University Hospitals of Derby and Burton
NHS Foundation Trust

TRUST POLICY FOR THE IDENTIFICATION OF RESEARCH MISCONDUCT AND FRAUD

Reference Number CL-CP/2009/012	**Version:** V6		**Status**	**Author:** **Job Title**
Version / Amendment History	Version	Date	Author	Reason
				Reformatted to meet NHSLA standards
	3	November 2014	Dr Ramila Patel	Review
	4	July 2017	Dr Teresa Grieve	Review
	5	Jan 2021	Dr Teresa Grieve	Review
	6	Jan 2024	Dr Teresa Grieve	Review

Intended Recipients:
This policy applies to all University Hospitals of Derby & Burton NHS Foundation Trust employees, substantive and honorary contract holders, students, and independent contractors who conduct research on Trust premises and/or using Trust facilities.

Training and Dissemination: Dissemination will be via the Intranet

To be read in conjunction with:
It should be read in conjunction with the Research & Development (R&D) Standard Operating Procedures (SOPs) for the conduct of research and with the Disciplinary of Employees Excluding Medical and Dental Staff - Overarching Policy for University Hospitals of Derby and Burton NHS Foundation Trust, Disciplinary of Medical and Dental Staff - Overarching Policy for University Hospitals of Derby and Burton NHS Foundation Trust, Freedom to Speak Up (Raising Concerns at Work) - UHDB Trust Policy and Procedure and Counter Fraud, Bribery and Corruption - Trust Policy and Procedure Policies.

In consultation with and Date:
Research and Development Strategy Group

EIRA stage One Completed Yes
Stage Two Completed No

Procedural Documentation Review Group Assurance and Date	Yes
Approving Body and Date Approved	Trust Delivery Group
Date of Issue	Jan 2021
Review Date and Frequency	Jan 2024 then every 3 years
Contact for Review	Asst Director Research & Development
Executive Lead Signature	 Dr Gis Robinson, Interim Executive Medical Director

Contents

1. Introduction

The UK Policy Framework for Health and Social Care Research (2020) sets in place principles, requirements and standards for all those involved in research in order to ensure that all research conducted is safe, of a high quality and contributes to improving the treatment and care of patients. Under the Framework, Trusts are required to take proportionate, effective action in the event of errors and breaches or if misconduct or fraud are suspected.

2. Aim and Scope

The aim of this Policy is to define what constitutes research misconduct and fraud and the procedure to be followed for identifying, reporting, investigating and management of suspected research misconduct and fraud.

This Policy is therefore intended to set out:

- The principles for good clinical practice in research.
- Ways of preventing and dealing with research misconduct and fraud.
- Training and education of Investigators, Researchers and Supervisors to help identify and prevent the occurrence of misconduct and fraud in research that they undertake.

This Policy applies to all University Hospitals Derby and Burton NHS Foundation Trust (Trust) employees, substantive and honorary contract holders, students and independent contractors conducting research on Trust premises and/or using Trust facilities. In the case of allegations of misconduct and fraud against temporary honorary post-holders, there must be consultation with the substantive employer. The Policy should be read in conjunction with the Research & Development (R&D) Department Standard Operating Procedures (SOPs) for the conduct of research and with the Disciplinary of Employees Excluding Medical and Dental Staff - Overarching Policy for University Hospitals of Derby and Burton NHS Foundation Trust, Disciplinary of Medical and Dental Staff
- Overarching Policy for University Hospitals of Derby and Burton NHS Foundation Trust,, Freedom to Speak Up (Raising Concerns at Work) - UHDB Trust Policy and Procedure and Counter Fraud, Bribery and Corruption - Trust Policy and Procedure Policies.

3. Definitions

There are various definitions in use to define research misconduct and fraud. The Cope Report describes the Medical Research Council (MRC) definition as the most pragmatic definition, and this will be used by the Trust.

Research misconduct and fraud:

- **It includes** the fabrication, falsification, plagiarism, misrepresentation or deception in proposing, carrying out or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research.
- **It includes** failure to follow established protocols (e.g. consent), including those of the Research Ethics Committee (REC), if this failure results in unreasonable risk or harm to humans, other animals or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others.
- **It includes** intentional, unauthorised use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings, data, hardware or software or any other substances or devices used in or produced by the conduct of research.
- **It includes** 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; improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes failure to disclose conflicts of interest.
- **It does not include** honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct unrelated to the research process. Similarly, it does not include poor research unless this encompasses the intention to deceive.

4. Principles of Good Practice

The Policy and Procedure for Misconduct and Fraud is based on the following principles of good practice:

- An understanding that a research study may not commence without written, favourable opinion of a Health Research Authority (HRA) and Research Ethics Committee where required, and, for Clinical Trials of Investigational Medicinal Products (CTIMPs) (i.e. any trial intending to use a medicine as the intervention or control), a Clinical Trial Authorisation (CTA) and, for a Clinical Investigation of a Medical Device, a Notice of No Objection from the Medicines for Healthcare Regulatory Authority (MHRA). All studies undertaken at the Trust must have Confirmation of Capacity and Capability from the Trust R&D Department in place before the study commences.

- Ensure the safety of all involved in the research through risk assessment of all significant hazards associated with the protocol.

- All research must undergo appropriate peer review. For Trust-sponsored research this will be as detailed in the Trust R&D Standard Operating Procedure (SOP) for Scientific Peer Review (SOP-RGE-017).

- Knowledge and familiarity with guidance and standards for best research practice, including the UK Policy Framework, The ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (R2) and The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.

- A Trust emphasis on prevention of research misconduct and fraud.

- The Trust will seek to ensure that all concerns raised are dealt with fairly and within an agreed time.

- The Trust will ensure that the principles of the Data Protection Act (2018) are adhered to particularly in relation to the storage of confidential documentation and in the protection of the professional reputation of members of staff regarding whom concerns/allegations are being made.

- Awareness of the existence of this Policy by all staff.

5. Systems for the Detection of Research Misconduct and Fraud

Throughout the lifecycle of a research study, quality assurance (QA) systems, such as monitoring and audit may identify concerns of actual or potential research misconduct and fraud. Concerns may also be identified via pharmacovigilance, statistical data analysis, Data / Safety Monitoring Committees (as in large multi-centre trials).

Concerns may be raised locally, by a member of staff or service user, or by an outside organisation, such as the external sponsor.

Concerns may be brought to the attention of the R&D Department in writing, verbally, anonymously or in person.

In addition to the above, any research project or organisation involved in research may be selected for inspection at any time by the competent authority e.g. MHRA, Human Tissue Authority (HTA) or any other regulatory agency

At the Trust the following QA systems relating to research activity are employed:

- Study monitoring and audit, either sponsor-led and/or undertaken by on behalf of the R&D Department.

- All Trust-sponsored CTIMPs will have in place, at study commencement, a monitoring plan based on risk-based approach.

- The 6 Monthly Study Status Reports (SOP-RGE-026).

- Statistical methods for the detection of data fabrication will be applied for all Trust Sponsored CTIMPs and other high-risk studies.

Ongoing Trust approval to undertake research is subject to Investigator compliance with R&D reporting requests and all other QA requirements.

6. Responsibilities for dealing with Research Misconduct and Fraud

The Assistant Director of R&D is responsible for reporting to the Clinical Director of R&D and the Executive Medical Director all cases of serious research misconduct and fraud identified or an allegation of serious research misconduct requiring further investigation. **The Executive Medical Director will have responsibility for informing the Assistant Director of R&D and / or Clinical Director of R&D of concerns raised under this Policy through "whistle-blowing", verbal or written complaints that require their consideration and / or action.**

- The Executive Medical Director / Delegate and the Assistant Director of R&D are responsible for liasing with all other involved directorates e.g. HR for Disciplinary action, Counter Fraud Specialists etc.
- The Assistant Director of R&D / Delegate is responsible for notifying the REC and the relevant regulatory body, where applicable of all allegations of serious research misconduct in Trust sponsored research.
- The Assistant Director of R&D / Delegate is responsible for notifying the research sponsor (for externally sponsored research) of all allegations of serious research misconduct and fraud and for ensuring that the REC and the relevant regulatory body, where applicable is informed.
- Where there is a conflict of opinion between the Trust and the external sponsor regarding whether an allegation of serious research misconduct should be reported the Trust reserves the right to report directly to the REC and the relevant regulatory body where applicable.
- The Assistant Director of R&D has a responsibility to report to the Research and Development Strategy Group where appropriate.
- The Chief Investigator (CI) / Principal Investigator (PI) must inform the Trust R&D Department of all Trust-related research i.e. human research that involves, patients, staff, data, samples, facilities and/or Trust premises.
- The Assistant Director of R&D is responsible for liaising and agreeing an investigation procedure with external organisations and employers when concerns are raised regarding staff members
- Where the Executive Medical Director, Clinical Director of R&D and Assistant Director of R&D are the subject of the complaint or report, the Chief Executive and / or nominee(s) will assume the responsibilities of the Executive Medical Director, Clinical Director of Research & Development and Assistant Director of R&D as described above.

7. Research Misconduct and Fraud Procedure

Individuals who wish to make a complaint may use one of the following channels:

- Any member of R&D Department staff – for escalation
- Clinical Director of R&D
- Assistant Director of R&D
- Executive Medical Director
- Through recommended channels for raising concerns (e.g. through local "whistle-blowing" procedures)
- Local Counter Fraud Investigators
- Chief Executive, in cases where the Executive Medical Director, Clinical Director of R&D and Assistant Director of R&D are the subject of the complaint.

The stages of investigation for an alleged case of research misconduct and fraud are set out in *Appendix 1*.

The aim of the procedure is to ensure where possible that concerns raised can be resolved through informal investigation, there may be occasions however when a formal investigation may be required.

Where the concern / complaint has been made not as a direct result of monitoring, auditing, inspection, anonymity and confidentiality should be maintained as long as possible.

Information will be exchanged for the proper conduct and conclusion of any case and disclosure of any information will be to those individuals who 'need to know'.

On occasion, the Trust may seek the involvement of an external adviser(s). e.g. Where a concern of serious financial impropriety is suspected, external advice may be sought from the police on the recommendation of the counter fraud services.

Reporting
The levels of reporting will be governed by the following criteria:

- The outcome of the particular stage of the review process.
- The main employer.
- The conditions set by the funding body.
- The regulations set by the professional body.

Documentation
Comprehensive and careful notes should be taken at each stage of the review and investigative process and must be maintained for audit trial purposes and record keeping. All notes should be stored in a safe and secure environment during the process and filed in the Executive Medical Director's Office once the matter is concluded. All documentation will be handled in accordance with the provisions of the Data Protection Act 2018.

Any one of the following may grant access rights to the records and notes: the Executive Medical Director, Chief Executive.

Sanctions may include but are not limited to the following:

- Verbal warning
- Written warning
- Remedial training relevant to the incident
- Referral to professional body e.g. GMC, RCN etc.
- Withdrawal of REC approval for the study
- Withdrawal of Trust approval for the study
- Exclusion from applying for Research Funding for a set period of time
- Banned from being a Chief Investigator/ Principal Investigator for future research
- Disciplinary Procedure invoked
- Dismissal / Termination of employment
- Referral of the case to the police

8. Revision

The Policy will be reviewed in January 2024 and thereafter updated on a three-yearly basis. The review will be undertaken by the Executive Medical Director, Clinical Director of R&D, Assistant Director of R&D and Head of Clinical Trials & Research Governance.

9. Acknowledgement

We acknowledge the assistance of the text of Addenbrooke's NHS Trust (2003) Policy and Procedure: Good Research Practice-Misconduct and Fraud, Trust R&D Department, which has been used in the preparation of this Policy document.

10. References

University Hospitals Derby & Burton NHS Foundation Trust Freedom to Speak Up (Raising Concerns at Work) Policy (POL-HR/1816/06) (2017).

UK Framework for Health & Social Care Research (Department of Health & Social Care 2020)

The Cope Report: Committee on Publication Ethics (2000)

NHS R&D Forum Advice for NHS Trusts: Research Misconduct and Fraud. Consultation Doc (July 04)

Medical Research Council *Policy and Procedure for Inquiring into Allegations of Scientific Misconduct* (December 1997 London)

Medical Research Council policy and procedure for investigating allegations of research misconduct (November 2014)

Appendix 1: Stages of Investigation

Informal Stage:

A complaint or concern is raised by an individual to a member of the R&D Department, the R&D Clinical Director, Assistant Director of R&D, Executive Medical Director or any appropriate person identified through a local policy for raising concerns (whistle-blowing). Awareness of issues of concern may also be received as a result of study monitoring/audit/inspection or by any other research related process.

The Assistant Director of R&D / Delegate must be made aware immediately or within a reasonably timely manner of any complaint or concern that has not been reported directly to them. The Assistant Director of R&D / or their deputy is responsible for informing the Clinical Director of R&D.

An audit trail of all communications must be maintained.

At this informal stage the Assistant Director of R&D / Delegate shall lead an initial investigation (except where there is a conflict of interest in which case an appropriate alternative individual will be appointed).

In the first instance, the complaint or concern may be resolved informally without a need for referral to the formal stages, if appropriate. If there is any doubt as to the seriousness of the matter, then the Executive Medical Director or the Clinical Director of R&D or the Chief Executive where the aforementioned are the subject(s) of the complaint must be consulted.

Formal Investigation:

Where the initial investigation during the informal stage determines that a formal investigation is required then the following process will be followed:

Stage	Process	Action
1. Raising complaint /concern	Clinical Director or Assistant Director of R&D, or Executive Medical Director receives communication of complaint **OR** The Chief Executive where the above are the subject(s) of the complaint	i. Complainant /or the person raising the concern to provide a detailed written statement in support of the allegation. Where a concern has been raised as a result of study monitoring / audit, then the written monitoring / audit report and any associated documentation may be provided. Where a concern has been received in the form of an anonymous telephone phone call the person taking the call must provide a written transcript outlining the content of the communication. ii. Researcher to be informed by the Executive Medical Director (or Chief Executive where applicable) that a complaint / concern has been made and that an assessment panel will be set up to review the complaint / concern
2. Investigation	Assistant Director of R&D (or Chief Executive where applicable) requests a full audit (triggered audit) of the research study involved	i Detailed written report to be provided to the Clinical Director and Assistant Director of R&D and Executive Medical Director (or Chief Executive where applicable)
3. Assessment	An Assessment Panel should be set up consisting of 2 members as a minimum	The following actions should then be taken: i. No case to answer – the researcher to

	i. Clinical Director R&D/ Assistant Director of R&D, Executive Medical Director or Nominee of the Executive Medical Director (or Chief Executive or nominee where applicable) ii. A representative of the lead employer (e.g. Trust, University or other) Panel to inform the Executive Medical Director (or Chief Executive where applicable) of their findings in writing within 7 days of receipt of the complaint, under the following headings: i. No case to answer ii. No case, but malicious intent iii. Minor concern iv. Major Concern	be informed ii. <u>No case, but malicious intent</u> – the researcher to be informed. The relevant HR Departments to be informed and for relevant action to be taken in respect of the complainant. iii. <u>Minor concern</u> – the panel to recommend actions for resolution of the concern for the Executive Medical Director (or Chief Executive where applicable) to consider and authorise if appropriate. Executive Medical Director (or Chief Executive where applicable) to then communicate with necessary parties. iv. <u>Major Concern</u> – to proceed to Stage 4 of the process
4. Formal Investigation	Investigation Team to be appointed consisting of **2** members as a minimum **and** an independent assessor i. Clinical Director R&D /Assistant Director, Executive Medical Director or nominee (or Chief Executive or nominee where applicable) ii. A representative of the lead employer (e.g. University or Medical Research Council) iii. Independent Assessor	i. Researcher to be advised of the detail of the complaint in order to prepare ii. Researcher to be given written notice of requirement to assist fully in the formal investigation process iii. Researcher to be informed of the membership of the Investigation Team iv. A written report of the findings to be prepared by the Investigation Team and presented to the Executive Medical Director (or Chief Executive where applicable)
5. Outcomes of Investigation	Executive Medical Director (or Chief Executive where applicable) to receive a report of the findings and recommendations of the Investigation Team.	Executive Medical Director (or Chief Executive where applicable) to recommend 1 or more of the following and to communicate recommendation(s) to the relevant parties: i. Implementation of all or some of the Investigation Team's recommendations. ii. Referral to Lead Employer recommending action under Disciplinary Procedures iii. Report to the Research and Development Strategy Group iv. Report to an external regulatory body
6. Appeal Process	Where disciplinary action has been invoked then the researcher would have access to a right of appeal through their Lead Employer's Disciplinary Procedure. If no disciplinary action has been invoked and the researcher wishes to appeal against the process of the investigation, then an appeal should be submitted under the Lead Employer's appropriate Appeals or Grievance Procedure.	

NB. Individuals to be advised of their right to representation during all of the above processes.

The length of time required for the formal investigation process will depend on the complexity and seriousness of the complaint/concern raised. However, even in the most complex and serious cases, the process from receipt of the complaint/reporting of the concern to outcomes of the investigation should ordinarily be no more than 6 months.