MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

Number:	UoMCTSOP02/2024/V7.0		
Title:	Document Control		
Version:	7.0	**Effective Date**	23 Feb 2024
Author:	Mohammed Zubair/ Lubica Stasinkova	**Proposed Review Date**	23 Feb 2026
Reviewed by: 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:** (approved by email)	

Version	Date	Reason for change
2.0	**January 2013**	Update of weblinks and office details
2.1	**May 2014**	Addition of version control statement for SOP
3.0	**August 2015**	Minor changes to text
4.0	**August 2016**	Update of weblinks, office details and minor changes to text
5.0	**March 2018**	Interim Update
6.0	**January 2023**	Minor changes, update of web-links, removal of text. Addition of clinical trial document version section 4.7
7.0	**February 2024**	Addition of process for electronic signatures to section 4.3. Reference to QMS documents added to 4.1.5. Clarifications throughout.

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 European Clinical Trials Directive 2001/20/EC ("the Directive") was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union.

It was transposed into UK law as the Medicines for Human Use (Clinical Trial) Regulations 2004, (SI 2004/1031), which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments, will be referred to as "the Regulations" in the rest of the document.

This document should be read in conjunction with the University's 'Policy on Clinical Trials'. The policy and therefore the SOPs extend to and cover the design and conduct of clinical investigations of IMP (including ATIMP), medical devices and other high-risk trials, that would fall under MHRA or only REC/HRA scope. The procedures outlined in Sponsor SOPs represent good practice for those involved in Clinical Trials and the outlined procedures in the SOPs must be followed by University researchers where agreed at study set-up.

All documentation related to Clinical Trials which falls under the Regulations has to be controlled by the Research Governance Equality and Integrity (RGEI) team on behalf of the Clinical Trials Management Group (CTMG). This is to ensure all staff are working to the approved and active version of all documents.

2.0 Purpose

This SOP relates to guidance for the creation, amendment, retention and destruction of documentation related to the Clinical Trials where the University is the named Sponsor. This SOP covers all documentation including "centrally produced documentation" (produced by the RGEIT e.g. standard operating procedures, policy documents, Quality Management documents and templates). The SOP also provides minimum Sponsor expectations for "locally produced documentation" (produced by team teams e.g. trial specific SOPs, documents for regulatory/REC submission).

3.0 Roles and responsibilities

There is no named document controller within RGEIT. All members of the RGEIT are responsible for following document control processes as described in this SOP.

CTMG are responsible for review and approval of centrally produced documentation.

RGEI Manager is responsible for review of centrally produced documentation.

RGEIT is responsible for ensuring that appropriate document control procedures are in place where trial related documents are locally produced.

Where a Chief Investigator (CI) is using this SOP for a trial, they are responsible for ensuring this SOP is followed by members of their trial team.

4.0 Procedures

4.1 Document control

4.1.1 All University-wide documentation related to Clinical Trials is created centrally and controlled by the Research Governance, Ethics and Integrity team (RGEIT).

4.1.2 All SOPs are given a unique document number, title, version number, author, effective date, review date and page numbers.

4.1.4 The active version of the document is available on the University intranet.

4.1.5 Centrally produced/controlled documents include (but are not restricted to):

- Policy for Compliance with The Medicines for Human use (Clinical Trials) Regulations 2004 and subsequent amendments (Investigational Medicinal Products) and other Clinical Research.
- Policy for compliance with the UK Medical Devices Regulations 2002 (UK MDR 2002) clinical investigation of medical devices.
- All Clinical Trials related SOPs.
- A list of all controlled documents (Document List 02/A).

4.1.6 Trial documents that are locally produced (e.g. a protocol produced by a trial team) are controlled by the Chief Investigator, CTU or relevant member of staff according to local document control policy for their trial team. Minimum requirements specified in section 4.7 should fulfilled.

4.1.7 As a minimum all locally produced SOPs (e.g. trial specific-SOPs or SOPs for trial team/CTU processes) should have a unique ID number, title, version number, author, effective date, proposed review date and page numbers.

4.2 Creation of documents

4.2.2 Documents will include the following:

- The University logo

- A footnote on each page, including any appendices, which includes the title of the document, the version and date, the page number, total number of pages and a prompt to check the Intranet for the latest version where relevant.
- Where possible job titles should be used to describe roles and responsibilities as opposed to names. This will negate the need for policy / document revision when post holders change.
- Draft procedural documents must be clearly marked as such using a 'watermark'.
- All procedural documents must be written in a style that is concise and clear using unambiguous terms and language.
- All abbreviations must be expanded on their first use in the document.

4.3 Approval

4.3.1 All University-wide Clinical Trials documents are circulated to the RGEI Manager for review and the chair of the CTMG for review, comment and approval.

4.3.2 Evidence of approval must be retained. Approval may be documented by means of a wet, dated signature on the document. Approval may also be documented electronically by email. An email approval must clearly describe the scope of the approval; stating the document being approved, version number if applicable, and that is being approved, e.g. 'this email documents my approval of document x version y'. Best practice is for a new email to be generated for the approval, but it is acknowledged that this may not always be possible. The email approval must be sent from an individual's email account, not a shared email account. The name of the approver must be clear in the email.

4.3.3 Email approvals must be saved in an uneditable format alongside the document being approved.

4.3.4 Electronic signatures provided from people external to the University of Manchester are also acceptable if the signature is embedded within the document (as can be done in certain software), or the document is provided in a format where it is not possible to manipulate the document on receipt.

4.4 Amendment

4.4.1 When a new or updated centrally produced document is approved, RGEIT should notify any relevant staff. Chief Investigators will be notified by email when a new document is available, for trials where the centrally produced SOPs are being used.

.

4.4.2 Revision numbers, dates and reasons for change are logged and controlled centrally by the RGEIT.

4.4.3 RGEIT is responsible for updating any relevant document lists or logs when new/updated documents are produced.

4.4.4 RGEIT is responsible for updating the intranet to replace superseded versions with current versions of documents.

4.5 Retention

4.5.1 The RGEIT will hold a working file of all current documentation. Active centrally produced SOPs and policy documents will be uploaded to the University intranet for access by relevant staff.

4.5.2 The RGEIT will keep an archive file with all superseded and obsolete documentation for reference.

4.6 Destruction

4.6.1 The intranet will only contain the current version and local sites should strike through all outdated versions of documents and mark superseded and replace with the current version as soon as it is available.

4.7 Clinical Trials document version control

4.7.1 All Clinical Trials documentation must be version controlled, using the version number and version date E.g. V1.0, Effective date DD MMM YYYY. HRA approved templates should be used where available.

4.7.2 All new document versions must be reviewed and approved by Sponsor (RGEIT). A version control history of documents is recommended for audit trail purposes.

4.7.3 All obsolete and current documents versions should be kept with a version control log filed in the Trial Master File with a brief description of the changes.

5 Consultation, Approval and Ratification Process

5.1 Consultation and Communication with Stakeholders

5.1.1 All University-wide Clinical Trials related 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.

5.2 Document Approval Process

5.2.1 Standard Operating Procedures are approved by the Chair of the CTMG or deputy, or the RGEIT Quality role.

5.2.2 Policies are ratified by the CTMG Chair/Deputy.

5.2.3 Locally produced trial documents are reviewed by RGEIT and approved by CTMG Chair/Deputy as part of the Sponsorship Approval process (see UoMCT SOP03 Processing Requests for Sponsorship).

6 Dissemination and Implementation

6.1 Dissemination

6.1.1 When approved, this document will be posted on the Clinical Trials pages of the University's RGEIT website. Only the current version will be available.

6.2 Implementation of Procedural Documents

6.2.1 Support and advice on the implementation of this document can be obtained via the RGEI Manager or the Chair of the CTMG.

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

7.1 Process for Monitoring Compliance and Effectiveness

7.1.1 The Chair of the CTMG/The RGEI Manager/RGEI Quality role will monitor compliance through regular audits.

7.1.2 Document contents will be reviewed against any changes to the applicable guidelines and regulations and take into account any feedback received from Chief Investigators.

7.2 Standards and Key Performance Indicators 'KPIs'

7.2.1 This document will be available on the University intranet.

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

References:

- Directive 2001/20/EC
- 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)
- Clinical Trials Toolkit information on 'Substantial Amendments', which can be accessed via/downloaded from
- http://www.ct-toolkit.ac.uk/routemap/substantial-amendments/
- UK Policy Framework for Health and Social Care Research
- https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=36863
- https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/
- UoM CT SOP03 Processing Requests for Sponsorship