POLICYFOR MANAGEMENT OF SUSPECTED RESEARCH MISCONDUCT

SOP NUMBER:	**Fife R&D SOP49**
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1. PURPOSE

This document describes the procedure for notifying, reporting and appropriately following-up suspected research misconduct in NHS Fife.

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 Research, Innovation and Knowledge (RIK) 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

2.1 This Standard Operating Procedure (SOP) applies to all NHS Fife staff involved in the oversight, management and conduct of research studies sponsored or hosted by NHS Fife.

3. POLICY

3.1 Research misconduct can range from minor misdemeanours to significant acts of misappropriation or fabrication. Unacceptable conduct includes fabrication, falsification, plagiarism, misrepresentation, breach of duty of care and failing to deal properly with allegations of misconduct, as defined by the Research Councils UK.

3.2 NHS Scotland Workforce Conduct and Whistleblowing policies set out the correct course of action for employers when investigating and responding to allegations of misconduct and fraud.

3.3 On discovery of suspected research misconduct, NHS Fife staff members involved in the oversight, management and conduct of research studies sponsored or hosted by NHS Fife are responsible for informing the R&D Quality & Performance Lead, or designee.

3.4 The R&D Quality & Performance Lead, or designee, is responsible for:

- Ensuring suspected research misconduct is reported to the Assistant Director Research, Innovation & Knowledge (RIK).
- Filing the details of all allegations and their outcome in the QA records.

3.5 The Assistant Director RIK is responsible for:

- Reporting suspected research misconduct to the NHS Fife Medical Director.
- Informing the substantive employer of the individual suspected of research misconduct (if applicable).

4. PROCEDURE

4.1 Reporting Suspected Research Misconduct

4.1.1 If any staff member suspects research misconduct, they must contact the R&D Quality & Performance Lead, or designee.

4.1.2 This initial contact may be made in person, via the telephone (contact details found at www.nhsfife.org/research) or via e-mail (fife.researchquality@nhs.scot). Anonymous telephone calls or e-mails will be accepted.

4.1.3 The individual reporting the event(s) must provide details of the event(s) including date(s) and location.

4.1.4 The reporter must not communicate any details or information regarding the suspected research misconduct to the individual suspected of research misconduct.

4.1.5 The reporter may seek guidance and support from their line manager, confidentially, regarding the nature of the event(s), unless there is a potential conflict of interest.

4.1.6 The reporter must not inform any other individuals and e-mail correspondence must be treated with extreme caution.

4.2 Investigation of Suspected Research Misconduct

4.2.1 Once a report of suspected research misconduct has been received, the R&D Quality & Performance Lead, or designee must use form Doc Ref 49-01 - Suspected Research Misconduct Report to record the details of the reported event(s).

4.2.2 The R&D Quality & Performance Lead must forward the completed 'Suspected Research Misconduct Report' to the Assistant Director RIK or designee.

4.2.3 The Assistant Director RIK or designee, must ensure that the NHS Fife Medical Director is informed of the event(s).

4.2.4 The Quality & Performance Lead must conduct an investigation into the circumstances surroundings the suspected Research Misconduct and discuss the outcome of this investigation with the Assistant Director RIK.

4.2.5 If it is deemed that the event does not constitute research misconduct, the R&D Quality & Performance Lead, or designee must record this in the Suspected Research Misconduct Report.

4.2.6 If it is deemed that the alleged misconduct is of a minor nature, it may be resolved informally.

4.2.7 Alternatively, the Assistant Director RIK must inform the Sponsor(s) representative(s) and arrange for the substantive employer of the individual suspected of research misconduct to be notified, if not already aware.

If the substantive employer is NHS Fife then the NHS Fife Human Resources Department must be contacted and the matter dealt with in accordance with NHS Scotland Workforce Conduct and Whistleblowing policies (NHS Workforce Policies | NHS Scotland).

If the substantive employer is another organisation or institution, the appropriate individual will be contacted to action procedures in accordance with the policy of that organisation/institution. The substantive employer will be asked to investigate the incident and to keep the Assistant Director RIK informed of the outcome.

4.2.8 The outcome of the investigation must be communicated to the individual suspected of research misconduct by their substantive employer.

4.2.9 If it is concluded that research misconduct did take place, remedial action will be determined by the substantive employer and undertaken as quickly as possible.

4.2.10 The sponsor(s) and host site (NHS Fife or external site for an NHS Fife sponsored multi-centre study) must also take remedial action in relation to the specific study, if required. This may include assessing and acting upon potential risk to participants or their data, stopping a trial or reporting the incident to regulatory bodies as appropriate. Where data has been used in publications then consideration must be given to inform Journal Editors.

4.2.11 The R&D Quality & Performance Lead, or designee, must file the Suspected Research Misconduct Form in the NHS Fife Quality & Performance folder in: S:\Research\QUALITY ASSURANCE.

5. ASSOCIATED DOCUMENTS

- Doc Ref 49-01 - Suspected Research Misconduct Report
- NHS Scotland Workforce Conduct Policy
  Conduct Policy Overview | NHS Scotland
- National Whistleblowing Standards
  Whistleblowing Policy Overview | NHSScotland

6. ABBREVIATIONS

R&D Research and Development
RIK Research Innovation and Knowledge

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Quality & Performance Lead	02 Nov 2023	New SOP

8. APPROVAL

Approved By	Date
Professor Frances Quirk, Research, Innovation & Knowledge Director NHS Fife Signature: 	09 Nov 2023