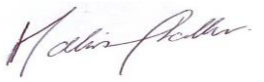
MANCHESTER 1824

The University of Manchester

Standard Operating Procedure

Number:	UM/SOPonSOPs/SOP01/2.0		
Title:	Preparation, review and issue of SOPs		
Version:	2.0 (January 2013)	**Effective Date**	01 June 2011
Author:	Mrs April Lockyer	**Review Date**	01 January 2015
Reviewed by : Prof Deborah Symmons		**Approved By:** Prof Nalin Thakker	
Position: Chair of Clinical Trials Management Group		**Position:** Associate Vice President for Research Integrity	
Signature: 		**Signature:** 	

Version	Date	Reason for change
2.0	**January 2013**	**Update of weblinks and office details**

When using this document please ensure that the version you are using is the most up to date either by checking on the Research Office website (http://www.staffnet.manchester.ac.uk/services/rbess/governance/) for any new versions or contact the author to confirm the current version.

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 must have clearly documented Standard Operating Procedures covering all aspects of conducting Clinical Trials. The SOPs also apply to all other projects that fall under the Research Governance Framework for Health and Social Care, 2nd Edition, Department of Health 2005.

A Standard Operating Procedure (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.

2.0 Purpose

This Standard Operating Procedure (SOP) describes the process for writing, approving, implementing and reviewing University of Manchester SOPs relating to Clinical Trials of Medicinal Products (CTIMP) – 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 to such trials and in conjunction with all applicable University policies and procedures and the policies and procedures of the relevant NHS Trust.

3.0 Procedure

3.1 Writing SOPs

A SOP should be written as soon as the need for a standard written procedure for an activity is required. It must be written by a suitable member (by experience and competency) of the University Research Office. The name of the author will be displayed at the top of the document in Table 1 (see Template for the production of University of Manchester SOPs, Appendix I the SOP Template, Appendix).

All amendments, advancements and new legislation must be incorporated into existing SOPs at the 12 month review point or sooner if required.

3.1.1 Front Page

- **Title of SOP**

- **Unique SOP number** for reference purposes.
  This will be located in the table on the front page and in the footer of the document. This number will state where the SOP originated (UoM - University of Manchester) the year it was produced, the SOP number and also the version number.

- **Version number control**

All SOPs require version control to ensure that individuals are using the correct version for the SOP. Version numbers should be written in the format N.n where N represents a finalised document and n represents draft versions prior to finalisation.

- **Effective date**
  All SOPs must have an effective date upon which the document will be implemented.

- **Author**
  The author shall be the individual member of the University Research Governance and Integrity Team who was primarily responsible for writing the SOP.

3.1.1 Contents and layout

The SOPs must be produced in the standard format outlined in Appendix 1. It should incorporate the following bold titles:

Background – this section should outline the reason for creating the SOP.

Purpose – this section should outline the aim of the SOP.

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

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.

Consultation, Approval and Ratification Processes – this section outlines the procedures for consultation and communication with stakeholders and the process by which the SOP has been approved.

Dissemination - this section details how the SOP will be implemented and disseminated.

Review, Monitoring Compliance with and the Effectiveness of Procedural Documents – this section outlines the process for monitoring compliance with and effectiveness of the SOP.

References and Bibliography – an ordered list of all documents referenced in the SOP must be provided in this section.

Associated University Documents – this section should list all associated University documents referenced in the SOP.

Appendices – all appendices referenced in the SOP must be listed accordingly and copies of the appendices provided at the end of the SOP.

3.2 Approval and authorisation

3.2.1 All SOPs will require final approval and authorisation. They will be reviewed by the Chair of the Clinical Trials Management Group. The Associate Vice President for Research Integrity will be responsible for authorising all SOPs produced by the Research Governance and Integrity Team. This individual will perform a final review of the SOP and once satisfied will authorise it by signing and dating the Table on page 1 indicating the date of approval. The signature on a SOP will authorise the associated forms which should show an identical issue date to the SOP.

3.3 Review and Amendment of SOPs

3.3.1 SOPs will be reviewed as necessary when there are changes in current processes, guidelines and regulations. A SOP can be suspended following evidence from an individual of a significant change in practice. If this is necessary, an email will be circulated to all relevant individuals and the SOP will be reviewed by the Research Governance and Integrity Manager, the Chair of the Clinical Trials Management Group, if appropriate, or other suitable member of the Research Governance and Integrity Team. The SOP will be amended and authorised in accordance with due process.

3.4 Distribution and storage

3.4.1 All SOPs will be added to the University Research Governance and Integrity Team website once authorised. It is the responsibility of all staff at the University of Manchester to check the website regularly to determine whether SOPs have been added or amended.

3.4.2 A master file containing all versions of SOPs will be kept in the University Research Governance and Integrity Team. This will be maintained and updated by the Research Governance and Integrity Team.

4.0 Consultation, Approval and Ratification Process

4.1 Consultation and Communication with Stakeholders

5.1.1 All University-wide Clinical Trials documents are written by a member of staff with relevant expertise and experience. Additional advice is sought from members of the research community within the University or external advisors, as necessary.

4.2 Document Approval Process

5.2.1 Standard Operating Procedures are approved by the Chair of the Clinical trials Management Group and/or Associate Vice President for Research Integrity.

5.2.2 Policies are ratified by the Research Conduct and Accountability Committee.

5 Dissemination and Implementation

5.1 Dissemination

5.1.1 When approved, this document will be posted on the Clinical Trials pages of the University's Research Governance and Integrity Team website. Only the current version will be available.

5.1.2 All Chief Investigators will be notified by email when the latest version of the document is available.

5.2 Implementation of Procedural Documents

5.2.1 Support and advice on the implementation of this document can be obtained via the Research Policy Officer (Clinical Trials) or the Chair of the Clinical trials Management Group.

6 Review, Monitoring Compliance With and the Effectiveness of Procedural Documents

6.1 Process for Monitoring Compliance and Effectiveness

6.1.1 The Chair of the Clinical trials Management Group/Research Policy Officer (Clinical Trials) will monitor compliance through regular monitoring and audits of CTIMPs.

6.1.2 Document contents will be reviewed as part of the monitoring and audits.

6.1.3 The outcome of any review – and any resulting amendments - will be reported to the Research Conduct and Accountability Committee.

6.2 Standards and Key Performance Indicators 'KPIs'

6.2.1 This document will be available on the University intranet.

6.2.2 This document must be reviewed at least every two years or when there are significant changes.

6.2.3 Awareness of the document will be delivered at any relevant University training sessions.

7 References and Bibliography

1. Cardiff University SOP for the preparation, review and Issue/Approval of SOPs
2. Imperial College London SOP for SOP writing and review
3. University Hospital of South Manchester NHS Foundation Trust SOP for Preparation, review and issue of SOPs.

8 Associated University Documents

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Position:		**Position:**	
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