MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

Number:	UoMCTSOP15/2024/V4.0		
Title:	Selection and Overview of a Clinical Trials Unit		
Version:	4.0	**Effective Date**	23 Feb 2024
Author:	Dr Mohammed Zubair/Lubica Stasinkova	**Review Date**	26 Feb 2026
Reviewed by : Dr Mohammed Zubair		**Approved By:** Prof Terence O'Neill	
Position: Research Governance, Ethics and Integrity Manager		**Position:** Deputy Chair of Clinical Trials Management Group	
Signature: 		**Signature:** Approval by email	

Version	Date	Reason for change
2.0	**August 2016**	
3.0	**March 2018**	Review and Update
4.0	**February 2024**	Periodic review

When using this document please ensure that the version you are using is the most up to date either by checking on the Research Governance, Ethics and Integrity Team website (https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/) for any new versions or contacting the author to confirm the current version. The document is part of Sponsor QMS system, designed to manage best practice throughout clinical research and study management.

1.0 Background

The University of Manchester in its role as Sponsor of a clinical trial has ultimate responsibility for the trial. The University may delegate defined functions and activities related to the conduct and delivery of a clinical trial to a UKCRC registered clinical trials unit (CTU). The guidance in this SOP may be used as a benchmark to assess the suitability of a CTU for involvement in a particular trial.

2.0 Purpose

To ensure legal and Good Clinical Practice (GCP) compliance, both the University in its capacity as the Sponsor of a clinical trial and the Chief Investigator (CI) need to have oversight of all functions and activities delegated to a CTU. The CTU will be considered to be legally responsible when agreeing to undertake functions and activities on behalf of the University, and must therefore comply with relevant legislation, GCP, and guidance required by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Research Ethics Committee (REC).

3.0 Procedures

3.1 Selection of Clinical Trials Unit

The process for adequately assessing and documenting the suitability of a CTU may vary according to the level of risk-based function and activity likely to be undertaken. The CI should assess a CTU for suitability using number 1 and one more of the following criteria:

1. Confirmation that the CTU has current UKCRC registration. The University is only able to Sponsor a trial if it is run via a UKCRC registered CTU. A full list of UKCRC Units is available on: https://ukcrc-ctu.org.uk/
2. Positive past experience with the CTU
3. Recommendation of the CTU from a credible source (e.g. MAHSC Partner and experienced CI or research team)
4. Review of the quality management system and written procedures (including organisational charts)
5. Evidence of experience of the CTU in running other clinical trials in the same clinical area or using the same methodology as the proposed trial

The final decision on the selection of the CTU must be approved by the University Clinical

This document/SOP is a controlled document.
Any printed version of this document may not be current.
It is the responsibility of colleagues to ensure that the most recent version of the document is accessed and the procedures stated within the document followed.
To access the most up-to-date version of this document please visit the University of Manchester Research Governance website:
http://www.staffnet.manchester.ac.uk/services/rbess/governance/

Trials Management Group (CTMG) before the University will agree to sponsor the trial. A CTMG approved CTU will be put on the UoM approved suppliers list and a process for periodical review of the CTU registration will be in place. The full UK CRC registration is awarded for a period of five years, follow by a Quinquennial Review of registration status, continuation of which will be confirmed by Sponsor.

3.2 Working with a selected CTU prior to submitting funding application

Once a CTU has been selected, the trial functions and activities that will be carried out by this unit must be clarified and documented in a delegation of responsibilities log (UOMSOP06 Delegation of Responsibilities). Such functions and activities may include, but are not limited to, methodology input, statistical support (trial statistician), pharmacovigilance, randomisation, data collection, database provision, monitoring etc. Costings for support should be negotiated with the CTU and factored into the funding application.

3.3 Contract

Once a CTU has been selected and funding secured, a contract must be put in place by the University to cover the activity and payment of the CTU with respect to the trial in question. The contract should contain information relating to the delegated functions and activities as well as the required standards for the work and how these will be monitored. Advice will be sought from the University Contracts team to ensure compliance with local requirements. In addition to trial specific activities, it is required that the CTU will be contracted to manage the following responsibilities on behalf of the sponsor as detailed in parts 4 and 5 of the UK Clinical Trial Regulations 2004:

Under Part 4: Good Clinical Practice and Conduct (GCP):

1) Put and keep in place arrangements to adhere to GCP
2) Ensure investigational medicinal products (IMPs) and medical devices are made available to subjects free of charge
3) Keep records of all deviations from GCP
4) Take appropriate urgent safety measures (if no other person is specified to do so)

Under Part 5: Pharmacovigilance:

1) Keep records of all adverse events reported by investigators. For medical devices, all adverse incidents must be reported to the MHRA using the MORE portal. Registration for the MORE portal is via the GOV.UK website.
2) Ensure recording and prompt reporting of Suspected Unexpected Serious Adverse Reactions (SUSAR's)

This document/SOP is a controlled document.
Any printed version of this document may not be current.
It is the responsibility of colleagues to ensure that the most recent version of the document is accessed and the procedures stated within the document followed.
To access the most up-to-date version of this document please visit the University of Manchester Research Governance website:
http://www.staffnet.manchester.ac.uk/services/rbess/governance/

3) Ensure investigators are informed of SUSAR's
4) Ensure all SUSAR's including those in third countries are entered into a European database
5) Provide annual list of suspected adverse reactions and a safety report for a CTIMP study

A copy of the signed and dated contract (and any subsequent amendments) must be filed in the Trial Master File.

3.4 Oversight of the Clinical Trials Unit

The CTU will be expected to communicate regularly with the CI and provide regular reports (as a minimum via Quarterly reports) to the Sponsor regarding trial progression and important trial related issues in order to meet its contractual, legislation, GCP, and MHRA/REC requirements.

The University may delegate a minimum level of pre-defined oversight of the activities of the CTU with respect to the trial to the CI which will be detailed in an agreement.

The University will conduct a vendor assessment (UOMSOP21 Vendor Selection and Oversight) on the chosen CTU as part of the Sponsor responsibilities, to assure the suitability of the services to be provided. Throughout the study, the Sponsor will choose to audit the CTU as part of the University Audit Programme, based on the risk assessment.

When there are issues with vendors and compliance with this SOP, this will be escalated to the Chair and Deputy Chair of the Clinical Trials Management Group (CTMG).

Where concerns arise regarding the conduct of the CTU, the University CTMG must be informed at the earliest opportunity.

4.0 References:

- Medical Device Regulations 2002 (as amended).
- The Good Clinical Practice Directive 2005/28/EC
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031)
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 1928)
- MHRA Good Clinical Practice Guide, 2012
- UKCRC Registered Clinical Trials Units | UKCRC
- UOMSOP06 Delegation of Responsibilities

This document/SOP is a controlled document.
Any printed version of this document may not be current.
It is the responsibility of colleagues to ensure that the most recent version of the document is accessed and the procedures stated within the document followed.
To access the most up-to-date version of this document please visit the University of Manchester Research Governance website:
http://www.staffnet.manchester.ac.uk/services/rbess/governance/

- UOMSOP21 Vendor Selection and Oversight

This document/SOP is a controlled document.
Any printed version of this document may not be current.
It is the responsibility of colleagues to ensure that the most recent version of the document is accessed and the procedures stated within the document followed.
To access the most up-to-date version of this document please visit the University of Manchester Research Governance website:
http://www.staffnet.manchester.ac.uk/services/rbess/governance/