The University of Manchester

Standard Operating Procedure

Number:	UoMCTSOP01/2024/V7.0		
Title:	Preparation, Review and Issue of SOPs		
Version:	7.0	**Effective Date:**	26 Feb 2024
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Version	Date	Summary of Changes
2.0	January 2013	Update of weblinks and office details.
2.1	May 2014	Addition of version control statement for SOP
3.0	October 2015	Minor changes to text.
4.0	August 2016	Update of weblinks, office details and minor changes to text.
5.0	January 2018	Review of process.
6.0	14 July 2020	Review of process.
7.0	26 Feb 2024	Update of review and approval process. Further detail added to process for SOP distribution and acknowledgement. Updated SOP template.

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1 Introduction

In order to be compliant with the European Directive on Good Clinical Practice in Clinical Trials (2001/20/EC) and The Medicines for Human Use (Clinical Trials) Regulations (2004 and subsequent amendments), and the Medical Device Regulations 2002, organisations conducting Clinical Trials of Investigational Medicinal Products (CTIMPs) and Medical Device trials must have clearly documented Standard Operating Procedures (SOPs) covering all trial activities that they conduct.

A SOP is defined by ICH Harmonised Tripartite Guideline for Good Clinical Practice as "Detailed, written instructions to achieve uniformity of the performance of a specific function". These SOPs are written instructions and records of procedures agreed and adopted by the University of Manchester (UoM).

2 Scope

This SOP describes the process for writing, approving, implementing and reviewing UoM SOPs relating to CTIMPs and Medical Device trials – i.e. all trials which come under the Regulations, where the University of Manchester is the Sponsor. The requirements of this SOP should be applied as a minimum for all University Research Governance, Ethics and Integrity (Clinical Trials) Team (RGEIT) SOPs and in conjunction with all applicable University policies and procedures.

Where an external vendor or NHS Trust has been contracted to undertake specific activities, their vendor's own SOPs may be used (where in place) for the activities they are performing, however the Sponsor must be provided with a copy of the vendor's SOPs (see SOP21 Vendor Selection and Oversight for further details).

3 Responsibilities

RGEIT
Writing SOPs. Control and oversight of all SOP development and dissemination. Tracking of review timelines and control of SOP updates. Storage of SOPs.

RGEI Manager
Review of all SOPs

Chair of CTMG/Deputy/Quality Role
Final review and approval of SOPs.

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4 Related Documents

Reference Number	Document Title
01/A	SOP Template
01/B	Distribution List

5 Procedures

5.1 Writing SOPs

5.1.1 A SOP should be written as soon as the need for a standard written procedure for an activity is identified. A process map or flow diagram may be used to aid in SOP development. The SOP must be written by a suitable member (by experience and competency) of the RGEIT.

5.1.2 SOPs should be written in English and the present tense, active voice. The SOP template (related document 01/A) should be used. Additional subheadings may be added to the SOP template as required for the SOP being written, but the subheadings in the template should be kept as a minimum in all SOPs produced. Content should be written following the guidance in the SOP template 01/A. “Should/should not” or “must/must not” should be used for requirements. “May/may not” should be used for suggestions.

5.1.3 All SOPs should be version controlled and have a unique reference number. SOPs should follow the document control requirements specified in SOP02 Document Control.

5.1.4 Where additional information or templates are required, these may be associated with the SOP as a related document. For example, audit report templates.

5.2 SOP Review

5.2.1 The SOP author will coordinate the review process and incorporate comments into updated drafts until a final version is agreed. All SOPs will be reviewed by the RGEI Manager (Clinical Trials) and any other University of Manchester staff member with relevant expertise and experience, where considered beneficial. The reviewer must not also be the author.

5.2.2 Additional input may be sought from members of the UoM Clinical Trials Management Group (CTMG), the research community within the

University or external advisors, as necessary.

5.2.3 Evidence of review should be documented.

5.3 SOP Approval

5.3.1 All SOPs require final approval from the Chair of the CTMG, Deputy Chair of the CTMG, or the RGEIT Quality role. The approver must not also be the author.

5.3.2 Reviewer and approver signatures may be documented either by obtaining wet-ink signatures on the first page of the SOP, or they may be documented electronically as per SOP02 Document Control, in which case the first page of the SOP must state the approver and reviewer's names, date of electronic approval, and "electronic/by email" in the signature box.

5.3.3 Once final approval has been received, an effective date must be added to finalise the SOP for dissemination. All finalised SOPs should be saved as PDF versions for distribution to prevent unauthorised changes.

5.3.4 Approval of a SOP will also authorise the related documents.

5.4 SOP Distribution

5.4.1 A list of SOP recipients is held and maintained electronically by the RGEIT (Distribution List 01/B). The list states which SOPs are required to be read by which members of staff. The list should be version controlled and approved by CTMG. SOPs will be distributed according to the list and a record of distribution must be kept.

5.4.2 SOPs that are appropriate for use outside of the RGEIT will be added to the University Research Governance, Ethics and Integrity Team website once effective, and superseded or obsolete versions removed. The SOP distribution list will identify which SOPs this is relevant to.

5.4.3 It is the responsibility of any staff at the University of Manchester who are using the SOPs to ensure they are working to the most recent version.

5.5 Acknowledgement and Training

5.5.1 On distribution, staff will be asked to read the SOP as soon as possible, or within 30 days of receipt. It is the responsibility of the staff member to update their SOP training log (see SOP025 Training) to document that they

have done this.

5.5.2 Where changes to SOPs are significant or when new SOPs are released, provision of SOP training should be considered.

5.6 Storage

5.6.1 Final versions of SOPs will be saved electronically and maintained by the RGEIT. Evidence of approval will be saved alongside final versions.

5.6.2 Superseded, obsolete and draft SOPs will be clearly marked as such and stored separately from current versions.

5.7 Periodic review and update of SOPs

5.7.1 SOPs will be reviewed 2 years after their effective date, or as necessary when there are changes in current processes, guidelines or regulations. If the SOP template 01/A has been updated since a SOP was released, the review should include transfer to the updated template. Updated SOPs should follow the same review and approval process as described in sections 5.2 and 5.3. SOPs may be made obsolete by RGEIT if the procedure it describes is no longer required, or if changed substantially enough to warrant an entirely new SOP being developed.

5.7.2 Requests for changes prior to the planned review date will be assessed by RGEIT, and a decision made as to whether the change requires an earlier update than scheduled. If not, the change request will be logged by the RGEIT to be considered at the next planned review.

5.7.3 SOP compliance and effectiveness will be assessed as part of monitoring and audit, and findings fed back to the CTMG.

6 References

UoMCTSOP02 Document Control
UoMCTSOP25 Training
UoMCTSOP21 Vendor Selection and Oversight
European Directive on Good Clinical Practice in Clinical Trials (2001/20/EC)
The Medicines for Human Use (Clinical Trials) Regulations (2004 and subsequent amendments)
ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (R2)