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

SOP NUMBER:	TASC SOP69 v1
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1. PURPOSE

This Standard Operating Procedure (SOP) details the requirements for the preparation and control of TASC Work Instructions (WIs) used in the conduct and/or oversight of clinical research studies to ensure that they are presented in a standard format in accordance with the TASC Quality Management System.

A SOP defines what needs to be done, who is responsible, and the purpose. If more detail is needed than is described in a SOP, a WI is used to describe how to perform a task. A WI is a detailed step-by-step guide describing how to implement the procedure. There can be several WIs associated with a single SOP.

2. SCOPE

This SOP will apply to any individual delegated to write, review, approve or manage WIs for any of the functional groups within TASC.

3. RESPONSIBILITIES

TASC Quality Assurance (QA) Manager or delegate:

- request a list of WIs from each functional group annually or sooner if any changes are required.
- maintain the list for oversight.

Functional Groups within TASC:

- each group is responsible for the upkeep of their WIs and must manage them according to this SOP.
- nominate a person and delegate to be responsible for WI management.
- identify an approver (e.g. Team Manager or Team Lead) to authorise WIs before implementation.
- have a WI on how to prepare and manage their own set of WIs.

Responsible person or delegate

- keep track of WI review dates to ensure that WIs remain current.
- maintain a Master File for storage of WIs current and previous with limited access so that inadvertent changes cannot be made by users.
- ensure that users have separate pdf or Read Only access to the group's current approved WIs.
- provide the TASC QA Manager (TASCQA@dundee.ac.uk) with a list of current WIs annually or sooner if any changes.
- be the point of contact for the TASC QA Manager (or delegate).

4. PROCEDURE

4.1 Preparation of a new WI

4.1.1 A new WI should be written as soon as the need is identified by a qualified and experienced individual.

4.1.2 Each new WI should be prepared using the TASC WI template (Doc Ref 133). The author will describe the procedure with sufficient detail to enable users to carry out the procedure accurately and consistently and to check against any relevant TASC SOP to ensure constancy in content.

4.1.3 Draft WIs and any associated documents should be shared amongst group members and other relevant personnel for review and comment.

4.1.4 Comments and suggested changes using track changes on the one document should be considered by the author and a final version agreed by the author and reviewers.

4.1.5 A unique Group identifier/WI number, effective date and review date will be assigned to the WI v1, e.g.

- Quality Assurance Team's unique group identifier would be QA WI001 v1, QA WI002 v1, QA WI003 etc.

- Research Governance Team's unique group identifier would be RG WI001 v1, RG WI002 v1, RG WI003 v1 etc.

4.1.6 A Group identifier/Doc Ref number, version number, effective date and review date will be added to any documents associated with the new WI.

4.1.7 The Document History table should be completed. Enter "New" under "Details of editions made" for the first version.

4.1.8 Each WI should state the author and approver (typically the Team Manager or Team Lead) with date of approval.

4.1.9 The responsible person or delegate will describe any required training.

4.1.10 The responsible person or delegate will create a pdf version of the WI Word version and ensure that all members of the group are notified and have access to the new WI and any associated documents (as referenced in the WI). Associated documents that are templates are not required to be converted to pdf versions.

4.2 Review of a WI

4.2.1 TASC WIs, and associated documents, will be reviewed every 2 years unless changes in legislation or procedures require an earlier review or the functional TASC group have documented a longer review period.

4.2.2 The responsible person or delegate will notify the WI author to review the current WI. If the author is unavailable, the role of author will be appointed to another appropriately qualified and experienced person who may/or may not take over authorship depending on the circumstances.

4.2.3 The author will be provided with the Word version of the WI. If any changes are made, these should be detailed in the Document History table. If no changes are made, this should also be recorded.

4.2.4 Associated documents should also be reviewed and any changes recorded on the Document History table of the WI.

4.2.5 The draft WI and any associated documents should be shared amongst group members and other relevant personnel for review and comment.

4.2.6 Suggested comments/changes should be considered and a final version agreed by the author and reviewers.

4.2.7 Upon approval, an updated version number, effective date and review date will be added to the WI. The WI version number will increase by an increment of 1, e.g. v1 becomes v2.

4.2.8 If an associated document is modified, the version will be increased by an increment of 1 and a new effective date added. This change should also be noted in the Document History table of the WI.

4.2.9 The author and approver (typically the Team Manager or Team Lead) and date of approval should be stated.

4.2.10 The responsible person or delegate will describe any training required.

4.2.11 The responsible person or delegate will create a pdf version of the WI Word version and ensure that all members of the group are notified and have access to the updated WI and any associated documents. Associated documents that are templates are not required to be converted to pdf versions.

4.3 WI management

4.3.1 The responsible person or delegate will allow time for staff training before release of a WI if required.

4.3.2 The Master WIs (Word and pdf versions) and associated documents will be securely stored in an access-controlled location (paper or electronic).

4.3.3 Superseded and withdrawn WIs and associated documents must be retained in designated folders in line with the relevant organisational retention policy.

4.3.4 Access to the Master WI Folder must be restricted to the responsible person and delegate.

4.3.5 Only pdf or Read-Only versions of current approved WIs should be made available to users.

4.3.6 Staff should update their training records for new or updated WIs.

4.3.7 The TASC QA Manager will be emailed at (TASCQA@dundee.ac.uk) with a list of current WIs annually or sooner if there are any changes.

5. ABBREVIATIONS & DEFINITIONS

QA	Quality Assurance
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
WI	Work Instruction

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 133 TASC WI template

7. DOCUMENT HISTORY

Version Number:	Reviewed by (job title):	Effective Date:	Details of editions made:
1	Valerie Godfrey (TASC QA Manager)	20/07/2026	New

8. APPROVALS

Approved by (job title)	Date
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	17 July 2026
Dr Valerie Godfrey (TASC Quality Assurance Manager) on behalf of TASC Clinical Research Guidelines Committee	16 July 2026