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SOP 220 Management of Suspected Fraud and Misconduct in Research

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Fraud, research misconduct, research integrity
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1.4			New template Substantial revision required: - definition of research misconduct was expanded in line with MRC definition - Clarification regarding misuse of external funding as potentially falling under the scope of fraud. - Update to the procedures to bring them in line with other NNUH policies.	B Brown, Sarah Ruthven, Jackie Orford, Jenny Longmore

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies downloaded from the website are only valid on the day of downloading.

1. Contents

2. Definitions of Terms Used / Glossary

NNUH	Norfolk & Norwich University Hospital
R&D	Research and Development
RIN	Research & Innovation Services
SOP	Standard Operating Procedure
Sponsor	The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project
UEA	University of East Anglia

3. Scope

To describe the principles, responsibilities and procedures to be followed when fraud or misconduct is suspected in research within NNUH and UEA

This policy applies to all personnel at NNUH and UEA conducting research, even if NNUH or UEA is not a substantive employer of the staff. This includes employees with permanent and fixed-term contracts, students, visiting researchers as well as bank and agency staff, staff on honorary contracts and those gaining access via a Research Passport Application.

This SOP also specifies the procedure to be followed for research Sponsored by the NNUH and UEA when a third party is involved in conducting research.

4. Introduction

The purpose of this SOP is to ensure that NNUH and UEA fulfil their requirements to identify and manage all reports of suspected fraud and misconduct appropriately, in accordance with UK law and the UK Policy Framework for Health and Social Care

Research. Equally, its aim is to create an environment where equal emphasis is placed on accountability and learning, and to ensure there is a mechanism to raise concerns without fear of reprisals, and respond with a compassionate approach to reviewing issues involving potential misconduct.

NNUH and UEA value the importance of producing high quality and safe research and rely on the personal and scientific integrity of individuals involved in research. Research misconduct is contrary to this value, places participants at risk, and erodes confidence in the scientific integrity of research as a whole and jeopardies the reputation of NNUH / UEA and their employees.

Fraud and misconduct in research is rare, but it shall be treated as serious. The investigation process for suspected or alleged fraud or misconduct must be managed in accordance with the highest standards of integrity, accuracy and fairness.

5. Definitions

5.1 Research Misconduct

For the purposes of this SOP the definition of research misconduct is taken from the Medical Research Council Policy and Procedure for investigating allegations of research misconduct (V1.4 November 2014).

Research misconduct means the unacceptable conduct, which includes fabrication, falsification, plagiarism, misinterpretation, mismanagement or inadequate management of data and / or primary material, and breach of duty of care.

Fabrication
• The creation of false data or other aspects of research, including documentation and participant consent

Falsification
• The inappropriate manipulation and/or selection of data, imagery and/or consents

Plagiarism
• The misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission

Misrepresentation
• misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data;

- undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication;
- misrepresentation of interests, including failure to declare material interests either of the researcher or of the funders of the research;
- misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held;
- misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution.

Breach of duty of care

Whether deliberately, recklessly or by gross negligence:

- disclosing improperly the identity of individuals or groups involved in research without their consent, or other breach of confidentiality;
- placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated;
- not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly and transparently;
- not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment;
- improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes failure to disclose conflicts of interest;
- inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes.

Improper dealing with allegations of misconduct

- failing to address possible infringements including attempts to cover up misconduct or reprisals against whistle-blowers.
- failing to deal appropriately with malicious allegations, which should be handled formally as breaches of good conduct.

5.2 Fraud, bribery and corruption

Fraud, bribery and corruption are defined by the Fraud Act 2006 and both NNUH and UEA have internal Anti-Fraud policies, which aim to protect the institution's funds and assets. This includes any funds or assets, provided to NNUH and UEA by external funders for the purpose of conducting research.

In addition to the legal obligations, receipt of external funds is frequently governed by contractual arrangements with external funders, which specify purpose and terms of use of the funding. A fraud can occur by deliberate use of external funding for purposes other than for which it was provided. In all cases the financial arrangements for a study must be approved prior to commencement of the study. It is the responsibility of the researcher to ensure that all costs associated with the project have been identified, that funding has been identified, that satisfactory arrangements are in place for the management of income and expenditure and that where there is double funding there is clarity regarding responsibility to ensure that the same elements of a project are not funded twice.

6. Rules

Responsibilities for reporting

All staff have the responsibility to be vigilant and report research misconduct and fraud. If staff witness or suspect that misconduct and fraud is taking place it should be brought to the attention of the NNUH or UEA immediately.

Integrity, fairness and learning

Once reported the matter will be dealt with in a way that protects the reporting individual and is fair to the person who has been reported.

The process will place an equal emphasis on accountability and learning, with a compassionate approach to reviewing issues involving potential misconduct. Focusing on improving and changing behaviour, conduct and practice within the organisation with an emphasis to act on improvements either at a personal or organisational level, in order to learn from experience and prevent or reduce mistakes or risk.

Role of R&D Department / RIN

The R&D Department / RIN is responsible for ensuring that all research sponsored by NNUH / UEA is conducted according to the laws that exist in the UK. It does not have an authority alone to make decisions that may affect employment of individuals. The investigation of misconduct itself will be conducted within the policies of the institution in which the concern is raised and, if necessary, with involvement of the relevant HR department of the employing institution.

NNUH Misconduct Policy – Trust Doc Reference 15355
UEA Procedures for Investigating Allegations of Research Misconduct made against students 2023/24
UEA Procedures for Dealing with Allegations of Misconduct in Research

Wider implications of fraud and misconduct

In cases of substantiated fraud and misconduct other institutions including professional and regulatory bodies, research journals, funders, sponsor and patients may need to be informed of the incident. Additional actions can be taken by the institutions in response.

Criminal prosecution and civil actions are possible sanctions in substantiated cases of fraud and misconduct.

7. Procedure NNUH

This procedure should be read in conjunction with Trust wide policies on reporting and investigating fraud and misconduct:

- Freedom to Speak Up: Raising Concerns (Whistleblowing) Policy – Trust Docs ref 688
- Misconduct Policy – Trust Docs ref 15355
- Anti-Fraud and Bribery Policy – Trust Docs ref 7428
- Cyber Code of Conduct – Trust Docs ref 982

7.1 Raising concerns

In most circumstances the easiest way to raise a concern is for the individual to raise this with their line manager. There is no necessity to wait for 'proof' nor to gather evidence (*Freedom to Speak up Policy)*

If the individual feels unable to raise the matter with the line manager, the concern can be raised directly with the Research Services Manager, the Director of Research Operations or Associate Medical Director of Research.

Concerns can also be raised with one of the Freedom to Speak Guardians ftsug@nnuh.nhs.uk

7.2 Addressing concerns

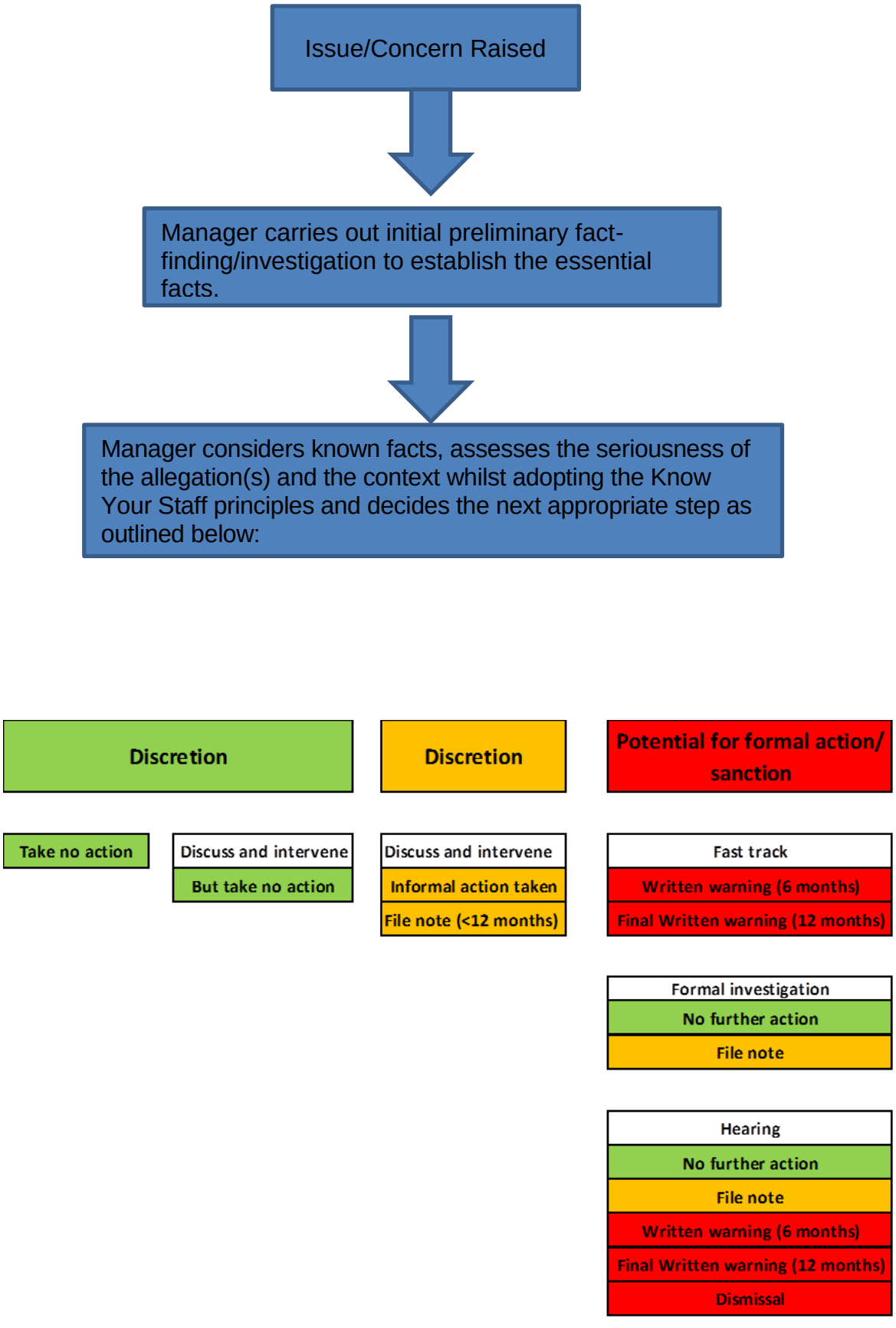
Detailed procedures and responsibilities for the handling of suspected fraud and misconduct as well as sanctions are set out in the Trust Misconduct Policy (see the reference at section 7). Below is the flow chart summarising the process.

On most occasions, it will not be necessary and/ or appropriate for managers to use the formal stage of the Misconduct Policy and informal discussion may be sufficient to collect sufficient background information, reinforce standards and support performance improvement.

Normally the informal discussion will be made between employee and their line manager, however individuals addressing concerns should have sufficient expertise to be able evaluate scientific and / or research issues.

SOP 220, Management of Suspected Fraud and Misconduct in Research

The below flowchart should be viewed in conjunction with the Trust's Misconduct Policy.
Misconduct Process Flowchart Trust Doc ref 18469



Particular Research Sanctions
In addition to the sanctions noted above, research sanctions may include (but are not limited to): removal from the particular project; increased monitoring of future research work; requirements to undertake specified training; withdrawal of funding for the research programme.

Other important considerations
At any stage of the process consideration should be taken by the manager on the possible impact of allegations and facts ascertained on the rights and safety of the participants as well as integrity of project. In the event of such impact the Research Services Manager and / or Director of Research Operations will liaise immediately with the Associate Medical Director for Research to agree actions. For projects sponsored by other organisations the R&D department will liaise with the sponsor. Similarly if NNUH received external funding for a research project, R&D department will lead on communication with the funder.

8. Procedure UEA

For UEA employees, please refer to UEA's Procedures for Dealing with Allegations of Misconduct in Research. UEA will consider the actions to be taken on receipt of an allegation and respond appropriately.

Where the incident involves any member of staff for whom NNUH is a substantive employer or staff working on NNUH Sponsored projects then RIN shall notify the R&D Office of any substantiated incidents of fraud.

9. Procedure for studies sponsored by NNUH /UEA but hosted at other institutions.

Where the incident involves activities on a research project sponsored by NNUH / UEA then the host institution shall notify the R&D Office / RIN of any substantiated incidents of fraud and misconduct.

10. References and Related Documents

References
Fraud Act 2006
ICH GCP E6 / SI 2004/1041
MRC policy and procedure for investigating allegations of research misconduct v 1.3
UK Policy Framework of for Health and Social Care Research v.3.3 7.11.2017
NNUH Anti-Fraud and Bribery Policy – Trust Docs ref 7428
NNUH Cyber Code of Conduct – Trust Docs ref 982
NNUH Freedom to Speak Up: Raising Concerns (Whistleblowing) Policy – Trust Docs ref 688
NNUH Misconduct Policy – Trust Doc Reference 15355
UEA Procedures for Investigating Allegations of Research Misconduct made against students 2023/24

UEA Procedures for Dealing with Allegations of Misconduct in Research	
UEA Fraud and Corruption Policy	
SOP No.	SOP Title
SOP 001	Production, Review, Approval and Control of SOPs Related to Research Activities

11. Approval

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12. Training Implication

Training Implication	**Yes**
Actions required	• Additional training may be required