

STANDARD OPERATING PROCEDURE FOR THE PROCESS OF LOCAL MANAGEMENT REVIEW AND APPROVAL OF ALL RESEARCH UNDERTAKEN IN NHS FIFE

SOP NUMBER:	Fife R&D SOP 11
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ISSUE DATE:	04/03/2024
EFFECTIVE DATE:	04/03/2024
REVIEW DATE:	04/03/2027

1. PURPOSE

This document describes the processes for the review and registration of research conducted in NHS Fife and the issue of Local Management Approval or acknowledgement, as appropriate.

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 the R&D SOP page of the Research, Innovation & Knowledge (RIK) section on the NHS Fife website (www.nhsfife.org/research) or for guidance, contact the R&D Department via fife.randd@nhs.scot.

2. APPLICABILITY

This SOP applies to all staff involved in the review and registration of research conducted in NHS Fife.

3. PRINCIPLES

- 3.1 Researchers wishing to conduct research in NHS Fife must obtain Local Management Approval (LMA). The Local Management Review must be completed, and the appropriate approvals obtained ¹ and contracts signed before any data collection/research activity can take place within NHS Fife.
- 3.2 Local Management Approval relates to the role of NHS Fife in hosting research, i.e., recruiting participants or conducting interventions. NHS Fife may also Sponsor research, for example where NHS Fife is the employer of the Chief Investigator and the process for obtaining Sponsor approval is covered by R&D SOP06.
- 3.3 For multi-centre studies, although the NHS Fife Research Team can discuss the study with the NHS Fife Research Approvals Team, the formal Local Management Approval process can only commence in NHS Fife once the appropriate documentation has been made available to the Research Approvals Team on SReDA by the NHS Research Scotland Permissions Coordinating Centre (NRS Permissions CC) and accepted by the Research Approvals Team.
- 3.4 Except where there are unusual issues or problems with the set-up of a study, Local Management Approval will be given within 15 calendar days of the receipt of a complete and valid document set. The local review clock can be temporarily stopped only in particular circumstances (see NRS-GUI-001 - Guidance for NRS Clocks).

¹ Caldicott, Information Governance, Letters of Access, REC, MHRA etc

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- 3.5 For low risk Non-CTIMP studies, the Local Management Approval Letter can be signed by the Assistant Director RIK.

For high risk non-CTIMP, CTIMP and Medical Device studies, the Local Management Approval letter and contracts/ agreements must be signed by the Medical Director/delegate.

- 3.6 The SReDA record for the study is considered to be the R&D file for that study, although copies of files such as contract/agreement and Local Management Approval letter will also be stored locally in S:\Research\PROJECTS\2 PROJECT DOCUMENTATION and EDGE.
- 3.7 Under the UK Policy Framework for Health and Social Care Research, there is no requirement for Local Management Approval for the establishment of research databases or tissue banks. For these research projects, only steps 4.2, 4.3 and 4.4 of the procedure below need to be completed. The approval process for the provision and use of human tissue samples is covered in NHS Fife R&D SOP 41.
- 3.8 Where NRS Permissions CC office advise that a study does not require local review, only steps 4.2, 4.3 and 4.4 of the procedure below need to be completed and only the Project Status on SReDA and the PI type on EDGE need to be completed.

4. PROCEDURE

4.1 Notification of New Research

- 4.1.1 The Research Approvals Team will normally be informed of proposed research by the Chief Investigator (CI), local Principal Investigator (PI) being invited to join the study, R&D Research nurse, commercial company conducting the study, study co-ordinator/Sponsor or by NRS Permissions CC office. Email notifications that come through a route other than from NRS Permissions CC office are saved in the Generic email box (fife.fiferesearchapprovals@nhs.scot) in the 'No Project ID' subfolder in the following format YYYY-MM - Study name/description.
- 4.1.2 The Research Approvals Team must record details of all research on the Study Approvals Tracker (S:\Research\PROJECTS\1 PROJECT TRACKING) and allocate a local Project ID (next sequential local R&D approval number).

4.2 Setting up Approvals Folder in Shared Network Drive

- 4.2.1 The R&D Quality & Performance Team (Q&P Team) must create a new Approvals study folder in S:\ PROJECTS\ 2 PROJECT DOCUMENTATION\ APPROVALS STUDY FOLDERS in the current year range folder (e.g., 2024-2026) and add the '1. FOLDER TEMPLATE' folder structure.

The new Approvals study folder must be named according to the convention [Local Project ID] – [Short study title] (e.g., 24-012 – EXAMPLE STUDY).

- 4.2.2 All documents saved in these folders must be named using the study number and appropriate document title.

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- 4.2.3 At the end of the study, any hard copy documents must be scanned and discarded (with the exception of wet ink signed contracts/agreements). All scanned and electronic documents must then be saved in S:\Research\PROJECTS\2 PROJECT DOCUMENTATION\APPROVALS STUDY Folders and any duplicate documents in the study folder deleted.

4.3 Setting-up Projects in EDGE

- 4.3.1 Using the study full title and/or study short title and/or IRAS number and/or Portfolio ID (if available), the Q&P Team must check under the 'Global Projects' tab to see if there is already a record on EDGE for the study.

- 4.3.1.1 If the study is already on EDGE, the Q&P Team must request access to the existing study as follows:

- Opening the study record
- Clicking on 'Organisation' then select 'Request Involvement'.

Notification should appear in due course to confirm that NHS Fife have been added to the study record.

- 4.3.1.2 If the study is not already on EDGE, the Q&P Team must add the new study to EDGE. To add a new study to EDGE:

- Click on 'Management', then 'Projects' then 'Add a New Project'.
- Complete as many fields as possible with the information available, then click 'save'.

- 4.3.2 Once NHS Fife have been added to the study record or the new study added to EDGE, the Q&P Team must:

- Add 'Admin Team' staff, Senior R&D Research Nurse or other involved research staff to the project on EDGE, giving them Project Manager rights.
- Add the exact location as a site (or NHS Fife if the exact location isn't known) and add the Senior R&D Research Nurse, PI or other appropriate research team member as 'Key Staff' member.
- Once available, check the SReDA study record and the study IRAS form to populate the relevant study fields on EDGE.

- 4.3.3 The following must be added to the project record on EDGE:

Q&P Team

- Approvals - LMA Review workflow
- Approvals – Memo form
- Approvals – R&D Additional Study Details form

Research Approvals Team

- Approvals – Risk Assessment form (for IRAS Category 1-4 studies only)
- Approvals Research Database/Tissue bank workflow

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4.4 Setting-up Projects in SReDA

4.4.1 For multi-centre studies NRS Permissions CC will upload the study documentation to the Scottish Research Database Application (SReDA) and make this available to the Research Approvals Team.

4.4.2 Where a study is single centre, the study record will normally not be initiated on SReDA by NRS Permissions CC and instead must be added by the Research Approvals Team.

4.4.2.1 To add a new study on SReDA:

- Go into 'WORKAREA'.
- Select 'New Study'.
- Complete appropriate fields.
- Click 'Add New'.

4.4.2.2 The Research Approvals Team must import the IRAS Form_xml format as follows:

- Open the study record.
- In study details tab click Import
- Click choose file.
- Select the xml IRAS Form to import.
- Click on upload.
- In the table, click on import file.
- Click on 'Yes' to import the file.
- Review any differences that SReDA identifies, and update as required.
- Once all the differences have been reviewed/corrected, click import.
- "Import Procedure Passed Successfully" will appear.

4.4.2.3 The Research Approvals Team must then upload all study documents to SReDA as follows:

- Open the study record.
- Click on 'Documents' tab.
- Click Add new documents.
- Click on 'Browse files'.
- Select the appropriate file to upload.
- Click 'Open'.
- Select received date.
- Select Folder, then save.

4.4.3 The Research Approvals Team and/or Q&P Team (as detailed in the LMA workflow) must add the local information to the study record on SReDA to complete the minimum dataset (see NRS Guidelines NRS-GUI-003-SReDA Minimum dataset available via the 'Document Store' tab in the 'Management' section of the Work Area on SReDA) and mark the 'SReDA Checks' section of the 'Approvals – LMA Review' workflow in EDGE as complete.

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- 4.4.4 The R&D Research Coordinator must start and stop the local review clock on SReDA as per NRS-GUI-001 - Guidance for NRS Clocks (available from the Document Store on SReDA).

4.5 Setting up TEAMS Channel

- 4.5.1 The R&D Research Coordinator must alert the Q&P Team (fife.researchquality@nhs.scot) via email when a new study is made available on SReDA. A new Microsoft Teams channel will be created in 'Fife R&D Q&P/Approvals'. The Q&P Team must add the following information to the first post:
- R&D reference number
 - IRAS Number
 - Study title
 - Principal Investigator name and email address (where applicable and available)
 - R&D Research Nurse (where applicable and available)

4.6 PI responsibilities

- 4.6.1 When instructed by the R&D Research Coordinator, the Q&P Team must send Doc Ref 11-02 - Principal Investigator Responsibilities Form to the PI, asking them to complete and return it. For studies supported by an R&D Research Team, the key contact from the Research Team must be copied into the email. A copy of the signed form must be filed in EDGE by the Q&P Team. The PI or delegate must also file a copy in the Investigator Site File.

4.7 Local Management Review and Approval Process

- 4.7.1 The Research Approvals Team and Q&P Team must record the progress of the Local Management Approval Process using the 'Approvals - LMA Review' workflow on EDGE.
- 4.7.2 When the Local Information pack (LIP) is received from the Sponsor, the Research Approvals Team must check the LIP against SReDA.
- 4.7.3 On receipt of the localised Organisation Information Document (OID) and Schedule of Events (SoE) or Schedule of Events Cost Attribution Template (SoECAT), whichever is relevant, and following completion of Generic Review (for multi-centre studies), the Research Approvals Team must collate, review, and check all the documentation to identify any site-specific issues.
- Note: Although a complete document set does not need to be provided immediately, **approval cannot be granted** until all appropriate documents are in place.*
- 4.7.4 For multi-centre studies, any questions relating to the study documentation must be referred to the NRS Permissions CC office (gram.nrspcc@nhs.scot) or the Generic Reviewer rather than directly to the CI/study centre.
- 4.7.5 Where there is funding available to the RIK department for research activity conducted as part of a study, the Research Approvals Team must record this in

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the 'Finance to be tracked on EDGE' attribute in the 'Approvals - Memo' form on EDGE and add a 'Finance - Study Set-up' workflow to the project on EDGE.

- 4.7.6 The Research Approvals Team must send a copy of the contract to an appropriate senior manager and a copy of the contract and costings to the R&D Business Accountant for review (see WI04). The R&D Business Accountant must complete the account details and:

- Track the progress of their review in the 'Finance – Study Set-up' workflow.
- Liaise with the R&D Research Coordinator to resolve any issues/queries with the costings/contract.
- Email the Research Approvals Team to confirm the review is complete once any issues have been resolved.
- Prepare and upload a Costings Template to the project on EDGE (where applicable), to enable the Research Team to capture all the Research Activity that has been completed.

The finalised contract (or OID where this is being used as the study agreement) must be sent to the Medical Director delegate as an authorised signatory for Fife Health Board.

- 4.7.8 For IRAS Category 1-4 studies, the Research Approvals Team must conduct a Risk Assessment of the study and complete the 'Approvals - Risk Assessment' on EDGE.

Note: For NHS Fife sponsored studies a more detailed Risk Assessment may be required (see R&D SOP07 - Assessment of Risk Associated with Research Studies Sponsored by NHS Fife).

- 4.7.9 The R&D Quality & Performance Lead must review the 'Approvals – Memo. and 'Approvals - Risk Assessment' entities and complete the 'Level of Annual Progress Monitoring Required' and 'No. of Consent Forms to be Checked' attributes in the 'Approvals – Memo' form.

- 4.7.10 The Research Approvals Team must be satisfied that all paperwork is in place, up to date and complete; that all questions concerning the conduct, cost and other implications of the study have been answered; that any contracts contain appropriate provisions and that overall, there are sufficient safeguards to protect NHS Fife, its patients and staff.

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- 4.7.11 Once all the study documentation is in place and all queries have been resolved, a draft approval letter must then be prepared by the Research Approvals Team (Doc Ref 11-06).

The following documentation is then emailed to the Assistant Director RIK by the Research Approvals Team:

- Draft approval letter
- The link to 'Approvals – Memo' form on EDGE
- Patient Information Sheet(s)
- Consent form(s)
- OID if applicable

The Assistant Director RIK (or the Innovation Manager in their absence) reviews the above documentation and if appropriate signs off the final attribute in the 'Approvals – Memo' form on EDGE and confirms study approval via email.

- 4.7.12 For non-CTIMPs, once the Assistant Director RIK (or the Innovation Manager in their absence) has confirmed approval their signature is added to the approved LMA letter and this is issued to the PI (cc'd to the CI, Study Co-ordinator, Research Nurse, Pharmacy, Student Supervisor, and others as appropriate).

- 4.7.13 For CTIMPs and Medical Device studies, once the Assistant Director RIK (or the Innovation Manager in their absence) has confirmed approval of the EDGE Memo and draft LMA letter, a copy of the draft LMA letter is sent to the Medical Director delegate for approval. Once approved the signature of the Medical Director delegate is added to the approved LMA letter and this is issued to the PI (cc'd to the CI, Study Co-ordinator, Research Nurse, Pharmacy, Student Supervisor, and others as appropriate).

- 4.7.14 Letters of Access must be issued by the Research Approvals Team, if required, once Local Management Approval has been granted. Honorary Research Contracts must be issued from Human Resources via R&D (see R&D SOP24).

4.8 Setting up a Study Record on CPMS

- 4.8.1 Where NHS Fife is the lead for an 'eligibly*' funded study, the R&D Research Coordinator will liaise with the CI and, where required, the Research Approvals Team and/or Q&P Team will set-up a study record on the Central Portfolio Management System (see <https://cpms.nihr.ac.uk/> for further information and guidance). The CI will also be made aware of the requirement for uploading of monthly recruitment data.

*The list of eligible funders can be found here:

<https://www.nhsresearchscotland.org.uk/education-and-funding/funding-for-nhs-research-infrastructure>

5. ASSOCIATED DOCUMENTS

Doc Ref 11-02 - Principal Investigator Responsibilities Form

Doc Ref 11-06 - Local Management Approval Letter Template

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R&D SOP06 - Sponsor Agreement for Research Projects Involving Humans, their Tissue and/or Data.
R&D SOP07 - Assessment of Risk Associated with Research Studies Sponsored by NHS Fife
R&D SOP24 - Research Passports, Honorary Research Contracts and Letters of Access
R&D SOP41 - Procedure for Obtaining Approval for the Provision and Use of Human Tissue Samples for Research in NHS Fife
NRS-GUI-001 - Guidance for NRS Clocks
NRS-GUI-003 - SReDA Minimum dataset
WI04 - Finance Processes for Commercial Studies

6. ABBREVIATIONS

CI - Chief Investigator
CTIMP - Clinical Trial of Investigational Medicinal Product
IRAS - Integrated Research Application System
MHRA - Medicines and Healthcare products Regulatory Agency
NRS Permissions CC office - NHS Research Scotland Permissions Coordinating Centre
OID - Organisation Information Document
PI - Principal Investigator
Q&P – Quality & Performance
RIK - Research, Innovation and Knowledge
SoE - Schedule of Events
SoECAT - Schedule of Events Cost Attribution Template
SOP - Standard Operating Procedure
SReDA - Scottish Research Database Application (<https://www.reda.org.uk/>.)


7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	31/10/2014	N/A – new SOP
2	Julie Aitken R&D Trials Facilitator	09/11/2017	Amended for consistency with NHS Fife SOP template. Amended to reflect current practice.
3	Aileen Yell R&D Research Coordinator	04/08/2020	Amended for consistency with R&D SOP template. Amended to reflect current practice - SSI replaced by OID and requirement for SoE and SoECAT added. Details regarding the process of Risk Assessment for hosted studies have been added. Doc Ref 11-01 has been withdrawn and new associated documents Doc Ref 11-04 and Doc Ref 11-05 have been added. Text refreshed throughout for clarity.
4	Penny Trotter R&D Research Coordinator	04/03/2024	Text rearranged throughout for clarity. Section 3 renamed as 'PRINCIPLES'.

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Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
			<p>Clarified that a risk assessment must be conducted by the Research Approvals Team for IRAS Category 1-4 studies only.</p> <p>Details added to outline the process for setting up project records on EDGE and SReDA, setting up a TEAMS channel for relevant studies and the delegation of certain tasks to the Q&P Team.</p> <p>The Quality & Performance Lead must review the study details and completed Risk Assessment and record the 'Level of Annual Progress Monitoring' and 'No. of Consent Forms to be Checked' in the 'Approvals – Memo' form on EDGE rather than adding QCC requirements.</p> <p>Added details for the review and approval/authorisation process for the Local Management Approval Letter and contract/study agreement.</p> <p>Doc Ref 11-03 withdrawn as Doc Ref 06-02 considered sufficient to document CI responsibilities.</p> <p>Doc Ref 11-04 withdrawn as this has been replaced by the 'Approvals – Risk Assessment' Form on EDGE.</p> <p>Doc Ref 11-05 Withdrawn as this has been replaced by the 'Approvals – LMA' Workflow and 'Approvals – Memo' Form on EDGE.</p> <p>Doc Ref 11-06 created to allow for versions control of the approval letter.</p>

8. APPROVAL

APPROVED BY	Date
<p>Professor Frances Quirk, Assistant Director RIK, NHS Fife</p> <p>Signature: </p>	04 March 2024

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