STANDARD OPERATING PROCEDURE FOR THE PREPARATION, APPROVAL AND REVIEW OF STANDARD OPERATING PROCEDURES FOR TAYSIDE MEDICAL SCIENCE CENTRE

SOP NUMBER:	TASC SOP01 v15
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EFFECTIVE DATE:	08 Oct 2026
REVIEW DATE:	08 Oct 2028

1. PURPOSE

This Standard Operating Procedure (SOP) documents the procedure for the preparation and control of TASC SOPs to ensure that they are presented in a standard format.

2. SCOPE

This SOP will apply to any individual delegated the task of writing or reviewing SOPs for TASC.

3. RESPONSIBILITIES

TASC Quality Assurance Manager (QA) or delegate:

- will control and manage TASC SOPs and associated documents to ensure that the current versions are available on the TASC website.
- will notify researchers and associated staff by email of new or revised versions of SOPs.

Researchers and other users:

- must refer to the TASC website to make sure that they are using the current version of a TASC SOP or associated document.

4. PROCEDURE

4.1 Preparation of a new SOP

4.1.1 A SOP should be written by a qualified and experienced individual as soon as the need is identified. The TASC Clinical Research Guidelines Committee (CRGC), the TASC QA Manager or the TASC R&D Director may nominate authors.

4.1.2 Each new SOP will be prepared using the TASC SOP template (Doc Ref 001). The author will describe the procedure in a concise manner with sufficient detail to facilitate accurate performance of the procedure.

4.1.3 Draft SOPs and any associated documents will be emailed to the TASC QA team (TASCSOPs@dundee.ac.uk) who will disseminate them to the CRGC for review and

approval within stated timelines. The CRGC will be asked if any staff training will be required before the SOP becomes effective.

4.1.4 Comments and suggested changes to the SOP will be considered and included if there is agreement from the author and reviewers.

4.1.5 When the SOP is approved by the CRGC, the TASC QA team will:

- assign a unique SOP number, version number, effective date and review date.
- assign a Doc Ref number, version number and effective date to any documents associated with the SOP.

4.1.6 The Chair of the CRGC will confirm approval of the SOP on behalf of the CRGC, by email to the TASC QA team. The R&D Director or delegate (Senior R&D Manager) will also send an email to confirm their approval.

4.1.7 The TASC QA Manager or delegate will ensure that new SOPs and associated documents are available on the TASC SOP website and update the TASC SOP Index List.

4.1.8 The TASC QA Manager or delegate will notify researchers and associated staff by email (email addresses provided by Research Governance) of new versions of SOPs.

4.2 Review of a SOP

4.2.1 TASC SOPs, with their associated documents, will be formally reviewed every 2 years unless changes in legislation or procedures require an earlier review.

4.2.2 The TASC QA team will notify the SOP author to review the current version of the SOP. If the author is unavailable, the CRGC, TASC QA Manager or R&D Director will allocate the role of author to an appropriately qualified and experienced person. This does not necessarily mean that this individual will automatically become the author. However, if an author is no longer available in the long term, the TASC QA Manager or R&D Director will reallocate the role to an appropriately qualified and experienced person.

4.2.3 The TASC QA team will provide the author with the current word version of the SOP. If amendments are required, the author may track changes, insert comments into the SOP, and summarise the amendments in the Document History table. If the SOP is reviewed with no changes required, this should also be recorded in the Document History table. Associated documents should also be reviewed and any changes recorded.

4.2.4 Following author review, the draft SOP and any associated documents will then be emailed to the TASC QA team (TASCSOPs@dundee.ac.uk) who will disseminate them to the CRGC for review and approval within stated timelines. The CRGC will be asked if any staff training will be required before the SOP becomes effective.

4.2.5 Comments and suggested changes will be considered and included if there is general agreement from the author and reviewers. If the author made no changes to the SOP at review date, CRGC will be informed.

4.2.6 When the SOP is approved by the CRGC, an updated version number, effective date and review date will be provided by TASC QA team. The SOP version number will increase by an increment of 1. If an associated document is amended, the version will be increased by an increment of 1 and a new effective date added.

4.2.7 The Chair of the CRGC will confirm approval of the SOP on behalf of CRGC, by email to TASC QA team. The R&D Director or delegate (Senior R&D Manager) will also send an email to confirm their approval.

4.2.8 The TASC QA Manager or delegate will ensure that revised SOPs and associated documents are available on the TASC SOP website and update the TASC SOP Index List if required.

4.2.9 The TASC QA Manager or delegate will notify researchers and associated staff by email (email addresses provided by Research Governance) of revised versions of SOPs.

4.3 TASC SOP management

The TASC QA team will:

- allow time for staff training if required before release of a revised or new SOP.
- store the Master SOPs and associated documents securely in the TASC Controlled Documents Folder. Access to the TASC Controlled Documents Folder will be restricted to the TASC QA Manager and delegates.
- archive superseded SOPs and associated documents in designated folders for a timeline according to current local instructions.

4.4 Work Instructions

TASC Work Instructions (WIs) are created by individual groups within and associated with TASC to cover local requirements. Each team is responsible for the upkeep of their own WIs in accordance with the TASC SOP on the preparation, approval and review of WIs for TASC.

5. ABBREVIATIONS & DEFINITIONS

CRGC	Clinical Research Guidelines Committee
QA	Quality Assurance
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
WI	Work Instruction

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 001: TASC SOP template

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:
12	Valerie Godfrey (TASC QA Manager)	06/10/2021	Signed SOP Master documents are now electronic rather than paper.
13	Valerie Godfrey (TASC QA Manager)	04/04/2023	Transferred to updated SOP template which is Accessibility compliant. Issue date removed. Changed to a single Approver with no signature required.
14	Valerie Godfrey (TASC QA Manager)	04/04/2025	Hot Tips mailing list no longer in use for sending update notifications. Section 4.4 (WIs) updated.
15	Valerie Godfrey (TASC QA Manager)	08/10/2026	Added: i) CRGC will be asked if any staff training is required before an SOP becomes effective, ii) the R&D Director, or delegate (Senior R&D Manager), will confirm SOP approval and iii) made reference to the new TASC WI SOP in section 4.4.

8. APPROVALS

Approved by	Date
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	07 Oct 2026
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	07 Oct 2026