




SOP Number 014
SOP Title Version Control

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Agreed by QA Focus Group	09 OCT 2017
Effective Date	27 NOV 2017
Review Date	26 NOV 2020

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed for version control and management of essential documents generated by the University of Oxford related to clinical research.

2. INTRODUCTION

Within the UK, the Medicine and Healthcare Regulatory products Agency (MHRA) and the Health Research Authority (HRA) require that key essential documents especially those submitted to them for authorisation be version controlled, as per good documentation practice.

For other clinical research related documents, it is good 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.

3. SCOPE

The scope of this procedure is for all essential documents generated by the University of Oxford for all clinical research studies sponsored by the University of Oxford, but may also be used for other clinical research studies at the discretion of the unit.

4. DEFINITIONS

Essential Documents

Essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.

Version control

Version control is the management of multiple revisions of the same document which ensures correct versioning and dates and that the current version is used at all times.

Superseded

Applies to an approved document that has been updated and replaced with a new version of the same document.

Retired / Obsolete / Withdrawn

Applies to a document where it has been decided that it is no longer relevant or required. No new version of the document has been issued.

5. RESPONSIBILITIES

Chief Investigator (CI)

The Chief Investigator 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.

Editor

The editor is the person identified to coordinate the authorship and review of a document, who is responsible for managing a specific document, and ensuring version control according to this SOP.

All Staff

Must ensure that 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.

6. SPECIFIC PROCEDURE

6.1 Initial Planning of the Document Development Phase

CI or delegate appoints the Editor to coordinate the development of the clinical research study essential document(s). Documents should always be written by qualified personnel with expertise in the area of the document. Templates should be used e.g. for SOPs, protocols, program validation, where available.

6.2 Naming Convention

The Editor must ensure all essential documents have a unique title / reference, version / revision number and date to distinguish one version from another.

6.3 Version Numbering and Referencing

6.3.1 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 places 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.

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

- The first draft of a document 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, draft versions of the updated document can be labelled draft version 1.1, 1.2 etc. and dated. The final version should then be labelled Version 2.0 and dated.
- In the case of a multi-centre trial, site or country specific versions of documents are likely and should be similarly controlled with the additional indication that the document is site specific e.g. *_version1.0 yyyy-mmm-dd_site12* and/or country specific e.g. *_version1.0 yyyy-mmm-dd_Austria*. When this additional indication is used the original version control must always be retained.

6.3.3 Wherever reference is made to another controlled document, you may use the instruction "see/refer to *insert document title*". The version number should not be included.

6.4 Electronic Essential Documents

6.4.1 These should be stored as pdf (portable document format) files where possible in an appropriate folder system, in an area restricted to authorised individuals only. In addition, it is important that the final writable original version is also retained with strict access rights to allow for future revisions to the document.

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 finalised 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-yyyymmdd_NN

6.5 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

6.6 Storage and Archiving

When filing electronically one should consider distinct 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 authorised individuals only. Both superseded and retired documents must be promptly segregated in the relevant folder and this information communicated.

See University of Oxford Core SOP 005 – Archiving of Essential Documents.

7. RELATED DOCUMENTS

University of Oxford Core SOP 005 - Archiving of Essential Documents

8. REFERENCES

None

9. 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