Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Research Misconduct And Fraud

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Approved by (name & role)	Dipak Patel Research Manager	**Date:** 24 Mar 2015	**Signature:**

Standard Operating Procedure

Research Misconduct & Fraud

This SOP has been produced in accordance with ICH GCP, the Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments, and local policies and procedures for investigating and responding to allegations of Research Misconduct & Fraud.

This SOP will outline the procedure for investigating and responding to allegations of research misconduct made against staff undertaking studies at Sheffield Teaching Hospitals NHS Foundation Trust (STH).

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Acronyms

GCP	Good Clinical Practice
IMP	Investigational Medicinal Product

Definition

This procedure is designed to deal with concerns relating to research misconduct. STH has adopted the following, non-exhaustive definition of misconduct and fraud which is based on guidance issued by the Wellcome Trust and RCUK:

"Where (an) individual(s) deliberately, dangerously or negligently deviate(s) from accepted practices. This specifically encompasses (but is not restricted to) unacceptable practices including fabrication, falsification, plagiarism, misrepresentation, breach of duty of care and improper dealing with allegations of misconduct. Research Misconduct does not include honest errors (unless deemed negligent) and differences in for example the design, execution, interpretation or judgment in evaluating research methods, or results or misconduct unrelated to the research. For the avoidance of doubt, Research Misconduct includes acts of omission as well as acts of commission.

Background and Principles

1. STH expects all research undertaken on STH patients, staff or premises to be conducted observing the highest standards of research practice. In pursuance of this, it is expected that employees of STH, and those working on STH premises, take steps to acquaint themselves with the Research Governance Framework, GCP guidelines and applicable Regulations.

2. STH has a Raising Concerns at Work Policy and this should be referred to where allegations of research misconduct and fraud arise, particularly from sources wishing to maintain anonymity.

3. Staff are encouraged to put their name to any allegation they make since part of the purpose of this procedure is to promote openness and discourage a fear of reprisals. Allegations made anonymously are far less capable of being addressed effectively but may be considered after taking into account the seriousness of the issue, the credibility of the allegation, the likelihood of being able to investigate the matter and confirm the allegation from alternative sources, and fairness to any individual mentioned in the allegation.

4. The identity of the person raising the matter will, if required, be kept confidential for as long as possible provided that this is compatible with an effective investigation. The investigation process may however at some stage have to reveal the source of the information and the individual making the allegation may need to make a statement as part of the evidence required. All allegations made under this Procedure will be treated in a confidential and sensitive manner.

5. Named individuals will be informed of the allegation(s) made against them and the supporting evidence and this will be confirmed in writing, taking all aspects of confidentiality into consideration. The point at which this occurs will depend upon the specific nature of the case.

   The named individual will be given an opportunity to respond and if they so wish can be accompanied by a work colleague or staff representative of his/her choice

6. The named individual will, in all circumstances where a *prime facie* case has been established and where formal action is to be taken, have the opportunity to put their case forward and respond to the allegations in accordance with the principles of natural justice and in accordance with agreed STH procedures.

7. Individuals making an allegation, which is found by subsequent investigation to be malicious and/or vexatious, may be subject to disciplinary or other appropriate action. Suspicions reported in confidence and in good faith which are not confirmed by subsequent investigation will not lead to any action against the person making the allegation.

8. Investigations will be conducted as speedily as possible, having regard to the nature and complexity of the allegation.

9. The outcomes of the process will be made known to relevant persons involved, including the person making the allegation and the person against whom the allegation has been made, whilst also maintaining confidentiality wherever possible.

10. Where the research is externally funded, in whole or in part, the STH shall have regard to any guidance issued by the relevant funding body and shall ensure that the Director of any such body is given appropriate information at the earliest opportunity concerning a substantiated allegation of research misconduct.

11. This procedure shall be operated in accordance with existing STH commitments and procedures on Equal Opportunities.

12. Whilst it is the responsibility of the Director of R&D to investigate research misconduct and fraud, the procedure recognises other mechanisms through which advice can be sought. For example, the Trust's Human Resource and Finance Departments may need to be contacted as they will have certain expertise in handling allegations of general misconduct or financial fraud.

13. Where the Research Misconduct has implications for clinical practice, the Clinical Director and Clinical Governance lead should be involved as appropriate.

14. Where a clinical incident which has implications for research is precipitated by an investigator, the Director of R&D should work in tandem with the Trust nominee leading the clinical investigation.

Procedure

1. Scope

The procedure below relates to allegations of research misconduct and fraud made against STH staff members including those individuals holding Honorary Contracts with STH. In the case of an allegation being made against an Honorary Contract holder, advice will be sought from the individual's employer (Academic Institution, NHS Trust or Company).

2. Purpose

The purpose of this procedure is to:

2.1 Enable individuals to raise legitimate concerns relating to research misconduct by staff within the course of their employment at STH.

2.2 Make clear to individuals who believe they need to make an allegation against a member of staff that allegations of research misconduct are taken seriously within STH.

2.3 Provide the opportunity for an individual who has inadvertently breached good practice to declare the problem openly, allowing the process to occur in a fair and transparent manner.

2.4. Provide a process for concerns to be raised, investigated and, where appropriate, acted upon in a fair and transparent manner and in confidence.

2.5. Act as a deterrent to potential perpetrators of research misconduct.

2.6. Strengthen the confidence of all parties (e.g. Research Funders, the individual making an allegation, staff) that STH maintains the highest standards of research conduct.

3. Process

3.1 All STH staff, including those holding honorary contracts, have a duty to report any incident of misconduct, whether this has been witnessed or whether it is suspected.

3.2. STH has a Raising Concerns at Work Policy and this should be referred to where allegations of research misconduct and fraud arise, particularly from sources wishing to maintain anonymity.

3.3 Allegations should be made in writing to the *designated person*, who shall normally be the Director of R&D copied to the Clinical Research Office (CRO) Director, Medical Director and Clinical Director of the relevant Directorate. However, where it is believed there exists a valid reason why the designated person should not be the Director of R&D, for example where the Director of R&D is connected in any way to the research in question, the allegation should be forwarded to the CRO Director who will in turn notify the Medical Director and the Clinical Director.

In all circumstances where an allegation is raised with a designated person who is not the Director of R&D, the alternative designate should make the Director of R&D

aware of the allegation as soon as is possible and appropriate, depending on the circumstances of the case.

Any individual wishing to make a disclosure, or to give further details as the matter is investigated, may be accompanied by a work colleague or staff representative of his/her choice

3.4. The Director of R&D shall lead an initial investigation (except where it is believed there exists a valid reason why the investigation should not be led by the Director of R&D, for example where the Director of R&D is connected in any way to the research in question. In this case an alternative individual will be appointed to lead the investigation).

Since the person conducting the investigation should not be the person who would ultimately take decisions based upon the outcomes of the investigation, the Director of R&D will not personally conduct the investigation and will remain separate from it, in order to maintain impartiality and fairness in the investigative process.

The Director of R&D will:

i) decide how an investigation should take place and what form it should take. A for cause audit may be undertaken according to SOP C126;

ii) appoint relevant person/s to investigate the allegation;

iii) decide whether there are grounds for proceeding further;

iv) in the event of financial implications, inform the Assistant Director of Finance.

If a serious allegation of fraud is made and is supported by credible evidence then the Trust has a duty to report this to the NHS Counter Fraud Service's Local Counter Fraud Specialist who will advise in deciding how the investigation should proceed in accordance with the Trust Fraud Policy and Response Plan. In some cases this may include the involvement of the Police.

v) seek advice from H.R as appropriate;

vi) where the individual holds an honorary contract, inform the individual's employer of the intention to pursue an investigation.

3.5. The process of the investigation will be recorded in the Research Misconduct and Fraud action log which will be filed in the R&D Master File.

4. Outcome of initial investigation

4.1. The Director of R&D will, when the matter has been investigated, decide whether the matter should be taken further and, if so, how it should be handled. Reporting of the allegations or findings of any investigation will depend on the nature of the allegation and it is therefore not appropriate to be prescriptive as to the level of reporting in every case. This may include the initiation of formal procedures within STH and reference to outside bodies, such as the study Sponsor, MHRA (for studies involving

IMPs[1]), Research Ethics Committee, study Funder, or the Chief Investigator's employer (if not the Trust).

4.2. The outcomes of any such investigations shall be reported to the Medical Director or Chief Nurse who will then consider what disciplinary actions should be taken.

4.3. Where the individual holds an honorary contract, the Director of R&D informs the individual's employer of the outcome of the investigation

[1] For investigations that relate to breaches of GCP during IMP studies reference should be made to the SOP C125 Non compliance and Management of Serious Breaches guidance on the appropriate actions to take.

Appendix 1

Associated Documents

	Document	Research Department Network Location	Website	Database	Created by
1	STH Raising Concerns at Work Policy and Procedure	n/a	http://nww.sth.nhs.uk/NHS/ControlledDocuments/	No	STH Trust
2	STH Fraud Policy and Response Plan	n/a	http://nww.sth.nhs.uk/NHS/ControlledDocuments/	No	STH Trust
3	UoS Research Misconduct policy	n/a	http://www.shef.ac.uk/hr/guidance/academicstaff/researchmisconduct	No	UoS
4.	SHU Research Misconduct Policy	n/a	http://www.shu.ac.uk/research/ethics/documents/Research-Ethics-Principles-and-Procedures_Oct2013.pdf	No	SHU
5.	Research Misconduct & Fraud Log	../../../../!_Working Drafts/Research Governance/Research Misconduct & Fraud/Action log.doc		No	BZ

Appendix 2 SOP revisions and history

SOP number & version	Effective date	Reason for change	Author
THIS SOP			
2.6	01 Apr 2015	Update of definition of Research Misconduct	EW
PREVIOUS SOPs			
2.5	01 Oct 2013		EW