STANDARD OPERATING PROCEDURE FOR SITE SELECTION & ACTIVATION

SOP NUMBER:	**Fife R&D SOP34**
AUTHOR:	**Fleur Davey**
ISSUE DATE:	**7th May 2025**
EFFECTIVE DATE:	**7th May 2025**
REVIEW DATE:	**7th May 2028**

1. PURPOSE

This document describes the procedure used for selection of collaborating sites and investigators.

Selection of the correct sites and investigators is crucial to the successful delivery of a clinical study and is a key component in meeting the requirements of GCP and the UK Policy Framework for Health and Social Care Research.

The quality of the data collected and the speed of collection depends primarily on who is responsible for participant identification and recruitment, study management, data collection and the way these activities are managed. Poor site selection can lead to low quality data, slow recruitment, and high levels of data queries.

The aim of this SOP is to provide a structured mechanism by which the CI and/or other members of the study team evaluate and select a site or investigator for participation in a clinical research study.

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), EDGE (https://www.edge.nhs.uk) and Q-Pulse. For guidance, contact the R&D Department via fife.randd@nhs.scot.

2. APPLICABILITY

This SOP applies to a Chief Investigator (CI) or other members of staff who are responsible for selecting sites and/or investigators for multi-centre clinical research studies sponsored or co-sponsored by NHS Fife.

3. PRINCIPLES

3.1 In accordance with ICH GCP Guidelines and the UK Policy Framework for Health and Social Care Research, it is the Sponsor's responsibility to select the investigator(s) and host sites. The Sponsor together with the CI and study team should ensure that each investigator is qualified by skills, training (including GCP) & experience and that sites and investigators have adequate resources (staff, equipment etc.), facilities (laboratories) and potential participants to properly conduct the study.

3.2 In order to evaluate sites and investigators, the CI or delegate must assess them against study specific criteria to ensure suitability, before the PI or site is formally engaged as a site.

3.3 The number of sites in the UK must be agreed with the RIK Approvals Team as part of the assessments for Sponsorship Approval. The Sponsor reserves the right to cap the number of sites, depending on the level of resource and ongoing compliance of the study.

Once the study has received confirmation of sponsorship, any changes to the number of sites must be submitted as an amendment for approval by the Sponsor (see R&D SOP20)

3.4 NHS Fife with clinical negligence scheme for Health Boards (CNORIS) indemnification, will only sponsor studies with sites solely in the UK.

4. PROCEDURE

4.1 Identification of Sites

Initial identification of collaborating sites should be by recommendation of the CI, based on their professional and personal experience of working with a potential collaborator.

Existing study PIs and NHS Fife staff can also recommend new sites and investigators. UK Sites can also be identified through the clinical research networks (CRNs) and NHS Research Scotland (NRS).

4.2 Evaluation of Potential Sites

4.2.1 The CI must define the selection criteria for suitable sites, prior to the start of the selection process.

The following list details the minimum criteria against which the site or potential PI should be evaluated:

- ***Interest of the PI*** - the initial interest of the investigator is a good indicator of their commitment to the study. This can be as simple as a Yes or No response to the initial contact.

- ***Qualification of PI*** - request current CV including details of recent and current studies and/or academic projects and publications.

- ***Experience of PI*** – request details of recent and current studies and/or academic projects and publications.

- ***Local resources*** – review qualifications, experience, and capacity available of the following:
  - Research Nurse, Study Coordinator or equivalent.
  - Clinical staff required for the study (e.g. other clinicians, nurses, relevant healthcare professionals)

- Laboratories (e.g. what is needed and available locally, experience, SOPs, Quality Assurance)
- IT infrastructure and support (e.g. compatible systems, security issues, equipment available or needed)
- Storage and security (e.g. samples, documentation, temperature control considerations, lockable rooms, filing cabinets)
- Host infrastructure (e.g. who is the local signatory, how are finance and legal issues managed?)
- Transport links (e.g. how easy is it to visit the site for training and monitoring, how long will it take to travel there?)
- Availability of and accessibility to specialist equipment needed for the study (e.g. imaging)

- ***Suitable participant numbers*** – request written evidence from the PI and/or other site staff (recent/current) of recruitment to other studies, how many eligible participants does the investigator(s) predict, how does the local participant population view clinical research, if available / known?

- ***Language barriers*** – what measures are available for translation and back translation of trial documentation if required in protocol?

- ***Budget*** – present start-up costs, per patient fee or project budget as appropriate, provide details of the funds available for equipment or consumables etc.

- ***Contacts*** – Collect contact details for Investigator(s), Research Nurse(s), labs, finance, legal, R&D personnel etc.

4.2.2 A study specific "Site and Investigator Evaluation Form" must be developed based on the criteria defined by the CI (see Doc Ref 34-01 for a template) and this must be completed for each site.

4.2.3 The "Site and Investigator Evaluation Form" must be completed by the potential PI, the CI or delegate. The CI or delegate may decide to visit a site prior to completing the form, to ensure suitable facilities are available or may conduct a TEAMS call prior to making the decision on selection of the site.

4.3 Evaluation outcome

4.3.1 Based on the response of the site representative and/or potential PI against the evaluation criteria, the CI or delegate must decide the suitability of the proposed investigator and/or site.

4.3.2 If the site and investigator are suitable, the CI or delegate will invite them to become a host site.

4.3.3 If the site and/or investigator are not suitable, the PI or site representative must be formally notified and thanked for their involvement to date. Where appropriate, feedback will be given to the PI or site representative as to why they were not selected.

4.4 A completed copy of the “Site and Investigator Evaluation Form” and associated correspondence for each site must be filed in the Study Master File (SMF).

4.5 Once sites have been selected and the Sponsor has confirmed sponsorship approval, the CI may apply for regulatory approvals.

4.6 The CI or delegate must request all site essential documentation from each individual site. As a minimum the following documents must be received from each site prior to site activation:

- Local Management Approval or equivalent
- Fully signed clinical trial site agreement or equivalent
- Copy of the PI’s signed CV and GCP certificate
- Completed delegation log.

4.7 Set up Investigator Site File

The CI or delegate must prepare an Investigator Site File Index based on Doc Ref 03-02. It is advised that the Investigator Site Files (ISF) are set up by the CI or delegate and distributed to sites as part of Site Initiation Visit (SIV).

4.8 Perform SIV at each site, train site staff, resolve all issues, and complete reports.

4.8.1 All sites must undergo a SIV prior to the CI activating the site to start the study (site activation). The aim of the SIV is to ensure that all sites and study staff are adequately aware of GCP, and trained in the protocol, study specific SOPs, source data and PI responsibilities before study activities begin. Doc Ref 34-02 provides a template which can be used to develop training slides for use during an SIV.

4.8.2 SIVs must only be conducted after the site has received Research Ethics Approval but may be conducted prior to the Sponsor confirmation that sites can be activated.

4.8.3 SIVs should be scheduled as close to site activation as logistically possible to ensure that training remains fresh in the mind of all site staff at the start of the trial. A refresher should be considered if the SIV was conducted more than 6 weeks prior to activation.

4.8.4 The CI or delegate performing the SIV must ensure that all study staff attending the SIV sign a Site Initiation Attendance Log (see Doc Ref 34-03).

4.9 Complete Site Initiation Report

4.9.1 The CI or delegate must complete an SIV report (using Doc Ref 30-01 as a template) and document any outstanding actions and send a copy of this to the site within 2 weeks of the visit.

4.9.2 If completion of the SIV report has been delegated to a person other than the CI, provide a copy of the initiation report to the CI to ensure CI oversight.

4.9.3 The CI or delegate must follow-up all outstanding actions with the site until these are resolved.

4.9.4 The original copy of each SIV report must be stored in the SMF.

4.10 Complete “Sponsored Studies – Site Activation Checklist” workflow on EDGE.

A “Sponsored Studies – Site Activation Checklist” workflow must be completed on EDGE by the CI or delegate for each host site, to ensure the minimum site checks have been performed prior to the issuing of the site activation email.

4.11 Notify sites of their activation by email.

Once initiations are complete and follow up actions are addressed (if applicable), each site must be issued with a “Site Activation” email.

Site activation email template should be used (Appendix A). This must be sent by the CI or delegate to the PI, monitor, and RIK Approvals Team.

The CI should be copied into this correspondence if this task has been delegated by them.

5. ASSOCIATED DOCUMENTS

Doc Ref 03-02 - Investigator Site File Index
Doc Ref 30-01 – Initiation Visit Report
Doc Ref 34-01 - Site and Investigator Evaluation Form
Doc Ref 34-02 - SIV Presentation Template
Doc Ref 34-03 – SIV Attendance Log

6. ABBREVIATIONS

CI	Chief Investigator
CRN	Clinical Research Network
GCP	Good Clinical Practice
ISF	Investigator Site File
NRS	NHS Research Scotland
PI	Principal Investigator
R&D	Research and Development
SMF	Study Master File
SOP	Standard Operating Procedure

7. REFERENCES

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/

8. DOCUMENT HISTORY

Version Number	Edited by (job title)	Effective Date	Details of Revisions Made
1	David Chinn Senior Research Advisor	30/03/2015	New - *Adapted from TASC SOP 51, version 1.0*
2	Julie Aitken R&D Trials Facilitator	06/12/2018	Reformatted in line with current SOP template. Revised to reflect current practice.
3	Julie Aitken R&D Quality & Performance Lead	18/03/2021	Minor changes to text only.
4	Fleur Davey Senior Research Nurse	07/05/2025	Title amended to also cover site activation. Requirement to obtain Sponsor approval for the number of sites added. Process for SIV added. Process for site activation added. Doc Ref 34-02 created. Doc Ref 34-03 created

9. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Associate Director RIK, NHS Fife Signature: 	07th May 2025

APPENDIX A

Site Activation Email template

SUBJECT: (*Insert trial acronym*) Clinical Trial Opening Notification

Dear Study Team,

Study name:
PI:
IRAS reference:

The above trial is now open to recruitment at (*Insert NHS Trust*).

Current versions:

Protocol: (version and date)

CRFs: (version and date)

Patient Information Sheet: (version and date)

Consent sheet: (version and date)

GP letter: (version and date)

Diary Card (where applicable): (version and date)

If you require any additional information, please contact (state name and contact details).

Kind regards

(Insert name)

(Insert job title)

(Insert contact details