# RESEARCH MISCONDUCT AND FRAUD POLICY AND PROCEDURES

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<td>Implementation date</td>
<td>01/09/2009</td>
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<tr>
<td>Version</td>
<td>1.0</td>
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<td>Supersedes</td>
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<td>Consultation undertaken</td>
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<td><strong>Target audience</strong></td>
<td>ALL STAFF INVOLVED IN RESEARCH</td>
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<td><strong>Supporting Procedure(s)</strong></td>
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<td><strong>Review Date</strong></td>
<td>JULY 2011</td>
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<td><strong>Lead Executive</strong></td>
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<td><strong>Further Guidance/Information</strong></td>
<td>R&amp;D DEPARTMENT, QMC CAMPUS:</td>
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1. **Scope**

The aim of this policy is to set out clearly what constitutes research misconduct and fraud and the processes to be followed when failure to comply with the relevant legislation frameworks is suspected and identified.

This policy relates to all NUH employees, students/trainees conducting research within NUH as well external researchers working in NUH under an honorary contract or a letter of access.

NUH requires all staff to undertake research in compliance with the following:


b) The Medicines for Human Use (clinical trials) regulations 2004

c) The Human Tissue Act 2004

d) The Mental Capacity Act 2004

e) The Data Protection Act 1998

f) Relevant NUH Policies and Procedures

- Disciplinary policy
- Policy on Fraud, Theft, Corruption and Financial Irregularities
- Clinical Incident Policy
- Research Monitoring and Audit Policy (forthcoming)

2. **Definitions**

According to the MRC Policy and Procedure for Inquiring into allegations of Scientific Misconduct, 1997, research fraud and misconduct are 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 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, unauthorized use, disclosure or removal, or damage to, research related property of another, including apparatus, materials, writings 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
judgment in evaluating research methods or results or misconduct unrelated to
the research process. Similarly, it does not include poor research unless it
encompasses the “intention to deceive”.

Examples of research misconduct/fraud include but are not limited to:

● Failure to obtain all necessary permissions (e.g. Ethics, MHRA, ARSAC, Trust
approval) to undertake a research project

● Failure to document consent appropriately

● Fabrication of research participants, results or analysis.

● Abuse of research funds or equipment.

3. Assignment of Responsibilities

The Trust R&D director or their delegate is responsible for the investigation of
any suspicion or allegation of research misconduct and fraud.

Where the researcher involved is not an NUH employee but holds an honorary
contract or a letter of access with the Trust, the researcher’s substantial employer
will be informed.

Where the study is only hosted but not sponsored by NUH, then the research
Sponsor will be informed. Under the Research Governance Framework, it is a
Sponsor’s responsibility to ensure that adequate arrangements are in place for
the detection, investigation and management of research fraud and misconduct.
It is therefore essential that any research partnership agreements specify
arrangements for the detection, reporting and investigation of research
misconduct.

4. Reporting Arrangements and Investigation

All allegations of misconduct in research will be treated seriously and fairly and
their merit investigated with integrity and sensitivity, in order to observe the
principle of no-detriment, such that neither the Complainant nor the Respondent
should suffer solely as a consequence of the fact that a good faith allegation has
been made.

Suspected research fraud and misconduct should be reported to the Director of
R&D or an appropriate delegate who will investigate in line with the policy an in
accordance with processes set out in section 5 Where necessary the R&D
director will seek expert or independent advice and make an early decision
whether or not to suspend temporarily Trust approval of the research project
concerned. Care will be taken to balance the risks to the safety and benefit to research participants.

The Medicines and Healthcare Regulatory Agency (MHRA) has the power of inspection of sites involved in the conduct of clinical trials of investigational medicinal products, and may identify research fraud or misconduct.

5. Process of investigation

The R&D Director or nominated deputy will conduct an initial informal review, followed by a formal in depth investigation if appropriate. The Trust undertakes to conduct investigation in a timely manner. An informal review will be completed in 30 days, and a formal investigation within 60 days. Failure to do so will require a written explanation to be communicated to the researcher and research sponsor.

An investigation will proceed as follows, and can be halted at any stage:

- Initial investigation by the R&D Director or nominated deputy
- Completion of a research governance “for cause” audit
- If research fraud or misconduct is suspected, the researcher’s employer will be informed. Notification of other parties such as the Research Ethics Committee, Sponsor, External funder, Local Counter Fraud Specialist and regulatory authorities such as the MHRA should be considered.
- It is likely that the researchers employing organisation will then assume responsibility for further formal investigation
- If NUH retains responsibility, either as the employing organisation, or by mutual agreement with the researches employers, a full investigation will be conducted by a panel constituted for the purpose. The panel will be selected at the discretion of the Director of R&D, but will include representatives of HR from the organisation employing the researcher and may include expertise in the field under investigation. Rarely the investigation will be chaired by an independent party. Members should have no direct involvement in the activity under investigation.
- The researcher will be informed of the outcome of the investigation within 2 working days.

Comprehensive notes will be taken at each stage of the review and investigative process. All notes should be stored in a safe and secure environment during the process and filed within the R&D Office once the matter is concluded. All documentation will be handled in accordance with the provisions of the Data Protection Act 1998.

The investigation of research fraud and misconduct will be conducted as far as possible in a manner that protects both the accused and the accuser. It is, however, good practice to present details of any allegation of research fraud and
misconduct to the accused, subject to the Trust’s Whistle Blowing Policy and Fraud and Corruption policy, and they be given the right to respond as an integral component of the investigation.

6. Outcomes of an Investigation
If the investigation concludes that research misconduct or fraud has taken place one or more sanctions may be appropriate:

- Withdrawal of NUH R&D approval for the specific research project
- Withdrawal of Trust or other funding
- Withdrawal or correction of pending or published abstracts and papers emanating from the research project in question
- Increase of the Risk Index for the research project in question, resulting in frequent auditing/monitoring and closer attention to future work originating from the researcher.
- Barring of the researcher from applying for future research funding or conducting any research within NUH.
- Revoking an honorary contract/letter of access
- Report researchers to ethics committees and professional bodies.