Title: Research Integrity, Fraud And Misconduct

Outcome Statement: Researchers and Trust staff will be informed about research fraud and misconduct, and will understand the systems in place for reporting and investigating such claims.

Written By: Brenda Jones
Reviewed: Bonnie Teague, Research Manager
In Consultation With: UK Research Integrity Office
Approved By and Date:
V 2.0 Research Governance Committee, 29th March 2012
V 3.0 Research Governance Committee, 26th June 2014
V3.1 Research Committee (Chair’s Action), 29th June 2017

References and Bibliography:

- Directions to NHS Bodies in Counter Fraud Measures (Secretary of State for Health, 2004)
- Committee on Publication Ethics COPE Report MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct (Medical Research Council, 1997)
- Statement on the handling of allegations of research misconduct (Wellcome Trust, 2002)
- Maintaining high professional standards in the modern NHS (Department of Health, 2003).
- UKRIO Recommended Checklist for Researchers (2009)

Associated Trust Policies: Trust Policy Counter Fraud and Corruption

Applicable To: All Trust staff and researchers holding honorary contracts or letters of access with the Trust

For Use By: All persons involved in the conduct of research in the Trust
Reference Number: R&D003
Version: 3.1
Published Date: 1st July 2017
Review Date: 5 years
Equality Assessment: Completed 27th June 2014

Reason for Development/Review: To set out clearly what constitutes research misconduct and fraud and the process to be followed when research misconduct is suspected, and updated to reflect new guidance around Research Integrity.

Implementation and Monitoring: The policy will be implemented and managed through the Research Office. Monitoring of policy will be based on individual review of reported cases. Policy and principles of Research Integrity is part of Research Training Programme Levels 2-4. Review of the policy may be required prior to the end date, depending on changes to national policy and guidance.
## Review and Amendment Log

<table>
<thead>
<tr>
<th>Version</th>
<th>Reasons for Development/Review</th>
<th>Date</th>
<th>Description of Change(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>To inform NSFT staff about expectations and sanctions regarding research misconduct.</td>
<td>November 2009</td>
<td>N/A</td>
</tr>
<tr>
<td>V2.0</td>
<td>Updates in UKRIO guidance and procedures Update to new Trust policy template.</td>
<td>1st April 2012</td>
<td>Changes in wording, formatting and references, roles and responsibilities.</td>
</tr>
<tr>
<td>V3.0</td>
<td>To update policy to include Research Integrity Officer and investigation procedures.</td>
<td>27th June 2014</td>
<td>1) Additional mention of Research Integrity Officer and role.  2) Include statement on non-NSFT employees working in research.  3) Include UKRIO guidance and check-list.</td>
</tr>
<tr>
<td>V3.1</td>
<td>To make minor amendments to Trust policy references.</td>
<td>29th June 2017 [Chair's Action-Minor Amendment]</td>
<td>1) Update of Trust Policy references  2) Update of Bibliography</td>
</tr>
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</table>
1.0 Introduction

The Norfolk and Suffolk NHS Foundation Trust requires all researchers working within the Trust to conduct their research to the highest ethical and scientific standards. All researchers must undertake their research in compliance with the Research Governance Framework and any other legislation or best practice guidelines currently in force. The purpose of this policy is to set out clearly what constitutes research misconduct and fraud and the process to be followed when research fraud or misconduct is suspected or identified.

This policy has been developed using the document NHS R&D Forum: Good Practice Guidance – Research Misconduct and Fraud, NHS R&D Forum, July 2004 and advice from the Trust Counter Fraud Officer. Additional guidance has been obtained through the UKRIO Code of Practice for Research 2009 (Appendix 1).

1.1 Key Principles

1.1.1 Processes relating to research fraud and misconduct must link into existing systems in the Trust.

1.1.2 Through supporting policies, research training and open discussion, the Trust will endeavour to promote an open and honest research culture that will act as a deterrent to research fraud and misconduct.

1.1.3 This policy relates to all researchers (including students) who are Trust employees or external researchers working in the Trust under an honorary contract or NIHR letter of access arrangements.

1.1.4 All research staff, including external staff with honorary Trust contracts, should have an appropriate level of supervision within the Trust as named in the contract or letter of access.

1.1.5 The Trust has a named Research Integrity Officer, whose chief responsibility will be to conduct an initial inquiry, and if there are grounds to do so, an investigation into allegations of research misconduct in the Trust. The Officer will be supported by the Research and Development department, who will conduct scheduled and triggered audit and monitoring visits on the Officer’s behalf and supply Research Governance-related documents and communications if deemed appropriate.

2.0 Purpose

To clearly define the definition of research fraud and misconduct, and the procedure for the reporting, investigations and consequences of allegations made against researchers in the Trust.

3.0 Definitions

3.1 Research fraud and misconduct 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 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.”

3.1.1 It also includes intentional, unauthorised use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings or devices used in or produced by the conduct of research.
3.1.2 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 deceive”.

3.1.3 Examples of research misconduct and fraud include but are not limited to
- Deliberate fabrication of research results or analysis
- Failure to obtain permission to undertake research
- Submitting the signature sheet for ethics from a different study
- Recruiting and consenting patients without ethics approval
- Failure to document consent appropriately
- Plagiarism
- Collusion in or concealment of research misconduct or fraud by others
- Abuse of research funds or equipment

3.2 Principles of Research Integrity (UKRIO)

3.2.1 Organisations and researchers should adhere to the following Principles, which set out the responsibilities and values relevant to research. While some elements may seem self-evident, and there is some overlap, these Principles aim to encourage all involved in research to consider the wider consequences of their work and to engage critically with the practical, ethical and intellectual challenges that are inherent in the conduct of high quality research, rather than treating codes of practice such as this as just another procedure to be followed.

3.2.2 EXCELLENCE: organisations and researchers should strive for excellence when conducting research and aim to produce and disseminate work of the highest quality. This Code, its Principles and its Standards are intended to support these goals.

3.2.3 HONESTY: organisations should work to create and maintain a culture of research that fosters and supports honesty in research. Researchers should be honest in relation to their own research and that of others. They should do their utmost to ensure the accuracy of data and results, acknowledge the contributions of others, and neither engage in misconduct nor conceal it.

3.2.4 INTEGRITY: organisations and researchers must comply with all legal and ethical requirements relevant to their field of study. They should declare any potential or actual conflicts of interest relating to research and where necessary take steps to resolve them.

3.2.5 COOPERATION: organisations and researchers should promote the open exchange of ideas, research methods, data and results and their discussion, scrutiny and debate, subject to any considerations of confidentiality.

3.2.6 ACCOUNTABILITY: organisations and researchers should recognise that in and through their work they are ultimately accountable to the general public and should act accordingly. They should ensure that any research undertaken complies with any agreements, terms and conditions relating to the project, and allows for proper governance and transparency. Researchers should follow the requirements and guidance of any professional bodies in their field of research. Researchers who are members of a regulated profession must follow the requirements and guidance of the body regulating their profession.

3.2.7 TRAINING AND SKILLS: organisations should provide training and opportunities for development for their researchers, and the necessary resources to enable them to conduct research to the required standards. They should support researchers in identifying unmet needs for training and development. Researchers should ensure that they have the necessary skills, training and resources to carry out research, in the proposed research team or through collaboration with specialists in relevant fields, and report and resolve any unmet needs identified.

3.2.8 SAFETY: organisations and researchers should ensure the dignity, rights, safety and wellbeing of all involved in research and avoid unreasonable risk or harm to research subjects, patients, participants, researchers and others. They should report and address any concerns relating to the dignity, rights, safety and wellbeing of those involved in research. Research should be initiated and continued only if the anticipated benefits justify the risks involved.
3.2.9 The above definition and principles of Research Integrity are taken from the UK Research Integrity Office (UK RIO), Code of Practice for Research, 2009.

4.0 Duties

4.1 The Research Integrity Officer with defined responsibility for instigation of an inquiry and investigation, or their delegate, is responsible for the investigation of any allegations of research fraud or misconduct in line with the Trust’s Policy on Counter Fraud and Corruption.

4.2 Where the researcher involved is not a Trust employee but holds an Honorary Contract or Letter of Access with the Trust, the researcher’s employing organisation should be informed. As far as possible care should be taken during an investigation to try to ensure that any investigation complies with the policies and procedures of the employing organisation of the researcher(s) involved so that any disciplinary action can be upheld should this be deemed appropriate.

4.3 Any organisation acting as research sponsor for studies approved under the Research Governance Framework must ensure that arrangements for the detection, reporting and investigation of research fraud and misconduct are in place for research projects that it sponsors.

4.4 For studies for which the Trust is sponsor, the Research and Development Office will undertake additional audit and monitoring duties for the studies that it sponsors, which are then reported and approved by the Research Integrity Officer.

4.5 When the allegation of research fraud and misconduct relates to a project with an external sponsor (for example an academic institution, a research council, charitable trust or commercial organisation) and the researcher involved is not a Trust employee, the sponsor should be informed and the Trust gain assurance that an investigation will be instigated. The sponsor must keep the Trust informed of the progress of the investigation at appropriate points.

4.6 Research Partnership agreements should specify arrangements for the detection, reporting and investigation of research misconduct.

4.7 Under the Research Governance Framework, researchers, chief and principle investigators and employers are responsible for detecting, reporting and investigating research misconduct and fraud.

4.8 The research team is required to clearly define individuals’ responsibilities in the performance of research, with support from the research and development office. These include: appropriate procedures for the collection and reporting of data and results; the responsibilities of faculty for the research conducted under their supervision; and, the accountability of authors for publications that bear their names.

4.9 NSFT Research Teams are recommended to complete the UKRIO Good research practice check-list in Appendix 2 and hold this in the Trial site/master file.

5.0 Reporting Of Suspected Research Misconduct And Fraud

5.1 Suspected research fraud and misconduct should be reported, in writing preferably, to the Trust Research Integrity Officer and/or Research Manager. Depending on the nature of the misconduct, the incident should also be raised in line with the Trust Policy on Counter Fraud and Corruption, Trust Complaints Procedure, Public Interest Disclosure Policy and Clinical Incident Procedure.

5.2 All allegations of misconduct in research shall be treated seriously and fairly and their merit investigated with integrity and sensitivity with due regard to the need to
• 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.

6.0 Investigation Of Suspected Research Misconduct

6.1 The Research Integrity Officer with responsibility for Instigating an Investigation within the Trust Policy on Fraud, Theft, Corruption and Financial Irregularities should instigate an investigation in line with that policy.

6.2 The Research Integrity officer with responsibility for Instigating an Investigation within the Trust Policy on Counter Fraud and Corruption should take expert advice where appropriate and make an early decision whether or not to temporarily suspend Trust approval for the research project concerned. Care should be taken to balance the risks to research participants, the risks to the project and the risks to the reputation of the researcher.

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

6.4 Informants of Research fraud and misconduct may be in sensitive positions relative to colleagues and superiors. Consideration should be given to the creation of mechanisms (such as confidential interviews and anonymisation of statements if deemed appropriate by the Research Integrity Officer for informal, confidential discussion of possible acts of research fraud, prior to the initiation of an inquiry, and provision to protect informants of retaliation.

7.0 Outcomes Of An Investigation

7.1 If the allegation of research fraud or misconduct is upheld additional sanctions to those identified through the Trust’s Policy on Counter Fraud and Corruption and Disciplinary Procedures may be appropriate. These other sanctions may include, but are not restricted to:

• Withdrawing formal Trust R&D approval for continuation of the particular research project
• Withdrawal of Trust or other research funding after informing the funder of the outcome of an investigation.
• Withdrawal or correction of pending or published abstracts and papers emanating from the research in question
• Changes to the staffing of the particular project
• More frequent auditing and closer monitoring of future work
• Barring of the researcher from applying for Trust R&D funds for a given period.
• Barring the researcher from conducting research within the Trust for a given period.
• Revoking an honorary contract
• Report Researchers to ethics committees and to their professional bodies

7.2 If the allegation of research fraud or misconduct is upheld, the Trust (through the Research Integrity Officer) should inform the Research Governance Committee and sponsor, and the sponsor should inform the Research Ethics Committee.
7.3 Care should be taken to try to ensure that the policies and procedures of the employing organisation of the researcher are complied with, as some sanctions are the responsibility of the employing organisation or the research sponsor.

7.4 If an allegation of research fraud and misconduct is upheld after research data has reached the public domain, it is the responsibility of the Research Integrity Officer to inform any relevant journal or publication bodies of the investigation and outcome.

7.5 Any records related to research investigations into fraud and misconduct (including but not limited to allegations, evidence, proceedings of inquiries and investigations) will be kept by the Trust for a minimum of 3 years after the end of the investigation and written report.

8.0 Policy Review

8.1 This policy will be reviewed every 5 years and updated in accordance with Research Integrity guidance (RIO)
The NSFT will:

a) ensure that good practice in research forms an integral part of their research strategy or policy;
b) establish clear policies and procedures that cover the Principles of good practice in research (see section 2) and offer detailed guidance on the Standards set out in this Code;
c) ensure that these policies and procedures complement and are in accordance with existing organisational policies, such as those for health and safety, raising concerns at work, management of finances or of intellectual property, and equality and diversity;
d) make sure that their researchers are aware of these policies and procedures and that all research carried out under the auspices of the organisation complies with them;
e) provide training, resources and support to their researchers to ensure that they are aware of these policies and procedures and are able to comply with them;
f) encourage their researchers to consider good practice in research as a routine part of their work; and
g) monitor these measures for suitability and effectiveness and review them where necessary.

NSFT Researchers should:

a) recognise their responsibility to conduct research of high ethical standards;
b) be aware of their organisation’s policies and procedures on good practice in research;
c) make sure that their research complies with these policies and procedures, and seek guidance from their organisation when necessary;
d) work with their organisation to ensure that they have the necessary training, resources and support to carry out their research; and

e) suggest to their organisation how guidance on good practice in research might be developed or revised.
### Appendix 2: Recommended Research Integrity Check-list for researchers

The Checklist lists the key points of good practice in research for a research project and is applicable to all subject areas. More detailed guidance can be found in section 3. A PDF version is available from www.uknio.org

<table>
<thead>
<tr>
<th>Step</th>
<th>Question/Requirement</th>
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<tbody>
<tr>
<td>1</td>
<td>Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it?</td>
</tr>
<tr>
<td>2</td>
<td>Is your research design appropriate for the question(s) being asked?</td>
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<tr>
<td>3</td>
<td>Will you have access to all necessary skills and resources to conduct the research?</td>
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<tr>
<td>4</td>
<td>Have you conducted a risk assessment to determine: (a) whether there are any ethical issues and whether ethics review is required; (b) the potential for risks to the organisation, the research, or the health, safety, and well-being of researchers and research participants; and (c) what legal requirements govern the research?</td>
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<tr>
<td>5</td>
<td>Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant?</td>
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<tr>
<td>6</td>
<td>Will your research comply with all requirements of legislation and good practice relating to health and safety?</td>
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<tr>
<td>7</td>
<td>Has your research undergone any necessary ethics review (see 4(a) above), especially if it involves animals, human participants, human material or personal data?</td>
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<tr>
<td>8</td>
<td>Will your research comply with any monitoring and audit requirements?</td>
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<tr>
<td>9</td>
<td>Are you in compliance with any contracts and financial guidelines relating to the project?</td>
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<tr>
<td>10</td>
<td>Have you reached an agreement relating to intellectual property, publication and authorship?</td>
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<td>11</td>
<td>Have you reached an agreement relating to collaborative working, if applicable?</td>
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<tr>
<td>12</td>
<td>Have you agreed the roles of researchers and responsibilities for management and supervision?</td>
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<tr>
<td>13</td>
<td>Have all conflicts of interest relating to your research been identified, declared and addressed?</td>
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<tr>
<td>14</td>
<td>Are you aware of the guidance from all applicable organisations on misconduct in research?</td>
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### When conducting your research:

<table>
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<tr>
<th>Step</th>
<th>Action</th>
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<tbody>
<tr>
<td>1</td>
<td>Are you following the agreed research design for the project?</td>
</tr>
<tr>
<td>2</td>
<td>Have any changes to the agreed research design been reviewed and approved if applicable?</td>
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<tr>
<td>3</td>
<td>Are you following best practice for the collection, storage and management of data?</td>
</tr>
<tr>
<td>4</td>
<td>Are agreed roles and responsibilities for management and supervision being fulfilled?</td>
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<tr>
<td>5</td>
<td>Is your research complying with any monitoring and audit requirements?</td>
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### When finishing your research:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
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<tbody>
<tr>
<td>1</td>
<td>Will your research and its findings be reported accurately, honestly and within a reasonable time frame?</td>
</tr>
<tr>
<td>2</td>
<td>Will all contributions to the research be acknowledged?</td>
</tr>
<tr>
<td>3</td>
<td>Are agreements relating to intellectual property, publication and authorship being complied with?</td>
</tr>
<tr>
<td>4</td>
<td>Will research data be retained in a secure and accessible form and for the required duration?</td>
</tr>
<tr>
<td>5</td>
<td>Will your research comply with all legal, ethical and contractual requirements?</td>
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Signed (NSFT Principal Investigator) ________________________Date (DD/MM/YYYY) _____________

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