UNIVERSITY OF LEEDS / NHS The Leeds Teaching Hospitals NHS Trust Standard Operating Procedure	Title	Version Control for Trial Documentation				
	Scope	Describes the process all staff must follow when applying version control to UoL/LTHT sponsored clinical trial documentation.				
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Details:

Original author:	Daniel Skinner, QA Portfolio Coordinator
Last reviewed by:	Phil Barry, QA Assistant
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Approval:

Version no. of SOP	Name of person approving this SOP	Date	Signature of the person approving this SOP
3.0	Clare E Skinner Head of Research Integrity and Governance Secretariat University of Leeds	07.02.2020.	Clare E
	Stephanie Britt QA Manager (Clinical Trials) University of Leeds / Leeds Teaching Hospitals NHS Trust	06/02/2020	S. Britt

Distribution & Storage:

Distribution to:

Investigators and all members of research teams conducting or assisting with a CTIMP trial sponsored by the University of Leeds or Leeds Teaching Hospital NHS Trust.

Location of document:

Paper: QA Department, Room 5, Research and Innovation Centre, St James' University Hospital

Electronic: http://www.leedsth.nhs.uk/research/information-for-researchers/key-documents
http://lthweb.leedsth.nhs.uk/sites/research-and-development/resources/Sponsored%20CTIMPs%20%28Quality%20Assurance%29

Contents

Please note: *This SOP should be used and followed in conjunction with other UoL / LTHT SOPs developed for researchers to support study set up and management. These can be found on the LTHT website or by contacting R&I / QA directly. For clinical trials where Leeds is not the trial Sponsor, please refer to any Sponsor SOPs for further information.*

Section A: Introduction

1.1. This standard operating procedure (SOP) outlines the procedure for appropriate version control of study wide documents for Leeds Teaching Hospitals NHS Trust (LTHT) or University of Leeds (UoL) sponsored CTIMPs.

1.2. This SOP aims to ensure standardisation and continuity in version control procedures between all members of research staff working on CTIMPs sponsored by the Leeds Teaching Hospitals NHS Trust (LTHT) or the University of Leeds (UoL).

1.3. Appropriate version control must be implemented to ensure all members of staff are able to distinguish between different iterations of the same document, and ensure any approved changes in a document can be easily tracked.

1.4. A full audit trail of all documentation used throughout the life of the trial must be maintained in the Trial Master File (TMF) and where applicable the Investigator Site File (ISF).

Section B: Applicability

1.1. This SOP is applicable to all staff involved in the creation and modifying of study documents for UoL/LTHT sponsored CTIMPs.

Section C: LTHT / UoL Sponsored CTIMP - Version Control for Draft and Approved Documents

1.0. Appropriate Version Control for Draft Documentation

1.1. Initial drafts

1.1.1. When creating a new document, a consistent numbering system must be used. Appropriate version control should be applied to **each** page of a trial document, and should be followed by the date on which the document was created / amended. The initial draft of any trial document should be named *'Version 0.1, insert date of draft'*.

1.1.2. When further changes to the initial draft are made, (prior to REC/HRA/MHRA submission) these must be numbered sequentially from *'Version 0.1'* to *'Version 0.2'* to *'Version 0.3'* etc. together with amending the date. This applies to all versions of documents submitted to Sponsor QA for review.

1.2. Finalising a draft document

1.2.1 Once all outstanding queries regarding content have been resolved and the document has been approved by the QA Office as ready for REC/HRA/MHRA regulatory submission, the document should be marked as *'Version 1.0'* and the *'draft'* and date label removed (if applicable).

2.0 Appropriate Version Control for Non-Substantial Amendments

2.1 When a non-substantial amendment to a document is required, the version number must be updated to demonstrate there has been a change to the document content.

2.2 For non-substantial amendments, once changes are made to the document the version number must be increased by 0.1 (e.g. *'Version 1.0'* would become *'Version 1.1'*).

2.3 All amendments must be submitted to the Sponsor QA Office for assessment and approval **prior** to submission to the relevant regulatory authorities (please see ***'QCRES_03_Researchers guide to Notification of Amendments for UoL / LTHT Sponsored CTIMPs'***).

2.4 To enable clear differentiation between multiple drafts of an amended document **prior to** regulatory submission, each draft should be labelled with a sequential draft number followed by the revision date (e.g. *'Version 1.1 - Draft 1, 26/07/2017'*; *'Version 1.1 - Draft 2, 27/07/2017'*; etc.).

2.5 Once all outstanding queries regarding content have been resolved and the document has been formally approved by the QA Office as ready for regulatory submission (via a signed ***CTT05_LTHT UoL Sponsor Notification of CTIMP Amendment*** form), the *'draft'* label should be removed (e.g. *'Version 1.1, 27/07/2017'*).

3.0 Appropriate Version Control for Substantial Amendments

3.1 When a substantial amendment to a document is required, the version number must be updated to demonstrate there has been a change to the document content.

3.2 For substantial amendments, once changes are made to the document, the version number must be increased to the next whole number (e.g. *'Version 1.0'* would become *'Version 2.0'* or alternatively, where a non-substantial amendment precedes a substantial amendment; *'Version 1.1'* would become *'Version 2.0'*).

3.3 All amendments must be submitted to the Sponsor QA Office for assessment and approval **prior** to submission to the relevant regulatory authorities (please see '***QCRES_03_Researchers guide to Notification of Amendments for UoL / LTHT Sponsored CTIMPs'***).

3.4 To enable clear differentiation between multiple drafts of an amended document **prior to** regulatory submission, each draft should be labelled with a sequential draft number followed by the revision date (e.g. *'Version 2.0 - Draft 1, 26/07/2017'*; *'Version 2.0 - Draft 2, 27/07/2017'*; etc.).

3.5 Once all outstanding queries regarding content have been resolved and the document has been formally approved by the QA Office as ready for regulatory submission (via a signed ***CTT05_LTHT UoL Sponsor Notification of CTIMP Amendment*** form), the *'draft'* label should be removed (e.g. *'Version 2.0, 27/07/2017'*).

4.0 Version History - Clean and Tracked Changes

4.1 All changes to documents must be made using the 'Track Changes' function on Microsoft Word. This provides a complete audit trail of the changes made, allowing the Sponsor and Regulatory Authorities to fully assess the changes and provide approval.

4.2 When submitting documents to the Sponsor and Regulatory Authorities, **both** clean and tracked versions must be submitted.

4.3 Both clean and tracked versions should be stored internally within the TMF/ISF for audit trail purposes.

5.0 Maintaining Records

5.1 All versions of documents must be retained in the TMF/ISF, in order to provide a clear audit trail of the changes made throughout the trial.

5.2 Electronic copies must be stored on the research team's departmental drive, and file names labelled accordingly to reflect the document's version control, for example:

'ExampleLocalProjectReferenceNumber_ExampleTrialName_Protocol_V1.2_20170512.pdf'

5.3 Superseded documents should not be removed from the TMF/ISF, but instead clearly marked as superseded by striking a single line through the document and annotating it as 'superseded', and adding a 'superseded' label to the electronic file name, for example:

'ExampleLocalProjectReferenceNumber_ExampleTrialName_Protocol_V1.2_20170512_superseded.pdf'

5.4 Once approved, the amended documentation must be communicated to all members of the research team, and all local support departments associated with the study (please see ***'QCRES_03_Researchers guide to the Notification of Amendments for UoL/LTHT sponsored CTIMPS'***).

5.5 For more guidance on appropriate TMF/ISF maintenance please see '***LTU_QM24_A Researchers Guide to Trial Documentation***'.

Section D: References

CTT05_LTHT UoL Sponsor Notification of CTIMP Amendment
LTU_QM24_A Researcher's Guide to Trial Documentation
MHRA Good Clinical Practice Guide 2012: p. 446, Version Control for Written Procedures.
MHRA Good Clinical Practice Guide 2012: pp. 124-125, 4.4 Version Control
QCRES_03 Researchers Guide to Notification of Amendments for UoL/LTHT Sponsored CTIMPs
REC/HRA Guidance: http://www.hra.nhs.uk/

Section E: Acronyms

CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
ISF	Investigator Site File
LTHT	Leeds Teaching Hospitals NHS Trust
MHRA	Medicines and Healthcare products Regulatory Agency
QA	Quality Assurance
R&I	Research and Innovation
REC	Research Ethics Committee
SOP	Standard Operation Procedure
TMF	Trial Master File
UoL	University of Leeds

Section F: Previous versions of Document

Version no.	Valid from	Approved by	Date approved
2.0	10/10/2017	Clare Skinner Louise Brook	24/10/2017
1.0	29/09/2016	Clare Skinner Louise Brook	05/10/2016