



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

SOP NUMBER:	TASC SOP047 v8
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REVIEW DATE:	26 Jan 2026

### 1. PURPOSE

This document describes the procedure for version control of essential documents 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 documents 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”.

Uncontrolled when printed. Please visit the [TASC website](#) for the latest version of this SOP.

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 Amendments 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 Amendment 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: Amendment 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.

## 8. APPROVALS

<b>Approved by:</b>	<b>Date:</b>
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	23 Jan 2024