

Board

2004

From: Research and Development

Date: May 2005

Subject: **Integrity in Research Policy**

For: **Approval**

Synopsis

The Department of Health's Research Governance guidance states that there should be 'systems in place to detect and deal with research misconduct'. 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.

Financial impact

N/A

Integrity in Research: Policy and Procedures

Introduction

1. This policy and its procedures form part of the wider management arrangements for governance within the Oxford Radcliffe Hospitals NHS Trust. This policy sets out standards for good clinical practice in research and describes the procedures for dealing with misconduct in research.
2. The Oxford Radcliffe Hospitals NHS Trust Counter Fraud Policy and Reporting Procedure (Trust Policy No. 48) deals with all financial misconduct including anything research related.

Statement of Principle:

3. The Trust expects all its staff and staff with honorary contracts to observe the highest standards in the conduct of their research and in pursuance of such high standards it is expected that they will:
 - 3.1. 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 Department of Health’s Research Governance Framework.
 - 3.2. Observe such legal and ethical requirements as are laid down by the Trust or Research Ethics Committees or other appointed bodies involved in their field of research.
 - 3.3. Take steps to ensure the safety of those associated with the research.
 - 3.4. Report any conflict of interest, whether actual or prospective, to the Trust.
 - 3.5. Observe fairness and equity in the conduct of their research.
4. Failure to comply with the policy may give rise to an allegation of misconduct. Misconduct in research may be grounds for disciplinary action and, if serious, for dismissal.

Definition of Misconduct

5. Misconduct for the purpose of this policy means the fabrication, falsification, plagiarism or deception in proposing, implementing or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice in implementing research.
6. It includes failure to follow an agreed protocol if this failure results in unreasonable risk or harm to humans or the environment and facilitating misconduct in research by collusion in, or concealment of, such actions by others. It also includes any plan or conspiracy or attempt

to do any of these things. In addition it includes intentional unauthorised use, disclosure of or removal of or damage to research related property of another, including apparatus, materials, writings or devices used or produced by the conduct of research.

7. It does not include honest error or honest differences in interpretation or judgment in evaluating research methods or results, or misconduct unrelated to research processes.

Responsibility

8. 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.
9. Suspicions reported in confidence and in good faith will not lead to disciplinary proceedings against the person making the complaint and the Trust's Policy on Raising Concerns will apply. However, in the event of a malicious allegation, appropriate action will be taken.

Confidentiality

10. 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.
11. 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
Advice can be sought through reference to the Trust's Policy:
Raising Concerns at Work Policy No 5

Procedures in the Case of Suspected Misconduct in Research

12. These procedures are without prejudice to the normal operation of the relevant disciplinary procedures of the Trust. 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 prevail.
 - 12.1. All employees of the Trust and those with honorary contracts have a responsibility to report to the Medical Director* any incident of misconduct whether this has been witnessed or suspected.

*Trust nominated Executive Director with defined responsibility for Research Governance.

- 12.2. On receiving the allegation the Medical Director will make a preliminary investigation to determine whether:
- There is no substance in the allegations and therefore no further action is necessary
 - The case is a minor one and can be dealt with on an informal basis
 - There is a serious case to answer

During these enquires, the Medical Director will normally wish to have a discussion with the researcher involved

- 12.3 In the event of there being a serious case to answer the following Trust policies will be followed.

Performance and Conduct Procedures for Medical and Dental Staff Policy No 4

Performance and Conduct Procedure (all other staff)

Staff Policy No 3.

- 12.4 At this stage the Medical Director will make a decision whether to suspend the research and if it is appropriate to inform the Research Sponsors of the ongoing investigation.

- 12.5 In cases where the allegation involves an honorary appointee the allegation will be reported to the employing organisation and a joint investigation will take place. It will be generally expected that the employing organization will take the lead in the investigation.

Sanctions

13. As well as sanctions identified within the Performance and Conduct policies other sanctions may include:

- 13.1 Withdrawal of formal Trust R&D approval for continuation of the particular research project
- 13.2 Withdrawal or correction of pending or published abstracts and papers from the research in question
- 13.3 Changes in staffing to the project
- 13.4 More frequent auditing and closer monitoring of future work
- 13.5 Barring the researcher from applying for Trust funds for a given period or from conducting research in the Trust for a given period.

13.6 Revoking an honorary contract

14. 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.
15. In the case of misconduct related to involvement in Clinical Trials of Medicinal Products, this will be reported to the Sponsor who will be responsible for reporting the misconduct to the Medicines and Healthcare Regulatory Authority.

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