STU-SOP-ADM-002 – Standard Operating Procedure on Document Control

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for the control of documents produced or used by Swansea Trials Unit (STU) and how such documents will be differentiated between versions.

2. Background

In compliance with the UK policy framework for health and social care and Good Clinical Practice (GCP) there is a requirement that project documents sent to an ethics committee, or which will require updating during the project are version controlled. Additionally, non-study documents such as policies, SOPs, forms, quality control and quality assurance data and risk assessments should be version controlled.

Some documents may not be formally version controlled (e.g. staff CVs) however, procedures should be in place to ensure these are updated regularly and only current versions are accessible.

An appropriate document control procedure should be applied to all documents produced by STU.

3. Roles and Responsibilities

The **STU Manager** is responsible for managing and overseeing document control for STU SOP and internal documents.

The **Quality Assurance Officer** (QAO) is responsible for assessing compliance of STU staff and researchers with the requirements for document control.

The **Chief Investigator** (CI) is responsible for the version control of all project level documents. The CI can delegate this responsibility but must maintain oversight.

The **Trial Manager** (TM) is usually delegated the role of managing the version control of project documentation.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Documents that require version control

Documents produced by STU or members of the research team relating to the conduct of the research project must be version controlled. Such documents include, but are not limited to:

- STU SOPs and associated documents
- Guidelines
- Research project protocol
- Documents given to research participants e.g. information sheets, participant diaries, posters etc.
- Case Report Forms (CRFs)
- Project Logs e.g. document, delegation, screening
- Data Management Plan
- Statistical Analysis Plan
- Trial specific SOPs

SOPs and policies should maintain a summary of changes made from previous versions. This will be in the form of a table of tracked changes on a word document, and a subsection for revision history. Research project specific documents will usually be updated using tracked changes, the superseded version retained and a document log kept as appropriate.

4.1.1 Externally produced documents

Many documents used in research projects are likely to have been produced by external authors/organisations e.g. ICH, GCP guidelines, equipment manuals, Trust or University policies. When accessed, it is important that current versions are used and that they are subject to control processes to ensure that updated versions are obtained.

External documents will have a different numbering system depending on their origin. These documents may be given an internal STU number to comply with the unit's document control procedure.

4.2 Drafting a document

All documents drafted by STU staff must comply with a standard numbering system. The version number and title should be consistent throughout the document.

All documents should have the following information available either on the front page or as a header/footer on each page:

- Page number
- Title, document number or code and version number – these should ensure that every document is uniquely identifiable.
- The effective date may be added to documents if appropriate (e.g. SOPs, policies)

Research project specific documents require the name of the trial and other identifier as appropriate:

- REC number
- ISRCTN /CT.gov number
- EudraCT number (CTIMPS, where required)
- The date
- A version number
- Page number format

Assigning version numbers will be completed in a consistent manner:

a. For STU internal documents the Document Review Group (DRG) Secretary will issue the version number and track each draft until completion before assigning the final version number.
b. For research project documentation a team member (usually the TM) will issue the version number and track each draft until completion before assigning the final version number.

4.2.1 Document development

During the development of the first version, each successive draft of the document must be numbered sequentially 0.1, 0.2, 0.3 etc. Multiple reviewers can indicate they have updated the draft by adding their initials to the end of the draft title e.g. V0.1AA-BB-CC. The first final version should usually be identified as Version 1.

The version number should be added at the end of the file name and within the final document i.e. on the title page and header or footer of each page (the document cover page need not have the number and date in the header or footer). The preferred format for the date is dd/mmm/yyyy.

4.2.2 Document amendments

During review, draft versions should be numbered sequentially as 1.1, 1.2, 2.1, 2.2 etc., with subsequent iterations being increased to the next decimal. Each amendment of the approved document should be assigned a new version number (i.e. V1, V2, V3 etc. and dated).

4.3 Electronic and Hard copy filing of documents

All STU SOPs, associated documents and policies will be held in Q-Pulse. For these documents, an electronic authorisation within Q-Pulse is acceptable. STU internal documents will be filed in an appropriate folder and kept securely if wet ink signed.

For STU documents, an electronic file will hold draft versions of documents clearly identifiable by filename.

For project specific documentation, a copy of draft and final version of research project documents should be filed in the Trial Master File (TMF), which may be electronic, paper or a hybrid system. If wet ink signatures are used, the original will be kept in the TMF.

A Version Control Log (STU-AD-TMP-003) should be kept for all key project documents.

All previous approved versions must be filed:

a. Electronically in a folder marked superseded / archived.
b. Hard copy in either a named file (STU documents) or a TMF for research projects.

At the end of the research project all versions must be archived according to STU-SOP-TC-001 Archiving.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-TMP-003	Version Control Log	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
DRG	Document Review Group
GCP	Good Clinical Practice
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
QAO	Quality Assurance Officer
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
TM	Trial Manager
TMF	Trial/Project Master File

8. Appendices

Appendix 1: Document History

Version No:	3	Effective Date:	25-Mar-2024
Description of changes:	Update numbering for version control to whole numbers only. Transferred to SOP Template v5.		