of Health and Life Sciences, the Associate Pro-Vice Chancellor for Clinical Research and the University Clinical Research Regulatory Oversight Committee (CRROC).

Other specialist departments may also include;

- Liverpool Clinical Trials Centre (LCTC)
- Records Management
- IT Services Department
- Laboratories, particularly the Good Clinical Practice (GCP) Laboratories
- Liverpool Magnetic Resonance Imaging Centre (LiMRIC)

The Senior Clinical Research Governance Manager will also liaise with the inspection team to draw up a timetable for the visit and attempt to ensure all relevant trial staff are available for interview during the inspection. If it is not feasible for these staff to be available arrangements should be made for their Job descriptions, CVs and Training records to be made available.

An e-mail group will be set up to ensure key staff are kept aware of developments and have the opportunity to contribute their own ideas and thoughts. This group may include the following people where appropriate:

- Head of Clinical Operations, Technology, Infrastructure and Environment Directorate

- Chair of Liverpool Health Partners (LHP) Joint Research Office (JRO) Sponsorship Committee
- Director of LCTC
- Head of Trial Management, LCTC
- Head of Quality Assurance & Regulatory Affairs, LCTC
- Directors of GCP Laboratories

Where a regulatory body selects a University department to be subject to an inspection (i.e. LCTC or a GCP Laboratory) it is expected that the department Quality Assurance Manager will take the lead on notifying appropriate personnel and departments and ensure the preparation for the inspection is undertaken. It is expected that the Senior Clinical Research Governance Manager will be invited to any inspection groups set up and will be kept up to date with all developments. Where a department does not have Quality Assurance Manager, or an identified lead, the Senior Clinical Research Governance Manager can provide support upon request.

6. The Preparation Required Ahead of an Inspection or Audit

In the case of a statutory MHRA GCP inspection a letter of notification will be issued 2-3 months in advance. The organisation is expected to produce, within 30 calendar days, a 'Pre-inspection Dossier' that will contain a request for information to help the Inspector(s). The current dossier request is available in electronic form from the MHRA. The Dossier will be completed by the appropriate person(s) from the departments that are to be inspected, with oversight provided by CRROC. The Clinical Research Governance Manager will usually be responsible for completing the Dossier on behalf of the Sponsor.

For other regulatory inspections the Senior Clinical Research Governance Manager will investigate and collate the documentation required for pre-submission to the inspectors.

It is noted that inspection by Regulatory authorities can be "Triggered" as a result an unforeseen occurrence or event. In such circumstances there will be no fixed notice period.

Once the Pre-inspection Dossier has been submitted to the MHRA the lead inspector will assess the information and confirm the dates of visit, the scope of the inspection and the CTIMPs that will be subject to inspection. The lead inspector will also confirm if part or all of the inspection is to be held remotely.

The lead inspector may request a number of documents to review ahead of the inspection; these are usually shared via Microsoft Teams directly with the MHRA. It is recommended that a limited number of individuals are added to the Teams channel, to ensure that only appropriate documents are provided, and documents are uploaded in a consistent manner.

Once confirmation of scope and trials has been received members of each relevant department will be asked to quality check relevant documentation and procedures and ensure all files and documents are easily accessible. Some examples are listed in the table below although it is noted that all

individuals involved in the management and conduct of CTIMPs should undertake ongoing responsibility and due diligence for ensuring documentation is completed and held correctly.

Designation	Documentation / Evidence / Action
Trial Coordinator/Manager	Check for completeness of Trial Master File and order but remember to look at content as well as 'presence' of documents Review all inclusion exclusion criteria for all participants who have entered the study. Check that participant recruitment records are current and complete. Check that completed consent documents have been signed and personally dated by both the participant and person obtaining consent. Check if any substantial amendments have been implemented and recorded.
Laboratory Manager	Systems for tracing samples Documentation relating to the cold chain (an uninterrupted series of storage and distribution activities which maintain a given temperature range)
Senior Clinical Research Governance Manager and delegated persons within the Clinical Research Governance Team (CRGT)	Ensure central SOPs are issued and within review dates Ensure Sponsor documentation is up to date

7. General Good Housekeeping Prior to Visit

If the UoL are hosting the inspection the Senior Clinical Research Governance Manager will be responsible for arranging the inspection visit and hosting the inspectors upon arrival. They will therefore undertake the following;

- Provide the inspection team with clear and concise directions to travel to the inspection venue by a variety of modes of transport;
- Book 2 meeting rooms; one for introductions, debrief and interviews and another for the storage of documentation. The second room may be located in the CTU managing the trial where appropriate. The rooms should be free of clutter and confidential material and flip charts and white boards are blank;
- Arrange appropriate access to electronic systems;

- Remind all staff to ensure that their computer is locked for use at all times when they are away from their desk;
- Arrange for security to issue the requisite number of visitor badges for the inspection team;
- Ensure adequate stationery is available;
- Arrange lunch and establish any specific dietary requirement for the inspection team.

8. The Inspection

The Senior Clinical Research Governance Manager will meet and greet the inspection team, confirm their identity and escort them to the designated meeting room. The drill in event of fire will be explained, and all designated exits shall be identified.

A pre-inspection meeting will be held to confirm the schedule of the inspection. This will be dependent on the specific requirements of the external inspection team requirements but will normally involve:

1. An opening presentation if appropriate;
2. A facilities tour;
3. Examination of documentation;
4. Staff Interview;
5. End of day review meeting.

A member of the Technology, Infrastructure and Environment Directorate CRGT will accompany the inspection / audit team at all times, except when they are undertaking document reviews.

A designated “runner” will retrieve and photocopy documents for the investigation / audit team. The runner will maintain a log of documents requested, produced and returned. This will be signed by the inspector each time a document has been examined and is no longer required. This process may differ if documentation is provided electronically. This should be established and agreed with the Inspectors.

9. Remote and Hybrid Inspections

The MHRA may conduct part or all of the inspection remotely, which will need to be planned for in advance. Most of the preparations will remain the same, however consideration should be given to;

- Facilities for holding meetings and interviews, ensuring that all attendees and interviewees can use the desired software
- Provision for sharing documentation, particularly paper-based documentation
- Remote access to electronic systems and records, ensuring that access is “Read Only”
- Provision of training for any electronic systems

- Designated contact person for the inspection team
- Locations of interviews, ensuring that the interviewees are provided a quiet, confidential space if required

10. Interview Principles

- When the inspection team request an interview with an employee of the University, the interviewee should be accompanied by a member of the Technology, Infrastructure and Environment Directorate CRGT.
- The interviewee will assume a friendly, co-operative, confident and professional attitude, and respond to questions in a **concise, factual and accurate** manner.
- If the interviewee is asked a question that they deem is outside of their scope of practice or outside of the inspector's authority, they should consult with their line manager.
- If the interviewee does not understand the question and/or context, the inspector should be asked for clarification.
- If the interviewee realises they have provided incorrect information they should take immediate action to rectify this by providing the correct information and have this action noted by the investigator.
- The interviewee should not solicit opinions from the Inspection Team or attempt to answer hypothetical questions.

11. Close out Meeting

A close out meeting will normally be held at the end of the final day of the inspection. This will be attended by the inspection team and the following staff where appropriate;

- Head of Clinical Operations, Technology, Infrastructure and Environment Directorate
- Senior Clinical Research Governance Manager
- Chair of LHP JRO Sponsorship Committee
- Director of LCTC
- Head of Trial Management, LCTC
- Head of Quality Assurance & Regulatory Affairs, LCTC
- Directors of GCP Laboratories

Other members may be invited to attend if required.

The purpose of this meeting is to provide a general review of the inspection visit and to allow the inspection team to communicate inspection observations and to agree a timescale for the production

of a formal report and University response. It is not appropriate to disagree with the findings raised at this time.

12. Post Inspection Follow Up

Following the close of the inspection a formal report will be issued by the Inspectors within the agreed time scales. Upon receipt of the formal report the Senior Clinical Research Governance Manager will produce a formal response in liaison with the appropriate departments. It is recommended that the MHRA guidance for formulating responses to GCP inspection findings is utilised for drafting the response. The Senior Clinical Research Governance Manager will also outline the Corrective Actions and Preventative Actions (CAPAs) to be undertaken and identify the departments or staff responsible for implementation of CAPAs to agreed timescales. The University Clinical Research Regulatory Oversight Committee (CRROC) will undertake oversight of the completion of the required CAPAs and ensure these are completed within agreed timescales. CRROC will not be responsible for oversight of CAPA assigned to external parties. The Senior Clinical Research Governance Manager will be responsible for coordinating and submitting periodic responses to the MHRA or regulatory authority where required, until the MHRA or regulatory authority are satisfied with the responses given and actions undertaken.

Artificial Intelligence (AI) may be used to assist in formulating the response to the MHRA; however, this must be utilised with care to ensure that the response is factually accurate and addresses the identified deficiencies. Organisations remain responsible for the accuracy of their responses to the MHRA and persons responsible for them are expected to verify factual claims. Materially false statements to inspectors are regulatory offences. These responsibilities do not change with the use of AI. More information can be found here - MHRA Blog - Use of AI for GXP inspection responses

13. Roles and Responsibilities

Roles and responsibilities are discussed throughout this SOP and is summarised here.

The Senior Clinical Research Governance Manager will be the lead person organising the inspection visit and all related actions and will be the main point of contact for discussions relating to the inspection.

All University staff members involved in the management and conduct of CTIMPs are responsible for ensuring timely responses to requests for information relating to inspections and providing support where required. This includes Chief Investigators, Trial Coordinators, Research Fellows, support staff and Professional Services staff.

14. Abbreviations

CAPA	Corrective Actions and Preventative Actions
CTIMPs	Clinical Trials of Investigational Medicinal Products
CRROC	Clinical Research Regulatory Oversight Committee

GCP	Good Clinical Practice
JRO	Joint Research Office
LHP	Liverpool Health Partners
MHRA	Medicines and Healthcare products Regulatory Agency
SOPs	Standard Operating Procedures
University	University of Liverpool

15. Associated Documents and References

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

MHRA guidance for formulating responses to GCP inspection findings

MHRA Blog - Use of AI for GXP inspection responses

16. Training and Resources

All staff members who may be involved in an inspection are required to read and understand this SOP.

17. Monitoring and Audit

During the period of an inspection (notification to final close) the Senior Clinical Research Governance Manager will ensure this SOP is adhered to.