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.

2. Purpose

To outline the process for applying version control to any documents relating to research projects that are managed outside Q Pulse.

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 Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge 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
REC	Research Ethics Committee
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

Clarification that the master copy of the final version of the protocol must have a wet signature

7. Method

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

7.1. Documents that require version control

Documents produced by CCTU or 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
- GP letter
- Documents given to research participants, e.g. Patient Information Sheet, Informed Consent Form, Patient ID Cards and where applicable, leaflets, posters, patient diaries, etc.
- Case report forms and completion guidelines
- Statistical analysis plan
- Data management plan
- Work guides/manuals (e.g. pharmacy manual, sample handling manual etc)
- Logs (delegation, screening, etc.)

7.2. Version control and naming convention

- Trial specific documents must include the following (as appropriate):
  - Name of the research project
  - IRAS ID and other identifiers (e.g. EudraCT Number for CTIMPS, ISRCTN)
  - Date document was created or revised
  - Version number
  - Page number
  - Author name (if appropriate)
- Assigning version numbers should be done in a consistent manner
- The first draft of the document 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
- Revisions to the document will be made by the relevant qualified person(s)
- 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).
- If the approver(s) requests changes the version number increases by a decimal point
- Once approved the document is assigned V1.0
- This final V1.0 is submitted for the relevant approvals (e.g. to Trust R&D, HRA, REC, MHRA, funders etc.)
- Each major/substantial amendment of the approved document should be assigned a new Version Number (i.e., V1.0, V2.0, V3.0, etc) and dated
- Every minor amendment should result in an increased sub-version number represented by the number following the decimal point (i.e. V1.1, V1.2, V1.3, V1.4, V1.5, etc. and dated

7.2.1. Protocol

- Every final, approved version of the protocol must have a CI wet signature and date and filed in the appropriate section of the TMF. Refer to CCTU SOP015
- A log of copies in circulation should be kept in the TMF.
- An electronic version of the protocol may be distributed in portable document format (.pdf) labelled or watermarked stating that they are considered uncontrolled and have the security applied to prevent editing

7.3. Filing of controlled documents

- All final, approved versions of documents 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.
- A version control table with details of document versions and dates of creation, approval and implementation should also be created and filed in the TMF along site the relevant documents

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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