

|  |
| --- |
| **SOP005 Version Control for LJMU Sponsored Clinical Research** |
| **Responsibility for Policy:** | *Robin Leatherbarrow* |
| **Relevant to:** | All staff and students conducting research |
| **Approved by:**  |  |
| **Responsibility for Document Review:** | *Dave Harriss* |
| **Date introduced:** |  |
| **Date(s) modified:** |  |
| **Next Review Date:** |  |
| **RELEVANT DOCUMENTS** |
|  |
| **RELATED POLICIES & DOCUMENTS** |
|  |

This SOP needs to be a useful resource for investigators –please contact sponsor@ljmu.ac.uk with any suggestions for improvements.

Table of Contents

[1. Introduction 2](#_Toc530141275)

[2. Scope of the procedure 2](#_Toc530141276)

[3. Procedure 2](#_Toc530141277)

[3.1. Who 2](#_Toc530141278)

[3.2. How 2](#_Toc530141279)

[4. Role and Responsibilities 4](#_Toc530141280)

[5. Abbreviations 4](#_Toc530141281)

[6. Associated Documents and References 4](#_Toc530141282)

[7. Monitoring and Audit 4](#_Toc530141283)

[8. Change History 4](#_Toc530141284)

# Introduction

Within the UK the Health Research Authority (HRA) require that key essential documents including those submitted to them for authorization be version controlled, as per good documentation practice.

For other clinical research related documents, it is good clinical practice and common expectation within the research community and from regulatory agencies that procedures must be in place to ensure the accountability, traceability, and consistency of these documents.

Document and version control allow you to track changes to documents for study conduct, review, and oversight and provide clarity as to which is the most recent document. All controlled documents need to be dated and versioned.

# Scope of the procedure

This standard operating procedure describes the procedure to be followed for version control and management of essential documents generated by LJMU staff and students for all clinical research sponsored by LJMU.

# Procedure

## Who

The SOP applies to LJMU staff and students who generate essential documents for clinical research sponsored by LJMU.

## How

Documents should always be written by qualified personnel with expertise in the area of the document. Templates should be used where available. All essential documents must have a unique title / reference, version / revision number and date to distinguish one version from another.

All essential documents must contain both the version number and date of the document on the document and in the file name. The placement of the version number will depend on the style of the document, but the most common place for version numbers are the document cover, or in the header or footer of each page. Within the file name and header/footer of a document the abbreviation <v> for version can be used.

N.B. The function ‘automatic date change’ in Word should not be used when recording the date of the document.

The versioning used must allow for the reconstruction of the document history. For example the following convention could be used;

* + - * The first draft could be labelled ‘**Draft version 0.1**’ and dated. Further draft versions could be labelled ‘**Draft version 0.2, 0.3**’ etc. and dated.
			* Then consecutive whole numbers for each new finalised version i.e. version 1.0 for the first, version 2.0 for the second and so on. Any form of change should result in a final version with the use of the next consecutive whole number.
			* The final original version of the document should be labelled ‘**Version 1.0’** and dated.
			* If amendments are necessary following review by a REC or other regulatory body then subsequent versions may be labelled ‘**Draft Version 1.1, 1.2’ etc.** and datedwhilst being drafted and reviewed and the version re-submitted for approval should be labelled ‘**Version 2.0’** and dated.
			* If the document is then amended again during the study then the version submitted for approval of the amendment will be labelled **‘Version 3.0’** and so on.

It is likely that documents will need to be updated during a project and it is important that amendment chronologies are kept, indicating the changes and the dates they are implemented. Old documents should be retained in the SMF alongside the amended version(s). Please remember that any amended documents, such as the protocol or informed consent forms, should be approved by the relevant bodies (the Sponsor(s), REC(s), regulatory bodies etc.) prior to implementing any changes to the study.

Electronic Essential Documents

An example of a naming convention for electronic copies is as follows;

* + - * The document title and the version number should be included in the document file name and also in the header or footer on each page within the document,
			* The date must be added to the file name and for finalized documents the date should also be included in the header and/or footer,
			* The words “draft” and “final” should be added to the end of the file name to indicate the status of the version
			* If more than one person works on a document it is helpful to add the initials at the end of the file name during the process of document development and/or review. E.g. XXX\_v0.3draft-ddmmyyy\_NN

Change history

The following information should be considered, records kept and in some cases details stated within the document;

* + - * Reason for change – if it is a revision of the essential document, state reason for change and list changes
			* Date issued, effective date and review date, if applicable.

Storage and Archiving

When filing electronically, one should consider folders for current version, superseded versions and retired/obsolete/withdrawn versions. Only current, approved, non-editable versions should be available at point of use. Each final document should be filed in the appropriate section with access restricted to authorized individuals only. Both superseded and retired documents must be promptly segregated in the relevant folder and this information communicated.

# Role and Responsibilities

The CI is responsible for ensuring that all essential documents required for the clinical research study are accessible and fit for purpose which includes appropriate version control. All staff must ensure they are trained to follow the processes for version control if this is a required task for their role. It is the responsibility of all staff to ensure that they are using the current controlled version of a document.

# Abbreviations

HRA Health Research Authority

LJMU Liverpool John Moores University

REC Research Ethics Committee

SMF Site Master File

SOP Standard Operating Procedure

# Associated Documents and References

To be completed

# Monitoring and Audit

Compliance with this SOP will be audited periodically as part of the LJMU REG audit plan.

# Change History

|  |  |  |  |
| --- | --- | --- | --- |
| Version No. | Effective date | Significant changes  | Previous version No. |
| 1.0 | See page 1 | This is the first version of this SOP | n/a |