MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

Number:	UoM/CTSOP01/2020/V6.0		
Title:	Preparation, Review and Issue of SOPs		
Version:	6.0	**Effective Date**	30/07/2020
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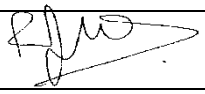
Reviewed by: Dr Mohammed Zubair		**Approved By:** Richard Drake	
Position: Research Governance, Ethics and Integrity Manager		**Position:** Chair of Clinical Trials Management Group	
Signature: 		**Signature:** 	

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	July 2020	Review of process

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1.0 Background

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) organisations conducting Clinical Trials of Investigational Medicinal Products (CTIMPs) must have clearly documented Standard Operating Procedures (SOPs) covering all Clinical 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).

2.0 Purpose and Scope

This SOP describes the process for writing, approving, implementing and reviewing UoM SOPs relating to CTIMPs – 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 UoM CTIMP SOPs and in conjunction with all applicable University policies and procedures and the policies and procedures of the relevant NHS Trust.

Where an external vendor has been contracted to undertake specific activities, the vendor's own SOPs will 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 UoM SOP21 Vendor Selection and Oversight for further details).

3.0 Roles and 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 (or deputy)	Final review, approval and sign off of all SOPs

4.0 Procedure

4.1 Writing SOPs

A SOP should be written as soon as the need for a standard written procedure for an activity is identified. It must be written by a suitable member (by experience and competency) of the University Research Governance, Ethics and Integrity Team (RGEIT). The SOP template in Appendix 1 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. All SOPs should be version controlled and have a unique reference number.

4.2 SOP Review

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.
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. Evidence of review should be documented.

4.3 SOP Approval

All SOPs require final approval from the Chair of the CTMG (or deputy). This individual will perform a final review of the SOP and once satisfied will authorise it by signing and dating the first page. Reviewer signatures should also be obtained at this point, and an effective date added to finalise the SOP for dissemination. The signature on a SOP will authorise the associated forms which should show an identical issue date to the SOP. All finalised SOPs should be saved as PDF versions for distribution to prevent unauthorised changes.

4.4 Distribution and storage

4.4.1 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. 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.

4.4.2 All Chief Investigators will be notified by email when a new or updated SOP is released, and instructed to destroy any previous versions held.
Signed hard copy originals of SOPs will be kept in the RGEIT office, and will be maintained and updated by the RGEIT. Superseded and obsolete SOPs will be clearly marked as such and stored separately from current versions.

4.5 Ongoing Review and Update of SOPs

4.5.1 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 in Appendix 1 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 4.2 and 4.3. 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.

4.5.2 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.

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

5.0 References

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

6.0 Appendices

Appendix 1: UoM RGEIT SOP Template

APPENDIX 1

The University of Manchester

Standard Operating Procedure

All blue text in this template is for guidance only and should be deleted during completion.

Number:	UoM/SOP(number e.g. 01)/(year effective)/(version e.g.V1.0)		
Title:			
Version:		**Effective Date**	DD/MMM/YYYY
Author:		**Review Date**	DD/MMM/YYYY
Reviewed by :		**Approved By:**	
Position:		**Position:** Chair of Clinical Trials Management Group	
Signature:		**Signature:**	

Version	Date	Summary of changes

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1.0 Background

This section should outline the reason for creating the SOP.

2.0 Purpose and Scope

This section should outline the aim of the SOP and its intended audience and application.

3.0 Roles and Responsibilities

This section should list the individuals with roles and provide details of their specific responsibilities in relation to the SOP concerned.

4.0 Procedure

This section should detail how the aims will be achieved. This will clearly indicate a step-by-step description of the procedure to be followed**.**

5.0 References

A list of documents referenced in the SOP must be provided in this section.

6.0 Appendices

All appendices referenced in the SOP must be listed here and copies of the appendices provided at the end of the SOP.