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

SOP NUMBER:	TASC SOP01 v14
AUTHOR:	Valerie Godfrey
EFFECTIVE DATE:	04 Apr 2025
REVIEW DATE:	04 Apr 2027

1. PURPOSE

To document the procedure for the preparation and control of TASC Standard Operating Procedures (SOPs) to ensure that they are presented in a standard format.

2. SCOPE

This SOP will apply to any individual delegated the task to write or review 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.
- notify researchers and associated staff of new or revised versions of SOPs by email.

Researchers and other users:
- must always 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 as soon as the need is identified. SOPs should be written by individuals who are recognised as being appropriately qualified and experienced to carry out the task. Authors may be nominated by the TASC Clinical Research Guidelines Committee (CRGC), the TASC QA Manager or the R&D Director.

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 and description to facilitate accurate performance of the procedure.

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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 TASC CRGC for review and approval within stated timelines.

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

4.1.5   When the SOP is approved by CRGC, 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 TASC CRGC will confirm approval of the SOP on behalf of CRGC, by email to the TASC QA team.

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

4.1.8   TASC QA Manager or delegate will notify researchers and associated staff of new versions of SOPs by email.

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   TASC QA team will notify the SOP author to review the current SOP. If an 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   TASC QA team will provide the author with a 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 highlighted.

4.2.4   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.

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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 TASC CRGC will confirm approval of the SOP on behalf of CRGC, by email to TASC QA team.

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

4.2.9   TASC QA Manager or delegate will notify researchers and associated staff of revised versions of SOPs by email.

4.3   SOP management

4.3.1   TASC QA team will:
- allow time for staff training before release of a SOP if required.
- 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 as appropriate.
- archive superseded SOPs and associated documents in designated folders indefinitely.

4.4   Working Instructions

4.4.1   TASC Working Instructions (WI) are created by individual groups within TASC to cover local requirements. Each team is responsible for the upkeep of their own WIs.

5. ABBREVIATIONS & DEFINITIONS

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

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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:
11	Tracy Petrie (Quality Assurance Support Officer)	18/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
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.

8. APPROVALS

Approved by	Date
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	02 Apr 2025

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