Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Organisational Oversight of CTIMPs

SOP029

Author	**Date of Approval**
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Approved on behalf of ratifying committee	**Date of Approval**
Professor Tony Marson (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
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Document History can be viewed on Ideagen Quality Management

Review Process Prior to Sign Off

Name of Committee	**Date**
Julia West (as delegated by CTOC) (v1)	24th January 2013
Prof Tom Walley in capacity as Chair of CTOC (v1)	5th February 2013

Name of Committee	Date
Joint Research Office Sponsorship Committee (v2)	12th May 2015
Chair of Joint Research Office Sponsorship Committee (v3)	24th April 2017
Joint Research Office Sponsorship Committee (v4)	10th May 2018
SPARK Sponsorship Committee (Version 6)	17th May 2022
Clinical Research Regulatory Oversight Committee (Version 7)	Email review 11th July 2024
Chair of Clinical Research Regulatory Oversight Committee (Version 8)	14th July 2026

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1. Introduction

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 set out the requirements for implementation of Good Clinical Practice (GCP) in the conduct of Clinical Trials of Investigational Medicinal Products (CTIMPs) within Europe and the UK. This SOP will use the term “Regulations" to cover the requirements of the UK legislation.

The University of Liverpool (University) is required to have oversight of all activity in which it engages in relation to CTIMPs. The University has implemented an oversight process for activity related to the conduct of CTIMP studies involving University members of staff. Oversight of University Sponsored CTIMPs is the responsibility of the Sponsorship Team, part of the Technology, Infrastructure and Environment Directorate within the Faculty of Health and Life Sciences reporting into the Liverpool Health Partners (LHP) Joint Research Office (JRO) Sponsorship Committee.

Oversight of the Quality Assurance activities of the Sponsorship Team and Quality Assurance and Clinical Trial activities of Liverpool Clinical Trials Centre (LCTC), the University GCP laboratories and Centre for Experimental Therapeutics (TherEx) is undertaken by the Clinical Research Regulatory Oversight Committee (CRROC).

2. Scope of Procedure

This SOP describes the process by which the University maintains oversight of CTIMPs.

3. Who

This SOP is aimed at staff within the University Technology, Infrastructure and Environment Directorate who are involved in oversight processes for University Sponsored research.

This SOP is also relevant to Chief Investigators, trial coordinators and other members of University Staff involved in University Sponsored CTIMPs.

4. When

This SOP should be applied by the Sponsorship Team and Technology, Infrastructure and Environment Directorate when conducting oversight activity.

5. The JRO Sponsorship Committee

The JRO Sponsorship Committee meets monthly to review and approve applications for Sponsorship on behalf of the University and the LHP Partner NHS Trusts and undertakes oversight of the University portfolio of Sponsored CTIMP studies.

The University engages in various activities in relation to CTIMPs and the committee receives reports and reviews information pertaining to the different activities as detailed in the following sections.

The committee receives reports in relation to oversight activities of CTIMPs and for taking appropriate action as detailed in the table below. JRO004 - JRO Sponsorship Committee UoL Oversight Reporting Schedule will be presented at the first meeting of each year to agree submission dates of oversight reports.

Area	Report(s)	Frequency	Action
Oversight of Sponsored research	Annual reports[1] and End of Trial declarations submitted to Sponsor, REC and MHRA	Monthly	Review
Regulatory Updates	Any updates in the previous period	Monthly	Information
Risk Review/Escalated Issues	Report on any arising risks identified since the previous meeting	Monthly	Review
Oversight of Sponsorship Systems	Review of NISSC[2] minutes	Monthly	Review
	Review of Sponsorship applications	Monthly	Approval
Oversight of Sponsor Quality Management	Review of Sponsor SOP's (dependent on the content, formal approval and ratification sits with CRROC)	As required	Review
Specific Oversight of University Sponsored CTIMPs	• Trial progress including trial status, key dates and recruitment progress • Safety Reports including: DSUR Compliance Report & SUSAR line listing • Monitoring Compliance Report • International sites report (where applicable to the trial) • TSC Recommendations to Sponsor	Twice yearly	Review

[1] Not required for CTIMPs or Research Tissue Banks
[2] NISSC – JRO Non-Interventional Sponsorship Sub Committee

6. University Clinical Research Regulatory Oversight Committee (CRROC)

The University of Liverpool (UoL) Clinical Research Regulatory Oversight Committee (CRROC) has a responsibility to oversee the regulatory framework and risk management of clinical research activities that are being undertaken at the University of Liverpool, and to manage organisational risk related to clinical research and ensuring actions are appropriately allocated, escalated and undertaken in a timely way, using a risk proportionate approach.

CRROC has responsibility for overall oversight of Sponsor, LCTC, GCP laboratory and TherEx compliance with ethical and regulatory standards. CRROC fulfils this responsibility by receiving reports from each area detailing the below;

Area	Report(s)	Action
Sponsor	• Quality Management System update and ratification of Sponsor SOPs • Sponsor Audit Summary and CAPA update • Current Sponsor Audit programme	Review
LCTC, GCP Laboratories and TherEx	• Summary of Portfolio • Risk Register • QMS documentation overview • Internal Audits (planned and ongoing), including a review of Reports, Responses or CAPAs • Current internal audit plan • External Audits / Inspections (planned and ongoing), including a review of Reports, Responses or CAPAs • Quality Issues (including Serious Breaches and Personal Data Breaches) • Safety Reporting	Review

7. Escalation

The Sponsor Team and wider Clinical Research Governance Team will escalate any concerns related to Sponsored CTIMPs first to the Chair of the JRO Sponsorship Committee and the CTIMP Co-Sponsor (where applicable). The Chair of the JRO Sponsorship Committee will advise on which committee to

escalate the issue to. The Chair of the JRO Sponsorship Committee will determine the need to escalate to the Chair of Clinical Research Regulatory Oversight Committee and to report to the University Research Integrity and Governance Committee. The Sponsor Team will also make decisions if issues need to be reported to the MHRA and/or REC.

8. Roles and Responsibilities

The Senior Clinical Research Governance Manager is responsible for

- Management of the Sponsor Quality System and ensuring progress is reported to CRROC as defined in Section 6
- Ensuring CTIMP oversight reports are provided to the JRO Sponsorship committee as agreed in JRO004.

CTUs and/or CIs managing and undertaking University Sponsored CTIMPs are responsible for providing updates and reports as requested by the Sponsorship Team.

9. Abbreviations

CAPA Corrective and Preventative Action

CI Chief Investigator

CRROC Clinical Research Regulatory Oversight Committee

CTIMP Clinical Trial of Investigational Medicinal Product

DSUR Development Safety Update Report

JRO Joint Research Office

LCTC Liverpool Clinical Trials Centre

LHP Liverpool Health Partners

REC Research Ethics Committee

SOP Standard Operating Procedure

TSC Trial Steering Committee

University the University of Liverpool

10. Associated Documents and References

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

JRO004 JRO Sponsorship Committee UoL Oversight Reporting Schedule

SOP024 Sponsor Quality Assurance

SOP025 Sponsor Audit

11. Training and Resources

Members of the Sponsor team, CIs, trial coordinators and other members of University Staff involved in University Sponsored CTIMPs should be aware of and familiar with this SOP. Training can be provided by the Clinical Research Governance Team upon request.

12. Monitoring and Audit

An internal audit of Technology, Infrastructure and Environment Directorate SOPs will be conducted at a minimum of every two years.