

# SUSPECTED RESEARCH MISCONDUCT

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## 1 Introduction

- 1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).
- 1.2 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 improper dealing with allegations of misconduct, as defined by the Research Councils UK.
- 1.3 NHSL and the UoE have guidelines/policies that set out the correct course of action for investigating and responding to allegations of misconduct and fraud. These are referenced in section 6.

## 2 Purpose

- 2.1 To describe the processes for notifying, reporting and appropriately following-up suspected research misconduct.

## 3 Scope

- 3.1 This Standard Operating Procedure (SOP) applies to ACCORD personnel and researchers participating in research studies sponsored by NHSL and/or the UoE, or hosted by NHSL.

## 4 Responsibilities

- 4.1 On discovery of suspected research misconduct, ACCORD staff members or members of the research team are responsible for informing the ACCORD QA Manager, or designee, or a representative of the sponsor(s).

- 4.2 The QA Manager, or designee, is responsible for;
- Ensuring suspected research misconduct is reported to the ACCORD Senior Management Team (SMT),
  - Reporting suspected research misconduct to the sponsor representative(s) (if applicable),
  - Informing the substantive employer of the individual suspected of research misconduct (if applicable),
  - Filing the outcome of the investigation(s) in the QA records.

## **5 Procedure**

### **5.1 Notification of Suspected Research Misconduct**

- 5.1.1 If any sponsor staff member or any member of a research team conducting a study sponsored by NHSL and/or UoE, or hosted by NHSL, suspects research misconduct, they will inform the ACCORD QA Manager, or designee, or a representative of the sponsor(s).
- 5.1.2 This initial contact may be made in person, via the telephone (contact details found at [www.accord.scot](http://www.accord.scot)) or via e-mail ([QA@accord.scot](mailto:QA@accord.scot)). Anonymous telephone calls or e-mails will be accepted.
- 5.1.3 The individual reporting the event(s) will provide details of the event(s) including date(s) and location.
- 5.1.4 The QA Manager, or designee, will use form CR014-F01 (Suspected Research Misconduct Report) to record the details of the reported event(s).
- 5.1.5 The reporter will not communicate any details or information, regarding the suspected research misconduct to the individual suspected of research misconduct.
- 5.1.6 The reporter may seek guidance from their line manager, confidentially, regarding the nature of the event(s), unless there is a potential conflict of interest.
- 5.1.7 The reporter will not inform any other individuals. E-mail correspondence must be treated with extreme caution and all parties involved in the incident must be reminded to follow local institutional policies regarding retention of sensitive emails

- 5.1.8 This process may be instigated by the QA Manager, or designee, following a suspected serious breach investigation (CR003 Suspected Serious Breaches) where research misconduct is suspected.

## **5.2 Investigation of Suspected Research Misconduct**

- 5.2.1 The QA Manager, or designee, will ensure that the ACCORD SMT is informed of the event(s).
- 5.2.2 If it is deemed that the event does not constitute research misconduct, the QA Manager will be informed and will record this in form CR014-F01 (Suspected Research Misconduct Report).
- 5.2.3 If it is deemed that the alleged misconduct is of a minor nature, it may be resolved informally.
- 5.2.4 Alternatively, SMT will instruct the QA Manager, or designee, to 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.
- 5.2.5 If the substantive employer is the UoE, the contact will be the Head of School for the research involved, or the Head of College if there is a conflict of interest.
- 5.2.6 If NHSL is the substantive employer, this will be the NHSL Fraud Liaison Officer.
- 5.2.7 If the substantive employer is another organisation or institution, the appropriate individual will be contacted to action procedures in accordance with the policy of the organisation/institution.
- 5.2.8 The substantive employer will investigate the incident and the ACCORD QA Manager, or a representative of the sponsor(s), will ask to be kept informed of the outcome.
- 5.2.9 The outcome of the investigation will be communicated to the individual suspected of research misconduct by their substantive employer.
- 5.2.10 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.
- 5.2.11 The sponsor(s) and host site will 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.

5.2.12 The QA Manager, or designee, will file the outcome of the investigation in the ACCORD QA records.

## 6 References and related documents

- CR014-F01 Suspected Research Misconduct Report
- CR003 Suspected Serious Breaches
- RCUK Policy and Guidelines on Governance of Good Research Conduct (April 2017)
- [NHS National Services Scotland Counter Fraud Services](#)
- [NHSL Whistleblowing Policy and Procedure](#)
- [UoE Research Misconduct Policy](#)
- [UoE Code of Practice on Reporting Malpractice and Raising Concerns Under the Public Interest Disclosure Legislation \('Whistleblowing'\)](#)

## 7 Document history

Version Number	Effective Date	Reason for Change
1.0	29 AUG 2016	Research Misconduct separated from CR003 into own SOP. Procedure updated with scope now including suspected research misconduct for hosted studies. Reference to NHSL and UoE policies and guidance added to introduction and section 6.
2.0	30 JUL 2018	Change of author. CR003-F02 document number changed to CR014-F01.
3.0	17 AUG 2020	UoE Code of Practice link updated in section 6.
4.0	21 SEP 2022	Change of author. NHS Lothian Whistleblowing Policy and Procedure link updated
5.0	22 OCT 2024	Following periodic review, SOP and CR014-T01 (v2.0) moved to new template. Change of author.

## 8 Approvals

Sign	Date
 AUTHOR: Lorn Mackenzie, QA Manager, NHSL, ACCORD	Oct 4, 2024
 Fiona McArdle (Oct 6, 2024 10:12 GMT+1) APPROVED: Fiona McArdle, Deputy R&D Director, NHSL, ACCORD	Oct 6, 2024
 Gavin Robertson (Oct 7, 2024 08:26 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	Oct 7, 2024












# CR014 Suspected Research Misconduct v5.0

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