Standard Operating Procedure CCTU/SOP031

Version Control of Clinical Research Project Documents

1. Scope

This Standard Operating Procedure applies to staff of the Cambridge Clinical Trials Unit (CCTU), Chief Investigators and their trial teams working on Cambridge Sponsored clinical research projects coordinated by the CCTU.

This SOP does not apply to documents managed through Q Pulse

2. Purpose

To outline the process for applying version control to any documents relating to research projects.

The Medicine and Healthcare products Regulatory Agency (MHRA) and the HRA both require that documents submitted are appropriately version controlled.

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Audit trail	A chronological record, set of records, and/or destination and source of records that provide documentary evidence of the sequence of activities that have affected at any time a specific operation, procedure, or event.
Controlled document	Documents are controlled when they must undergo formal review and approval, controlled distribution, and their revision status, approval body and date of approval is evident in order to maintain the integrity of the document's content.
Version control	Version control is the process by which different drafts and versions of a document or record are managed. . Each time the content is changed, a copy of the content is saved and its identifier (version number) is incremented to indicate its difference from the previous copy. It provides an audit trail for the revision and update of the various versions.

Clinical research project	Any research project involving human subjects. This can be a CTIMP, non-CTIMP, device investigation, epidemiological study etc.

3.2. Abbreviations

Abbreviation	Meaning
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
OOH	Out of Hours (test)
REC	Research Ethics Committee
SAP	Statistical Analysis Plan
TMF	Trial Master File

4. Undertaken by

Chief Investigators and their trial teams

All CCTU personnel have a responsibility to ensure compliance with this SOP

5. Items Required

CCTU/SOP015 TMF/ISF Essential Document Management

6. Summary of Significant Changes

Standardisation of a file naming convention

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

7.1. Document identifiers

Trial specific documents must include identifiers in the document e.g.:

- Name of the research project (Trial ID)
- Date document was created or revised
- Version number
- Page number x of y format

Other identifiers as appropriate e.g.:

- IRAS ID
- ISRCTN
- R&D Number
- CCTU Number
- Authors name

Consider which identifiers should be replicated in the header or footer for ease of identification and to ensure no loss of documents

7.2. Documents that require version control

- Documents produced by the CCTU or the research team members relating to the conduct of clinical research projects must be version controlled. This includes but is not limited to:
- Clinical trial/clinical research project/study protocol/Trial level SOPs
- GP letters
- Participant facing documents e.g.
    - Patient Information Sheets
    - Informed Consent Forms
    - Patient ID Cards and where applicable, leaflets, posters, patient diaries, etc
- Case report forms and completion guidelines
- Variables list
- Statistical analysis plan
- Data management plan
- Work guides/manuals (e.g. pharmacy manual, sample handling manual etc)
- Logs (delegation, screening, etc.)

7.3. File naming convention

- Filenames should follow the same format "study + title + version number + date (eg:20JUL2022)", where title is a few words giving the purpose/type of the document
    - Eg: Trial ID Protocol v2.0 21Jun2022
- Please include any other relevant information in the 'title' section eg: site name or patient number as required for identification
    - Eg: Trial ID Cambridge OOH file note v1.0 21Jun2022
- Do not add any unnecessary information if not needed for identification
- File names that are too lengthy will not be saved or opened appropriately in the shared drive

7.4. Version control

7.4.1. Development of documents until version 1.0

- Assigning version numbers must be done in a consistent manner
- The first draft should be labelled draft version 0.1 and dated
- Subsequent drafts will have an increase of '0.1' in the version number e.g. 0.2, 0.3, 0.4 etc) and dated
- Once approved, the document is assigned V1.0
- V1.0 is submitted for approvals (e.g. to Trust R&D, HRA, REC, MHRA, etc.)

7.4.2. Subsequent substantial amendments to documents

- Revisions to the document will be made by the delegated qualified person(s)

- The manager/owner of the document (usually the coordinator)must ensure all comments and revisions are collated and included into the final version
- Version changes should be tracked during this process
- Subsequent drafts will have an increase of '0.1' in the version number e.g.0.2, 0.3, 0.4 etc) and dated
- Once all reviewers have provided comments and these have been addressed, the Chief investigator or delegated person will approve the document (by paper or electronically as appropriate)
- Once approved they are assigned a new version number (i.e. V2.0, V3.0, etc) and dated. Documents will follow this "one dot" version-control process (V2.0, V3.0) when there are no minor amendment versions applicable. Examples include:
    - Case report forms
    - Trial study databases
    - Randomisation system specifications
    - Statistical Analysis Plans (SAP)

7.4.3. Subsequent minor amendments to documents

- Revisions to the document will be made by the delegated qualified person(s)
- The manager/owner of the document (usually the coordinator)must ensure all comments and revisions are collated and included into the final version
- Version changes should be tracked during this process
- 2 dots are used, so "V1.3.1" will be the first draft of a minor amendment between V1.3 and V1.4
- Once all reviewers have provided comments and these have been addressed, the Chief investigator or delegated person will approve the document (by paper or electronically as appropriate)
- Once approved, the documents are version controlled by the number following the decimal point (i.e. V1.1, V1.2, V1.3, V1.4, V1.5, etc. and dated
- Examples of documents that may need a minor amendment:
    - The Protocol
    - Participant facing documents
    - Risk assessments forms, monitoring plans
    - Trial manuals

7.5. Collating external collaborator comments into master document

When working with collaborators across multiple organisations/groups, it is the responsibility of the trial coordinator or delegated individual to collate all the comments into a single 'master' draft document and version control these master drafts according to the file naming convention before saving in the shared drive.

7.6. Complex or external documents used in the CCTU

- Where multiple related documents or IT systems are provided e.g:
    - Internally by CCTU e.g. The UAT for internally built databases

  - Externally e.g. A randomisation system externally supplied, with a specification written in house
- Ensure that the version numbering provided by the supplier is recorded in an appropriate internal document with any relationships between documents or systems made clear
- A file note may be necessary for particularly complex document sets

7.7. Filing of controlled documents

- Approved versions must be printed and filed in the TMF (see CCTU/SOP015)
- Superseded, approved versions must be marked as 'Superseded' with a line through the first page initialled and dated. All superseded versions of approved documents must be kept in the TMF
- Electronic WORD or PDF versions of documents should also be kept to allow sharing electronically and for revisions to be made as necessary

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

10. Associated Documents

CCTU/SOP006 Archiving in the CCTU

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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