Royal Papworth Hospital
NHS Foundation Trust

Document Title: Version Control of Study Documents

Document Number: PTUC SOP060

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	October 2028

Summary of Amendments

Version:	Modification:
4.0	Minor administrative changes
5.0	Minor administrative changes. Reviewed for changes in regard to the new clinical trial R3 regs.

Key related documents:	SOP077 Data Management Overview

Key Points of this Document

a. This document sets out the procedures to be followed by all Staff who are involved in the preparation of study documents for Royal Papworth sponsored research studies.

b. It provides guidance on the correct use of version numbers in the production and finalisation of study documentation.

1 Purpose and Content

a. This document defines the procedure for the writing and preparation of study documents for use in Research Studies and Clinical Trials which are managed by Royal Papworth Trials Unit Collaboration (PTUC) or sponsored by Royal Papworth NHS Foundation Trust.

b. The document clarifies the requirements for accurate version control of study documents produced for Royal Papworth sponsored research studies as to comply with the requirements stated in ICH GCP guidelines.

c. The document aims to provide clear guidance on how to produce correctly version controlled documentation and how these should be reviewed and updated.

d. Version control is the process by which different drafts and versions of a document are dated and managed. It provides an audit trail for the drafting and updating of a finalised version of a document. Version control must be used when more than one version of a document exists, or when this is likely to be the case in the future.

e. For version control of Case Report Forms see SOP077 Data Management Overview.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are involved in advising on, writing or reviewing documents for research studies managed by Royal Papworth Trials Unit Collaboration (PTUC) or sponsored by Royal Papworth NHS Foundation Trust.

b. Staff preparing study documents must comply with the requirements set out in section 4.

c. The Chief Investigator (CI) and their trial teams are responsible for the version control of the documents. All relevant staff must be notified of any changes to version controlled documentation and ensure appropriate training is given, if required, following the new version.

d. The CI must ensure that if they delegate the role of version control to another member of the research team, that they have sufficient knowledge and expertise.

3 Policy

a. This SOP is mandatory and, as per the Trust's Research Governance framework, non-compliance with may result in disciplinary procedures.

4 Procedure

Development of documents until version 1.0

a. The first draft should be labelled draft version 0.1 and dated.

b. A 'draft' water mark should be used on all draft versions of any documents to provide clarity and avoid ambiguity. The watermark must be removed once the document is finalised.

c. Subsequent drafts will have an increase of 0.1 in the version number e.g. 0.2, 0.3, 0.4 etc. and dated.

d. Procedures should be in place to ensure that in addition to the completed version, each draft version of the document is saved and clearly identified by its file name.

e. Once approved the document is assigned V1.0.

f. The version number and review date, (if required) will be documented on the footer of each document.

g. In general, V1.0 is submitted for approval (e.g. to Trust R&D, MHRA, HRA, REC etc.)

Subsequent modifications to documents

a. Revisions to documents will be made by the delegated qualified person(s).

b. Version changes should be tracked during this process.

c. Subsequent drafts will have an increase of 0.1 in the version number (e.g. 1.1, 1.2, 1.3 etc) and dated.

d. Once approved the document will be assigned the next sequential number (e.g. 2.0).

e. This process should be repeated for every revision made to a document.

f. A copy of each finalised and approved document should be stored in the appropriate section of the trial master file.

g. Superseded versions of final documents must be clearly marked and archived appropriately. If this is paper the document should be scored through, marked as superseded, initialled and dated. Electronic word or PDF versions of superseded documents should be moved to a superseded document folder within the eTMF.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved date]
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	October 2028