Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Monitoring of University Sponsored trials

SOP011

Author	**Date of Approval**
Karen Jennings-Wilding	27th July 2026
Approved on behalf of ratifying committee	**Date of Approval**
Professor Tony Marson (Chair of Clinical Research Regulatory Oversight Committee)	24th July 2026

Document Control

Issue Date	27/07/2026
Effective Date	27th July 2026
Review Date	27th 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)	9th June 2015
Chair of Joint Research Office Sponsorship Committee (Version 2)	27th July 2017
Chair of SPARK Sponsorship Committee (Version 2.1)	11th July 2022

Name of Committee	Date
Vice-Chair of Clinical Research Regulatory Oversight Committee (Version 3)	5th August 2024
Chair of Clinical Research Regulatory Oversight Committee (Version 4)	24th July 2026

Contents

1. Introduction 3
2. Scope of Procedure 3
3. Who 3
4. When 3
5. How 3
6. Roles and Responsibilities 5
7. Abbreviations 5
8. Associated Documents and References 5
9. Training and Resources 5
10. Monitoring and Audit 5

1. Introduction

The International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines state "The aim of monitoring is to ensure the participants' rights, safety and well-being and the reliability of trial results as the trial progresses. Monitoring is one of the principal quality control activities" . This role is usually performed by a study specific monitor, or delegated other.

The purpose of monitoring is to verify that:

- The rights and well-being of the participants are protected
- The reported trial data are accurate, complete, and verifiable from source documents.
- The conduct of the trial is in compliance with the currently approved Protocol, participant and other documentation and any modifications that have been implemented on the study
- The conduct of the trial is in compliance with GCP and the applicable regulatory requirements such as the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

2. Scope of Procedure

The purpose of this Standard Operating Procedure (SOP) is to describe the monitoring procedures for Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices (CIMDs) sponsored by the University of Liverpool.

3. Who

This SOP is applicable to anyone involved in the conduct and management of University sponsored CTIMPs or CIMDs. This includes, but is not limited to, Trial Monitors Chief Investigators (CI) and Trial Coordinators.

4. When

This SOP should be referred to when a monitoring plan for a University Sponsored CTIMP or CIMD is being developed, and throughout the duration of the research

5. How

It is the responsibility of the Sponsor to undertake monitoring of CTIMPs and CIMDs to ensure appropriate oversight of the study and to be assured that it is conducted, recorded and reported in accordance with the protocol. Effective monitoring can also provide useful feedback to the Sponsor for continuous process improvement. This function is delegated to trial specific monitors for University Sponsored CTIMPs being managed by a Clinical Trials Unit (CTU), or appropriately trained person for sponsored CTIMPs not being managed by a CTU (see also SOP003[1]).

[1] Requirements for CTIMPs not being managed by a CTU

A monitoring plan must be established for University Sponsored CTIMPs or CIMDs. For trials managed by a CTU it is expected that the CTU template be used. For trials managed outside of a CTU TEM024[2] provides a skeleton plan for implementation.

Monitoring can be undertaken using different methods and the trial risk assessment (see also SOP010 [3]) will inform the most appropriate method for the trial. The usual methods undertaken are on site monitoring where the trial monitor undertakes periodic visits to recruitment sites or remote monitoring where sites provide information to the monitor for review. The risk assessment will form an integral part of drawing up the monitoring plan, and will be taken into account when deciding which method of monitoring is required. Factors such as the objective, purpose, design, complexity, blinding, number of trial participants, investigational product, current knowledge of the safety profile and endpoints of the trial should be considered. The level of resource available should also be taken into account, especially where on-site monitoring is considered. The Sponsor and central research team may need to assess if members of staff in the R&D office or in the site research team could be utilised to monitor sites, or if this function needs to be delegated to a specialist contractor. It is noted that monitoring should be performed by persons not involved in the clinical conduct of the trial at the site being monitored.

For most CTIMPs, regardless of the monitoring approach being taken, it is expected that most sites will undergo a site initiation visit to ensure the research team are appropriately trained on the protocol, specific procedures, data collection tools and any study specific equipment. This can be carried out either face-to-face or remotely via teleconference but this is usually defined as the first monitoring visit. The monitoring plan will then define the number of site visits required and at which time points these will take place. The first visit following recruitment commencing is usually after a set number of participants.

Remote monitoring can be particularly useful in large, multi-centred CTIMPs where on-site monitoring would have a large resource implication. Remote monitoring will rely heavily on extensive communication with sites, and the cooperation of the site to provide the required information in a timely manner. Although some documentation such as consent forms and laboratory reports can be reviewed remotely the participants full medical records will not be available for review, and so checklists and questionnaires must be used effectively to ensure information is obtained correctly.

All sites should undergo a formal close out procedure to ensure a complete and independent record of the study at that site is available, and archived as per the requirements in the protocol. This may be carried out by an on-site visit where documentation and archiving facilities are assessed or via remote methods where questionnaires and checklists are completed by the site.

The University, as Sponsor, will retain oversight of the monitoring plan by receiving copies of the risk assessment and monitoring plan before finalisation and by receiving annual reports from the CTU or team managing the research with an outline of the monitoring activities and compliance with the monitoring plan.

[2] Clinical Trials Monitoring Plan Template
[3] Risk Assessment of Clinical Trials

6. Roles and Responsibilities

Research Monitor

Developing the monitoring plan with appropriate colleagues

Arranging the monitoring visit

Escalating findings to Sponsor and study team as appropriate and undertaking follow up

Report monitoring progress to the Trial Steering Committee

University Clinical Research Governance Team

Receive annual reports of monitoring activity

Report any issues to the Liverpool Health Partners (LHP) Joint Research Office (JRO) Sponsorship Committee for Sponsor oversight

7. Abbreviations

CTIMP	Clinical Trial of Investigational Medicinal Product
CTU	Clinical Trials Unit
ICH/GCP	International Conference on Harmonisation of Good Clinical Practice
SOP	Standard Operating Procedure

8. Associated Documents and References

ICH Harmonised Guideline for Good Clinical Practice E6(R3)

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

TEM024 Clinical Trials Monitoring Plan Template

SOP010 Risk Assessment of Clinical Trials

SOP003 Requirements for CTIMPs not being managed by a CTU

9. Training and Resources

All members of staff undertaking monitoring activities must be appropriately trained to undertake the role.

10. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.