STANDARD OPERATING PROCEDURE FOR THE PREPARATION, APPROVAL, REVIEW AND DISTRIBUTION OF STANDARD OPERATING PROCEDURES AND WORK INSTRUCTIONS

SOP NUMBER:	**Fife R&D SOP01**
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1. PURPOSE

This document describes the procedure used for the preparation, approval, review and distribution of Standard Operating Procedures (SOPs) and Work Instructions (WIs) relating to Research & Development (R&D) in NHS Fife. The purpose of this document is to ensure that NHS Fife R&D SOPs and WIs are of a consistently high standard, have a standard format and comply with the principles of Good Clinical Practice (GCP).

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This SOP applies to any individual delegated the task to write, review, manage, distribute or acknowledge SOPs and WIs relating to Research & Development in NHS Fife.

3. POLICY

3.1 NHS Fife R&D SOPs and WIs should be viewed as generic documents that apply to clinical research that NHS Fife sponsors or hosts.

3.2 NHS Fife R&D SOPs and WIs, together with NHS Fife R&D Policies, are key elements of the NHS Fife R&D Quality Management System for clinical research.

3.3 NHS Fife R&D SOPs and WIs must be formally reviewed every three years unless changes in legislation or procedures require an earlier review.

4. PROCEDURE

4.1. Preparation of a New R&D SOP

4.1.1 A new R&D SOP must be drafted as soon as the need for a standard written procedure has been identified. SOPs must be written by an appropriate individual, determined by the NHS Fife Assistant Director Research, Innovation & Knowledge (RIK) or the R&D Quality & Performance Lead, who is recognised as being appropriately qualified and experienced to carry out this task.

4.1.2 The SOP number must be in the format: Fife R&D SOP*number*.

4.1.3 Each new SOP must be prepared in accordance with this SOP using the Fife R&D SOP Template (Doc Ref 01-01).

4.1.4 Each page must show the SOP number, the version, the date the SOP is effective from and the page number.

4.1.5 Associated documents, e.g., forms or templates that are provided with the SOP must each be given a Document Reference number (Doc Ref *SOPnumber*-01, -02, -03 etc.), a version number and an effective date.

4.1.6 The draft SOP must be circulated for review by appropriate member(s) of the NHS Fife R&D Operational Group, as determined by the Assistant Director RIK.

4.1.7 The final draft must then be reviewed and signed by the Assistant Director RIK or the Executive Lead for Research, Innovation & Knowledge.

4.1.8 Details of the new SOP must be included in an update at the next NHS Fife R&D Operational Group and the minutes of this meeting (including this update) circulated to the RIK Oversight Group. Meeting.

4.2. Preparation of a New WI

4.2.1 A new WI must be produced if there is a need identified for more detailed instructions for a process or procedure described in an SOP. WIs must be written by an appropriate individual, determined by the Assistant Director RIK or R&D Quality & Performance Lead, who is recognised as being appropriately qualified and experienced to carry out this task.

4.2.2 The author must ensure that the WI complies with any governing SOPs.

4.2.3 The WI number must be in the format: Fife R&D WI*number*.

4.2.4 Each new WI must be prepared in accordance with this SOP using the Fife R&D WI Template (Doc Ref 01-02).

4.2.5 Each page must show the WI number, the version, the date the WI is effective from and the page number.

4.2.6 Associated documents, e.g., forms or templates that are provided with the WI must each be given a Document Reference number (Doc Ref WI*number* -01, -02, -03) a version number and an effective date.

4.2.7 The draft WI must be circulated for review by appropriate member(s) of the NHS Fife Operational Group determined by the Assistant Director RIK.

4.2.8 The final draft must then be reviewed and signed by the Assistant Director RIK.

4.2.9 Details of the new WI must be included in an update at the next NHS Fife R&D Operational Group Meetings.

4.3. Formal Review of R&D SOPs and WIs

4.3.1 The R&D Quality and Performance Lead must notify the SOP or WI author, or another individual nominated by the Assistant Director RIK or R&D Quality and Performance Lead if the author(s) is no longer able to take responsibility for the document, that review is required.

4.3.2 If amendments are required, the reviewer must track changes into the SOP or WI and insert details of any amendments in the Document History table.

If the SOP or WI is reviewed with no changes, this must also be recorded in the Document History table by the reviewer.

4.3.3 A new version number, issue date, 'effective from date', and review date must be inserted on the front page. If an associated document is amended, the version number of this document must be increased, and a new effective date added.

4.3.4 Amendments to the SOP or WI and any associated documents must be reviewed by an appropriate member(s) of the NHS Fife R&D Operational Group, determined by the Assistant Director RIK.

4.3.5 The final draft of a revised SOP must be reviewed and signed by the Assistant Director RIK or the Executive Lead for Research, Innovation & Knowledge.

4.3.6 The final draft of a revised WI must be reviewed and signed by the Assistant Director RIK.

4.3.7 Details of revised SOPs and WIs must be included in an update at the next NHS Fife R&D Operational Group Meetings.

4.4. Management of SOPs and WIs

4.4.1 The Assistant Director RIK will oversee the management of NHS Fife R&D SOPs, WIs and associated documents. The day-to-day management of the SOPs and WIs will reside with the R&D Quality & Performance Team, to ensure that current versions are available via StaffLink, EDGE, Q-Pulse and the R&D section of the NHS Fife website (SOPs only).

4.4.2 Electronic copies of current R&D SOPs, WIs and associated documents must be stored as PDF and WORD files in the 'R&D SOP Controlled Documents' folder in S:\Research\HOW TO\SOPs and POLICIES\R&D SOP Controlled Documents. Access to this folder will be restricted to the Assistant Director RIK and to delegated R&D staff with responsibility for managing the preparation, review and distribution of SOPs and WIs.

4.5. Distribution of SOPs and WIs

4.5.1 Once approved and signed off, each new or revised SOP and WI must be uploaded to StaffLink, EDGE, Q-Pulse by the R&D Quality and Performance Team.

4.5.1.1 Admin permission level and guidance on uploading documents to StaffLink is provided by the NHS Fife Communications Team (fife.communications@nhs.scot).

4.5.1.2 Guidance on uploading documents to EDGE is available from the KnowledgeBase on EDGE (https://www.edge.nhs.uk/KnowledgeBase/1/Sections/2/Articles/41).

4.5.1.3 Guidance on uploading and distributing documents in Q-Pulse is available via the document 'Document Control in Q-Pulse' in the R&D External Documents folder in Q-Pulse.

4.5.2 New or revised SOPs, WIs and associated documents that require a training period before they become effective must be uploaded into the 'R&D SOPs & WIs in Training Period' folder of the R&D page on StaffLink as soon as they are issued, to allow time for staff to read, understand and receive appropriate training. A notification must also be sent to all relevant R&D Department staff (see distribution lists Doc Ref 01-03, and Doc Ref 01-04) by sharing a Priority Post via StaffLink.

The SOP, WI and associated documents will become effective within 4 weeks of their issue date. At their effective date the R&D Quality & Performance Team must delete the SOP, WI and associated documents from the 'R&D SOPs & WIs in Training Period' folder on StaffLink and add them to the active SOP or WI folder.

4.5.3 At their Effective Date all SOPs, WIs and associated documents must be made active on Q-Pulse and distributed by the R&D Quality and Performance Team to all relevant R&D Department staff (see distribution lists Doc Ref 01-03, and Doc Ref 01-04) for either acknowledgment (copy holders) or notification only, as determined by the Assistant Director RIK.

4.5.4 If a document has only minor amendments *e.g.,* typographical that will not require subsequent staff training, then it must be uploaded directly to the appropriate active folder on StaffLink and distributed via Q-pulse. The document will therefore be immediately effective with no training period required.

4.5.5 The R&D Quality and Performance Team must also arrange for the NHS Fife Web Team (fife.webteam@nhs.scot) to upload new or revised SOPs to the R&D section of the NHS Fife website.

4.6. Acknowledgement of Documents on Q-Pulse

4.6.1 All copy holders must read and acknowledge the SOP, WI or associated document and by doing so they will be confirming that they are aware of the document, have read it and have undertaken any necessary training required to implement the procedures described.

4.6.2 Staff who are notified only, are not required to acknowledge the SOP, WI or associated document.

5. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 01-01 - Fife R&D SOP Template
Doc Ref 01-02 - Fife R&D WI Template
Doc Ref 01-03 - SOP Distribution List
Doc Ref 01-04 - WI Distribution List

6. ABBREVIATIONS

GCP Good Clinical Practice
R&D Research and Development
RIK Research, Innovation and Knowledge
SOP Standard Operating Procedure
WI Working Instruction

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	31 Oct 2014	Updated text from Tayside Medical Science Centre (TASC) version 6.0 to remove details of previous TASC SOPs. Issue date, procedure for control of SOPs and SOP associated documents and SOP archiving retention time added. Watermark text changed.
2	Julie Aitken R&D Trials Facilitator	18 Oct 2016	Contact person has been amended. New or revised SOPs will be uploaded initially on to a SOP training intranet page. The timeline for SOP training has been changed from 4-6 weeks to up to 6 weeks (section 4.3.5). SOPs that require no amendments at review will not require a training period. Further details of the procedure for preparation and approval of WIs has been added.
3	Julie Aitken R&D Trials Facilitator	04 Oct 2018	SOP and WI templates updated. Text revised to clarify and reflect current practice. Watermark removed and replaced with statement indicating document uncontrolled

			when printed.
4	Julie Aitken R&D Quality and Performance Lead	21 May 2021	Changed title to cover distribution of SOPs. Review period amendment from every 2 years to every 3 years Updated to include the process of uploading and distributing documents via StaffLink, EDGE and Q-Pulse. Updated to include the process for R&D Staff to acknowledge documents via Q-Pulse.
5	Julie Aitken R&D Quality and Performance Lead	22 June 2022	SOPs are now signed off by the Assistant Director RIK or Executive Lead for RIK. Appropriate authors of SOPs and WI are now identified by the Assistant Director RIK or R&D Quality & Performance Lead. Details of new and revised documents are provided in an update to the R&D Operational Group Meeting and the minutes of this meeting (including this update) circulated to the RIK Oversight Group. Updated NHS Fife Communication Team to NHS Fife Web Team for upload of new or revised SOPs to the R&D section of the NHS Fife website. Added RIK abbreviation.

8. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director Research, Innovation & Knowledge, NHS Fife Signature: 	22 June 2022