Research Misconduct Policy

Division: Trust-Wide
Document No (if Trust-Wide): R&D P06

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
All employees of the Trust engaged in research, including individuals employed by a third party, by external contractors, as students, as locums or as agency staff	As required	R&D Department staff, Research active staff

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KEYWORDS:	Clinical research, misconduct, integrity, allegation, confidentiality
Summary of changes since the previous version	New policy, to comply with NIHR funder terms. Research Misconduct is managed in line with the Trust's Freedom to Speak up and Disciplinary Policies. This new Research Misconduct Policy clarifies the definition of Research Misconduct, the responsibilities for investigating allegations and possible sanctions relating to cases of Research Misconduct.

1. Executive summary

1.1. All research at the Trust is overseen by the Research and Development (R&D) department. The Trust expects all its employees to observe the highest standards in the conduct of research.

1.2. Misconduct in research can have serious consequences for research participants, research generalisability and usefulness, as well as having a negative impact on individual researchers, employers, funders, and the wider public, leading to damage to public trust in research.

1.3. All staff have a responsibility to be alert to the risk of Research Misconduct and to follow procedures correctly, to minimise the opportunity for misconduct to occur.

1.4. Research Misconduct constitutes deliberate, reckless or negligent action rather than an honest mistake.

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1. Purpose of the policy

1.1. The UK Policy Framework for Health and Social Care Research v3.3 dated 07/11/2017 states that employers of the chief investigator and members of the research team are expected to "***take proportionate, effective action in the event of errors and breaches or if misconduct or fraud are suspected***."

1.2. The Concordat to Support Research Integrity (Universities UK) declares that employers of researchers are responsible for ***"demonstrating that they have procedures in place to ensure that research is conducted in accordance with standards of best practice; systems to promote research integrity; and transparent, robust and fair processes to investigate alleged research misconduct."***

1.3. In addition, the Researcher Development Concordat (Universities UK) states that researchers must "***use available mechanisms to report staff who fail to meet the expected standards of behaviour, particularly in relation to discrimination, harassment, bullying, and research misconduct.***"

1.4. It is also a recommendation of good practice that all NHS Trusts undertaking, sponsoring, funding, and hosting research have a clear Board-approved policy that includes the identification and handling of Research Misconduct.

1.5. The purpose of this document is to define and clarify the potential causes of Research Misconduct and clarify the Trust procedures for:

1.5.1. The reporting of allegations of Research Misconduct in line with the Trust's Freedom to Speak Up Policy (PEO-22),

1.5.2. The investigation of such reports in line with the Trust's Disciplinary Policy (PEO-06).

2. Scope of the Policy

2.1. This document applies to all areas of the Trust, and all employees of the Trust, including individuals employed by a third party, by external contractors, as students, as locums or as agency staff.

2.2. This document applies to Research, as defined by the UK Policy Framework for Health and Social Care Research, from which new and generalisable findings are derived.

3. Definition of terms

3.1. "**Research Misconduct**" includes the following, deliberate, reckless, or negligent actions:

- failure to obtain appropriate permission to conduct research;
- deception in relation to research proposals;
- unethical behaviour in the conduct of research, for example in relation to research participants;
- unauthorised use of information which was acquired confidentially;

- deviation from Good Clinical Practice, where this results in unreasonable risk of harm to humans;
- fabrication, falsification, or corruption of research data;
- distortion of research outcomes, by distortion or omission of data that do not fit expected results;
- dishonest misinterpretation of results;
- publication of data known or believed to be false or misleading;
- plagiarism, or dishonest use of unacknowledged sources;
- misquotation or misrepresentation of other authors;
- inappropriate attribution of authorship;
- attempting, planning, or conspiring to be involved in research misconduct;
- inciting others to be involved in research misconduct;
- collusion in or concealment of research misconduct by others;
- failing to declare or appropriately manage conflicts of interest;
- undertaking regulated activity when you are barred from such activity;
- failing to declare your removal from a professional register by a regulatory body, or conditions placed on your registration, where your role in a research study requires a professional registration;
- fraud or other misuse of research funds or research equipment.

3.2. Fraud or other misuse of research funds or research equipment may be dealt with under the Trust's Counter Fraud and Corruption Policy (CO-06).

4. Roles and responsibilities

4.1. The Chief Executive has overall responsibility for the integrity and conduct of clinical research conducted within the Trust.

4.2. The Chief Medical Officer/Responsible Officer has delegated authority and is responsible for ensuring that this policy is approved and followed by staff working within the Trust and that it is reviewed in a timely manner. Also, that it complies with The Medical Profession (Responsible Officers) (Amendment) Regulations 2013.

4.3. The Director of Research has delegated authority and is responsible for working with the Deputy Director of Research to ensure that all concerns are addressed in an appropriate manner.

4.4. The Deputy Director of R&D is responsible for receipt of concerns with regard to possible Research Misconduct and for ensuring that such concerns are investigated and followed up to conclusion.

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

5. Procedures

5.1. The Trust expects all its employees to observe the highest standards in the conduct of their research and in pursuance of such high standards it is expected that they will:

5.1.1 Take steps to acquaint themselves with available guidance as to "best practice" whether in relation to matters of research policy, finance, or safety relevant to their area of research e.g. the UK Policy Framework for Health and Social Care Research; the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.

5.1.2 Observe such legal, ethical, managerial, and training requirements as are laid down by the Trust or by Health Research Authority (HRA) or other appointed bodies involved in their field of research.

5.1.3 Take steps to ensure the safety of those associated with the research.

5.1.4 Report any conflict of interest, whether actual or prospective, to the Trust. Please see also the Trust's Declaration of Interest Policy (CO-10).

5.1.5 Observe fairness and equity in the conduct of their research.

5.1.6 Comply with the requirements of an individual's Professional Registration, as set out by their Professional Body/Council, where relevant.

5.1.7 Failure to comply with the policy may give rise to an allegation of misconduct in research. Research Misconduct may be grounds for disciplinary action and, if serious, may be considered as gross misconduct which can result in dismissal or withdrawal of an honorary contract with the Trust.

6 Confidentiality

6.1 Suspicions reported in confidence and in good faith, even if proven to be unfounded, will not lead to disciplinary proceedings against the person raising the concern and the Trust's Freedom to Speak Up Policy (PEO-22) will apply for qualifying disclosures. However, in the event of a malicious allegation, appropriate action will be taken.

6.2 All allegations will be investigated in the strictest confidence. All those who are involved in the procedures for investigating an allegation including witnesses, representatives and people providing information, evidence and/or advice have a duty to maintain confidentiality.

6.3 However, for an allegation to be investigated fully and appropriate action taken, it may be necessary to disclose the identity of the complainant to the person who is the subject of the complaint. The complainant will be advised before such disclosure is made.

6.4 In cases of possible, suspected, serious Research Misconduct, the Trust may have a contractual requirement to inform the research funder/s of the allegation and keep the funder/s informed of progress with the investigation.

6.5 In cases where the allegation involves an honorary appointee, the staff member's substantive employing organisation may be informed of the allegation and subsequent investigation, as appropriate.

7 Procedure in the Case of Suspected Misconduct in Research

7.1 These procedures are without prejudice to the normal operation of the relevant disciplinary procedures of the Trust (NBT Disciplinary Policy (PEO-06) and Maintaining High Professional Standards Policy for Medical Staff (PEO-11)). They are set out by way of guidance only and may be varied to suit the circumstances of a particular case. In the event of any conflict between these procedures and the relevant disciplinary procedure of the Trust, the latter shall take precedent.

7.2 Reports of Research Misconduct, either witnessed or suspected, should be made directly to, or escalated to, the Deputy Director of R&D in the first instance.

7.3 On receiving the allegation, the Deputy Director of R&D will assess whether any immediate action is required to prevent further risk or harm to employees, research participants or the Trust or immediate action required to protect data and research integrity.

7.4 This will be followed by a preliminary investigation lead by the Deputy Director of R&D, or nominated R&D Senior Team representative, to determine whether: there is no substance in the allegations and therefore no further action is necessary; the case has substance but does not meet the threshold of research misconduct and can be dealt with outside of this policy or if there is evidence of Research Misconduct, which would need to be referred to the Director of R&D and Chief Medical Officer.

7.5 In the event of there being a case to answer, the investigation of such reports will occur in line with the Trust's Disciplinary Policy (PEO-06).

7.6 Where an allegation of Research Misconduct is being formally investigated, the Director of Research/Chief Medical Officer will make a decision whether to suspend the research and if it is appropriate to inform the Sponsor (as defined in the UK Policy Framework for Health and Social Care Research) of the ongoing investigation.

7.7 As well as sanctions identified within Trust Disciplinary Policy, other sanctions, through the authority of the Director of Research, may include:

7.7.1 Withdrawal of pending grant submissions led by the individual concerned.

7.7.2 Withdrawal of the individual concerned from co-applicant roles on partner grants.

7.7.3 Withdrawal of Confirmation of Capacity and Capability for continuation of a research project and, possibly, any research projects in which the individual concerned has involvement.

7.7.4 Withdrawal of pending abstracts and papers from the research in question.

7.7.5 Submission of a Letter of Apology and/or Expression of Concern, Retraction or Withdrawal request for published abstracts and papers from the research in question.

7.7.6 Changes in staffing to relevant research project/s.

7.7.7 More frequent auditing and closer monitoring of future work.

7.7.8 Barring the individual concerned from conducting research in the Trust for a given period.

7.7.9 Revoking an honorary research contract.

7.8 Where a researcher feels that they have been unfairly sanctioned, this should be addressed through the Trust grievance procedures.

7.9 In the case of misconduct, professional groups may also be subject to disciplinary action by their professional bodies. Doctors are responsible to the General Medical Council for their professional conduct as researchers, as well as clinicians. Similarly, nurses, health visitors and midwives are responsible to the Nursing and Midwifery Council.

7.10 In the case of misconduct, the Sponsor will be informed and will be responsible for reporting the misconduct to REC/HRA, if it is appropriate to do so.

7.11 In the case of misconduct related to involvement in Clinical Trials of Medicinal Products or Devices, this will be reported to the Sponsor who will be responsible for reporting the misconduct to the Medicines and Healthcare products Regulatory Authority, if it is appropriate to do so.

7.12 Attention will be drawn to this policy as a condition of Sponsor approval and/or Confirmation of Capacity and Capability.

8 Monitoring effectiveness

8.1 The below table details the monitoring procedures in order that NBT can be assured that compliance with a policy is being met. It identifies both the processes for monitoring compliance and the actions to be taken where deficiencies and non-compliance are identified. This table must be completed in all policies.

8.2 This section describes how the implementation of the policy will be monitored. Audit activity should form part of all policy monitoring; therefore an audit tool/checklist must be appended (or reference made to a national audit the Trust participates in on a regular basis). The below table should be populated with the key areas currently being monitored in addition to any monitoring criteria as required by regulators such as the CQC. This table can be extended as required.

What will be monitored	**Monitoring/ Audit method**	**Monitoring responsibility *(individual/group/ committee)***	**Frequency of monitoring**	**Reporting arrangements *(committee/group the monitoring results are presented to)***	**How will actions be taken to ensure improvements and learning where the monitoring has identified deficiencies**
Volume of allegations	CaseworkER tracker	R&D Senior Team	Annual	Trust Research Group	Audit of all allegations, identify any trends or patterns from which corrective actions could be implemented.
Compliance with policy	Review volume of formal vs informally resolved cases and outcomes	R&D Senior Team	Annual	Trust Research Group	Audit of all allegations and decision-making processes against policy.

9 Associated policies/documents

This document should be read alongside the following policies:

9.1 Freedom to Speak Up Policy (PEO-22)

9.2 Disciplinary Policy (PEO-06)

9.3 Counter Fraud and Corruption Policy (CO-06)

9.4 Declaration of Interest Policy (CO-10)

9.5 High Professional Standards Policy for Medical Staff (PEO-11)

10 References

10.1 UK Policy Framework for Health and Social Care Research UK Policy Framework for Health and Social Care Research - Health Research Authority

10.2 The Concordat to Support Research Integrity The Concordat to Support Research Integrity

10.3 Researcher Development Concordat researcherdevelopmentconcordat.ac.uk