UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST

POLICY ON INVESTIGATING AND HANDLING RESEARCH MISCONDUCT

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POLICY ON INVESTIGATING AND HANDLING RESEARCH MISCONDUCT 01-10-2008

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1 Objective of this policy

1.1 This policy provides staff with guidance on the procedures that they must follow if they suspect or believe research misconduct has occurred.

1.2 The aim of the policy is to bring about improvements in an employee's conduct of research. The Trust accepts that breaches of Research Governance may occur and expects managers to deal with these firmly but sensitively and in accordance with this policy.

1.3 The purpose of this policy is:

- To protect the safety, well being, dignity and rights of research participants.
- To be supportive and corrective.
- To prevent research misconduct.
- To ensure that all allegations are investigated in a professional and consistent manner.

1.4 The policy applies to all persons employed by the Trust, whether full or part-time, Honorary Contract holders including Non-Executive Directors (all referred to as employee in the remainder of this document).

1.5 This policy will on occasion need to be read in conjunction with other Trust Policies/Procedures. These include:

- Procedure for Handling Poor Performance
- Statement on the relationship between Clinical Incident reporting and Disciplinary Procedures
- Speaking out Policy
- Health and Safety Policy
- Disciplinary Policy and Procedure

1.6 The policy should be read in conjunction with the Research Governance Framework for Health and Social Care.

2 Definitions

2.1 The policy deals particularly with matters of suspected research misconduct.

2.1.1 Research Misconduct

'Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards'
Royal College of Physicians of Edinburgh, 2000

Research misconduct includes the following, whether deliberate, reckless or negligent:

- Failure to obtain appropriate permission to conduct research
- Deception in relation to research proposals
- Unethical behaviour in the conduct or research, for example, in relation to research subjects
- Unauthorised use of information which was acquired confidentially
- Deviation from good research practice, where this results in unreasonable risk of harm to humans, other animals or the environment
- Fabrication, falsification or corruption of research data
- Distortion or 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
- Fraud or other misuse 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

*ARMED – Research Misconduct 2003**

**This list is not exhaustive.*

2.1.2 Complainant

The ‘complainant’ is the person making the allegation of misconduct in research.

2.1.3 Respondent

The ‘respondent’ is the person against whom the allegation of research misconduct is made.

3 Responsibilities

3.1 All Staff

3.1.1 Each employee has the responsibility of being familiar with the principles of good research practice described in the Research Governance Framework for Health and Social Care.

3.1.2 Each employee has the responsibility of reporting their concerns through the procedures detailed in section 5 if they suspect or believe that research misconduct has occurred.

3.2 Research active staff

3.2.1 Each research active employee has the responsibility to conduct research in accordance with the principles of good research practice

described in the Research Governance Framework for Health and Social Care.

3.3 Management

3.3.1 Management has the responsibility for establishing systems and controls, which minimise the probability of research misconduct occurring.

3.3.2 Steps which managers can take to minimise the risk include:

- Allowing access to appropriate training in research methodology and governance.
- Ensure adequate supervision of researcher

3.3.3 The UH Bristol Research and Development Department has responsibility for establishing systems of monitoring and audit of research and providing training in research methodology and governance.

3.3.4 The Research and Development Department has the responsibility to take immediate action where suspected research misconduct is reported to them.

3.4 Human Resources

3.4.1 The Human Resources Department has the responsibility to support managers through the provision of briefing/training and to provide practical assistance in investigations and hearings.

3.4.2 No formal disciplinary hearing can take place without a Human Resources practitioner supporting/advising the panel.

3.5 Chief Executive

3.5.1 The overall responsibility for this policy rests with the Chief Executive.

4 Principles

4.1 Since any allegation of research misconduct is serious, the operation of this policy by the Trust shall accord with the following:

- So far as is possible, the Trust shall throughout its enquiries and formal investigation (if any) take all reasonable measures to preserve the anonymity of the complainant. The identity of the complainant will not be made known to the respondent without obtaining the complainant's prior written consent. In the event that an enquiry or investigation cannot progress without revealing the identity of the complainant, how to proceed will be discussed with the complainant.

- The principles of natural justice shall be observed, that is to say the respondent shall be fully informed about what he or she has to answer and shall have the fullest opportunity to reply. At all stages, a colleague/Trade Union/Professional Association representative, or a friend, not acting in a legal capacity, may accompany the respondent.

4.2 Formalising expected procedures in key areas:

4.2.1 All allegations of misconduct in research shall be treated seriously and fairly and their merit investigated with integrity and sensitivity.

4.2.2 In all enquires and in any action taken as a result of their outcome, due regard shall be given to the need:

- To protect researchers against malicious, frivolous or ill-founded allegations of research misconduct.
- To protect the position and reputation of those alleged to have engaged in misconduct in research where such allegations are not confirmed.
- To protect the position and reputation of those who make allegations of research misconduct in good faith, i.e. in the reasonable belief on the basis of any supporting evidence that misconduct in research may have occurred.
- 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.

5 Notifying suspected research misconduct

5.1 It is important that staff feel able to report their suspicions to someone with whom they feel comfortable and without fear of recrimination.

5.2 The usual method of reporting suspected research misconduct is as follows:

- If an employee suspects or believes research misconduct may have occurred it should be reported to the Head of Research Management as a matter or urgency, who will inform the Director of Research and Development.

5.3 In some cases the member of staff may prefer to report their suspicions to an individual other than the Head of Research Management or elect to remain anonymous. Other reporting options available therefore include:

- Line Manager
- Divisional General Manager
- Human Resources Manager
- Director of Research and Development

5.4 In all cases the fact that concern has been raised must be reported to the Director of Research and Development.

5.5 If a member of the public should draw a suspicion of research misconduct to the attention of an employee, it is imperative that the Director of Research and

Development is informed through the systems identified in section 5. The matter should be dealt with in the same way as any other suspected research misconduct, as well as in compliance with the Trust's complaints procedure.

5.6 In all cases these communications must be confidential so that no other individual becomes aware of the concern.

6 Investigating suspected research misconduct

6.1 If research misconduct is suspected it is critical that all investigations into the suspected research misconduct are carried out in a proper and sensitive way. Hence it is extremely important that the steps detailed in this section are strictly adhered to. Staff should not normally take further action themselves.

7 Preliminary Inquiry

7.1 The Director of Research and Development, with the Head of Research Management will consider the available evidence.

7.2 The Director of Research and Development (or the Head of Research Management) will contact the appropriate HR manager for advice.

7.3 The result of this process will be one of the following:

i. The concern of suspected research misconduct is unfounded, either because it is mistaken, is frivolous or otherwise without substance, and the matter should be dismissed. Advice will be given to the complainant on why the concern is unfounded. Should the concern be related to another matter, e.g. capability it will be referred to the Line Manager to be dealt with in accordance with the appropriate policy.
ii. There is some justification in the allegation of research misconduct but the matter does not warrant formal investigation. Corrective action may be recommended. The General Manager will be informed of what action is required.
iii. There is insufficient evidence to decide whether the concern qualifies as research misconduct. A formal investigation is required.
iv. The available evidence is sufficient to constitute a prima facie case. A formal investigation is required.
v. The alleged incident is serious e.g. gross misconduct, suspension should be considered. A formal investigation is required. The procedures detailed in the Trust Disciplinary Policy must be followed.

7.4 A report summarising the available evidence and the decision of the preliminary inquiry will be written by the Head of Research Management and lodged with the Director of Research and Development.

7.5 Where the allegation is dismissed the Research and Development Department will retain of the report for a period of seven years following the employee's date of leaving.

7.6 Where a formal investigation is required, the report of the preliminary inquiry will be made available to the person(s) conducting the investigations.

7.7 The preliminary inquiry will aim to be completed within 10 days of the allegation being made.

8 Formal Investigation

8.1 If it is decided that a formal investigation is required, with a view to possible internal disciplinary hearing, the investigation will be conducted in accordance with the procedures detailed in this section, with reference to the UH Bristol Disciplinary Policy and Procedure. Any subsequent disciplinary proceedings must be conducted in accordance with the UH Bristol Disciplinary Policy and Procedure.

8.2 The Director of Research and Development will, in confidence, inform the Chief Executive of the allegation of research misconduct and the need for a formal investigation.

8.3 The Director of Research and Development will, in confidence, inform the appropriate General Manager and the Medical Director of the nature allegation of research misconduct and the need for a formal investigation. Wherever possible the identities of the complainant and respondent will not be disclosed.

8.4 In consultation with the relevant UH Bristol Executive and/or General Manager the Director of Research and Development will appoint an appropriate manager(s) to conduct the formal investigation; one of whom will usually be the Head of Research Management unless through previous involvement or action they are compromised.

8.5 Where the respondent holds an honorary contract with UH Bristol the Director of Research and Development will, in confidence, inform the Director of Research or equivalent of the employing organisation of the allegation of research misconduct and the need for a formal investigation. The employing organisation will appoint an appropriate person to assist with the formal investigation as required.

8.6 Where the respondent holds a joint appointment with UH Bristol and another organisation e.g. a University or other NHS Trust, the Director of Research and Development at UH Bristol will, in confidence, inform the Director of Research or equivalent of the 'other' organisation(s) of the allegation of research misconduct and the need for a formal investigation. The 'other' employing organisation(s) will appoint an appropriate person(s) to assist with the formal investigation as required.

8.7 The Chief Executive will appoint a 'Panel' to review the findings of the formal investigation. The Panel will consist of a Chair and two impartial reviewing officers with appropriate expertise and seniority. Each member of the panel will confirm in writing that their appointment to the Panel involves no conflict of interest.

8.8 The Human Resources Department will provide assistance with the conduct of the proceedings.

8.9 During the proceedings the investigating officer(s) will keep the UH Bristol Director of Research and Development fully informed of all developments relating to the allegation.

8.10 The investigation will be conducted in confidence. At this stage so far as is reasonably practicable no information shall be made available, which could lead to the identification of the complainant or the respondent.

8.11 In consultation with the Director of Research and Development, the investigating officer(s) will be free to determine the detailed approach to the conduct of the investigation.

8.12 The investigating officer(s) will inform the respondent in writing of the nature of the allegation and due process. The respondent will be invited to respond with any written comments within five working days. The investigating officer will take into consideration any comments received.

8.13 The investigating officer(s) will, in confidence, inform the respondent's Line Manager of the allegation and due process.

8.14 The complainant and respondent will be asked to produce relevant documentary evidence such as laboratory notebooks, witness statements, correspondence or computer records to support the allegation of misconduct and the explanation.

8.15 The investigating officer(s) shall be free to seek confidential advice in writing from experts in the relevant subject both within and outside the Trust but in doing so they shall at this stage make no information available so far as is reasonably practicable which could lead to the identification of the complainant or the respondent

8.16 The investigating officer(s) will discuss the findings of the formal investigation with the Panel.

8.17 If the Panel's preliminary conclusion is that the allegation of research misconduct is upheld, the full case, with supporting evidence, shall be put to the respondent for comment. Any further evidence produced by the respondent at this stage shall be investigated.

8.18 If the Panel's preliminary conclusion is that the allegation of research misconduct is not upheld, the Panel shall consider whether, prior to reaching its

full conclusion, it is appropriate that the case, with such supporting evidence as the Panel deems to be appropriate, shall be put to the complainant for comment. Any further evidence produced by the complainant shall be investigated.

8.19 The process described in 8.14 and 8.15 shall be repeated until the Panel is satisfied that natural justice has been served and further investigations are not warranted and that it can reach a final conclusion on the allegation of research misconduct.

8.20 During the investigation all records and related evidence shall be kept confidential. Records of interviews shall be agreed with the interviewee. The Chief Executive or Director of Research and Development shall provide confidential secretarial cover as necessary and shall draft a written report for the panel of the investigation undertaken (including a list of all documentation and evidence received) and of it's findings.

9 Findings

9.1 The outcome of the Panel review process will be one of the following:

i. The allegation of research misconduct is unfounded, and will be dismissed.
ii. The allegation is proven beyond reasonable doubt; the allegation of research misconduct is upheld.

9.2 The Chair of the Panel will inform the respondent and complainant in writing of the decision of the Panel.

9.3 The Chair of the Panel will inform, in writing, the Chief Executive, who will in turn inform the Trust Board of the decision of the Panel.

9.4 In the event that the Panel dismisses the allegation of research misconduct all reasonable steps shall be taken to preserve the position and reputation of the respondent and provided the allegation is considered to be made in good faith, the complainant.

9.5 Should the Panel conclude that the allegation of research misconduct is upheld the Chief Executive, in consultation with the Medical Director (or other appropriate senior officer), shall decide on what actions need to be taken either under the Trust's disciplinary procedures or otherwise. Such action may include informing the relevant Research Ethics Committee, the appropriate professional body, the grant – or contract awarding body and the editors of those journals in which the respondent has published articles directly stemming from the research that was the subject of the investigation.

9.6 A copy of the written record on the investigation and decisions will be lodged with the Director of Research and Development for a period of six years.

10 Appeals

10.1 Any appeal regarding the decision of the Panel, or complaint, will handled in accordance with the UH Bristol Appeals Policy.

11 Malicious Intent

11.1 If, on completion of the necessary inquiries and investigations (if any), the allegation is deemed to be malicious. The Director of Research and Development will inform the Trust's Chief Executive, who may in accordance with the Trust's disciplinary procedures invoke appropriate disciplinary action against the complainant.

12 Conflicts of Interest

12.1 Where an allegation of research misconduct is made against the Director of Research and Development, the Chief Executive will be informed immediately. The Chef Executive will consult with the Medical Director on the appropriate course of action.

12.2 Where the Director of Research and Development is unable to Chair the Panel due to a conflict of interest, the Chef Executive will be informed immediately. The Trust board will appoint a person with appropriate expertise and seniority to Chair the 'Panel'.

13 Suspension of Research

13.1 At any stage in the proceedings the Director of Research and Development, in consultation with the Chief Executive, reserves the right to suspend research activities relating to the allegations. This may happen, but is not limited to, where public health and safety is considered to be at risk, where the safety and well-being of research subjects or staff are considered to be at risk or where there is reasonable indication of possible violation of civil or criminal law.

13.2 The Director of Research and Development will inform the Lead Investigator in writing that Trust approval for the research in question has been revoked and the study must not recruit any further subjects until full approval has been granted once more. Dependent on the nature of the complaint, the study and the risk to patients, follow-up of subjects already recruited may also be prohibited.

13.3 The Lead Investigator will be invited to respond and the comments taken into consideration.

13.4 The Director of Research and Development will inform, in writing the relevant Research Ethics Committee(s) of the withdrawal of approval.

13.5 The Director of Research and Development reserves the right to inform collaborating centres of the withdrawal of UH Bristol R&D approval. This may happen, but is not limited to, where public health and safety is considered to be at risk, where the safety and well-being of research subjects or staff are considered to be at risk or where there is reasonable indication of possible violation of civil or criminal law. In this event, the Director of Research and Development will inform the Lead Investigator in writing. The Lead investigator will be invited to respond and the comments taken into consideration.

13.6 In the event that R&D approval is withdrawn permanently or for a significant period of time the Director of Research and Development will inform, in writing, the research sponsor.

13.7 Where the UH Bristol is the research sponsor, in the event of R&D approval being withdrawn permanently or for a significant period of time the Director of Research and Development will inform, in writing, the research funder(s).

13.8 In the event that R&D approval of a suspended study is re-instated, the Director of Research and Development will inform, in writing, the research sponsor.

13.9 In the event that R&D approval of a suspended study is re-instated, the Director of Research and Development will inform, in writing, the relevant Research Ethics Committee(s).

13.10 Where the UH Bristol is the research sponsor, in the event that R&D approval is re-instated the Director of Research and Development will inform, in writing, the research funder(s).

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