

Policy

Misconduct and fraud: good research practice

1 Scope

Trust-wide: for use by staff when undertaking research activity.

This policy should be read in conjunction with the Trust's misconduct and fraud: good research practice [procedure](#).

2 Aim

To ensure:

- the safety of those involved with research;
- that there is fairness and equity in the conduct of research taking place in the Trust.

3 Introduction

Research and development is essential for the NHS so that it can achieve its aim of continual quality improvement. Whilst pursuing research, NHS Trusts must ensure that there are proper systems and processes to protect and safeguard the wellbeing of both participants and researchers.

This policy sets out principles for good clinical practice in research, in particular, ways of preventing and dealing with research misconduct and fraud. Education and training of both supervisors and researchers will therefore play a major part in helping to prevent incidence of misconduct and fraud.

This policy applies to all Trust employees. It also applies to individuals appointed on honorary contracts with the Trust. Individuals appointed to an honorary contract will be required to give their agreement to abide by the terms of this policy. The policy has been drawn up in full consultation with the Clinical School and the Medical Research Council. The University and Medical Research Council have existent policies in research misconduct.

The policy and accompanying procedure form part of the wider management arrangements for governance within the Trust. The documents make clear the arrangements in place for personnel to raise concerns over the conduct of research within the Trust.

Research and Development Department

Corporate Development Directorate

3.1 Context

In keeping with the main precepts in NHS research and development (R&D), the policy and procedure emphasise the view that patients and consumers are not simply passive subjects on whom research is carried out but are seen as active participants in the research process.

The Trust's research governance framework sets in place systems and processes which ensure that all research is:

- safe,
- of a high quality and
- contributes to improving the treatment and care of patients.

All research active organisations are required to have implemented a plan for research governance¹. Part of the requirement contained in this plan refers to 'systems to detect and deal with research misconduct and fraud.'

Additionally, sponsors and funders who provide major grants for NHS related research might make specific requirements for host institutions.

3.2 Definition

'Research misconduct and fraud' is defined as:

The fabrication, falsification, plagiarism 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, including those of the Local Research Ethics Committee and Tissue Bank Committee, if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others.
- It also 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 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 deceive².

3.3 Principles

The policy and procedure for *Good Research Practice – Misconduct and Fraud* is based on the following principles of good practice:

- Awareness of the existence of this policy and procedure will form an important first step in good research practice. All staff involved in

research will be made aware of this policy and procedure and their responsibilities under it.

- The Trust places considerable emphasis on prevention of misconduct and fraud.
- The medical director will have responsibility for informing the Research Governance Committee of any matters raised under this policy which require their consideration and/or action. In turn, the Research Governance Committee has a responsibility to report to the Clinical Governance Committee where appropriate.
- The Trust will seek to ensure that all concerns raised are dealt with in the timescale set out in the procedure.
- The Trust will seek to ensure that due consideration is given to safeguarding the confidentiality and professional reputation of members of staff regarding whom concerns are being made.
- All research must undergo an external independent peer review and must be submitted to the Local Research Ethics Committee for approval.
- Approval by the Trust R&D Office must be sought for all research that involves patients, patient samples (blood, tissue etc) and patient data and Trust infrastructure (eg research equipment): see the [Trust management approval for research studies](#) policy and procedure.
- All commercially led research must comply with the Trust's [externally funded commercial research activity](#) policy.
- Under the research governance framework, the principal investigator (PI) is responsible for the conduct of his or her research team. If a PI is unsure of due process in relation to any of the above points then s/he should contact the Trust R&D manager for advice.

4 Responsibilities

All employees of the Trust and those with honorary contracts have a responsibility to report any incident of misconduct whether this has been witnessed or suspected.

Suspensions reported in confidence and in good faith will not lead to disciplinary proceedings against the person making the complaint and the Trust's [raising concerns \('whistleblowing'\)](#) procedure will apply. However, in the event of a malicious allegation, appropriate action will be taken.

5 Monitoring compliance with and the effectiveness of the policy

Any reports of misconduct and/or fraud will be reviewed as per this policy and the effectiveness of this policy will be monitored by those involved with the review process as and when they occur. The format of the monitoring

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will be undertaken as a review and any results will be reported to the Research Governance Committee.

References

1. Department of Health *Research Governance Implementation Plan Guidance Notes 2000*
2. Medical Research Council *Policy and Procedure for inquiring into allegations of scientific misconduct* London MRC 1997

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

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