STANDARD OPERATING PROCEDURE FOR THE USE OF VERSION CONTROL OF STUDY DOCUMENTS USED IN HEALTH AND SOCIAL CARE RESEARCH STUDIES

SOP NUMBER:	TASC SOP047 v9
AUTHOR:	Patricia Burns
EFFECTIVE DATE:	26 Jan 2026
REVIEW DATE:	26 Jan 2028

1. PURPOSE

This document describes the procedure for version control of essential records used in health and social care research studies.

2. SCOPE

This SOP is intended for use by all staff who have the responsibility for maintaining records for health and social care research studies that are sponsored or co-sponsored by the University of Dundee and/or NHS Tayside.

3. RESPONSIBILITIES

Chief Investigator: to ensure study staff involved in the study adhere to this SOP, other staff as appropriate dependent on their role and activity.

4. PROCEDURE

4.1 Documentation must be version controlled with a version number and version date printed on each page of the document. This can be the footer.

4.2 In any application for Sponsorship, documents must be identified as “draft” in the first instance.
Example:
“Protocol Draft Version 1: 01.01.2019”, the documents may become:
“Protocol Draft Version 2: 01.01.2019”,
“Protocol Draft Version 3: 01.01.2019” etc as account is taken of required changes.

The format for naming documents must be consistent throughout the study.

4.3 Once Sponsorship is confirmed, the word “Draft” is no longer appropriate, and the documents must be updated to Version 1.
Example: “Protocol V1: 01.02.2019”.

This ensures that Version 1 is the document that goes to the Research Ethics Committee (REC) and other approvers as required.

4.4 No change can be made to any approved study document without approval of the Sponsor following the TASC SOP on Modifications to Healthcare Projects.

4.5 Any changed documents should be given a new version number and date.

4.6 Version numbering should never use decimals (e.g. V1.1, V2.3 etc) as this does not permit an adequate audit trail.

4.7 New versions of approved documents should be documented on the Modification Log (Doc Ref 087).

4.8 In addition to documents submitted for Sponsor approval, version control for other study documents and templates e.g. Data Management Plans, Operational Manuals and Case Report Forms (CRF) must be maintained.

5. ABBREVIATIONS & DEFINITIONS

CRF	Case Report Form
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 087: Modification Log

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
7	Patricia Burns (Senior RGM)	03/02/2022	Scheduled review. Addition to text in section 4.1 to say that the version number must be on each page of the document.
8	Patricia Burns (Senior RGM)	26/01/2024	Scheduled review. Addition to text in section 4.2 to say that the format for naming documents must be consistent throughout the study.
9	Patricia Burns (Senior RGM)	26/01/2026	Biennial review. Vocabulary changed in line with ICH-GCP R3 updated terms.

8. APPROVALS

Approved by:	**Date:**
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	21 Jan 2026