brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

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Research Misconduct and Fraud

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	Signature	**Date**
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Version History

Version	Date	Reason for Change	Author
1.0	09th June 2015	R&D Manager is now Head of R&D, Gas committee now referred to as OMG; quality and safety, Research Governance & Quality Assurance Manager is now Quality Assurance Manager, Whistle Blowing Policy & Procedure is now version 3, 19th May 2014	Hannah Butler
2.0	05th Jan 2017	SOP Training Matrix added and Committee names updated	Gemma Earl

1. Purpose

The purpose of this document is to detail the process of reporting and investigating allegations of research misconduct and fraud against BSUH employees or any person conducting research on BSUH premises or patients. The SOP should be used in conjunction with existing relevant policies and procedures within BSUH NHS Trust.

2. Introduction

The UK Research Integrity Office's (UKRIO) define misconduct of research as:

- fabrication
- falsification
- misrepresentation of data and/or interests/involvement
- plagiarism
- failures to follow accepted procedures and legislation that applies to research or to exercise due care in carrying out responsibilities for:
    - avoiding unreasonable risk or harm to humans
    - the proper handling of privileged or private information on individuals collected during the research

Although allegations of research misconduct are rare, a procedure for reporting and investigating these allegations needs to be in place to ensure fair and thorough investigations for all parties involved.

The procedure for reporting and investigating allegations of research misconduct at BSUH will be conducted in line with the UKRIO 'Procedures for the Investigation of Misconduct in Research' protocol. An outline of these procedures is detailed below.

For the purpose of this SOP, the complainant is the person making the allegations of research misconduct. The respondent is the person whom the allegation of research misconduct is being made against. He/she will be an employee, past or present, of BSUH (Brighton and Sussex University Hospital NHS trust).

3.0 Responsibilities

The Head of Research and Development (HRD) is responsible for receiving allegations of research misconduct, initiating investigations and ensuring they are supervised appropriately and ensuring the investigation is documented and reported. In the absence of the HRD, the Quality Assurance Lead (QAL) will have this responsibility. The allegation of misconduct should be dealt with along side the Trust's 'Raising Concerns (Whistle-blowing) Policy and Procedure'. This document can be found on the Trust intranet or a hard copy can be requested from Human Resources.

The Local Counter Fraud Specialist is responsible for investigating reports of potential fraud.

The Chief Investigator is responsible for having a key role in the detection and prevention of research misconduct. All researchers involved in a study have a responsibility to report any suspected research misconduct.

If any BSUH employee suspects research misconduct, this should be reported to the HRD without delay in line with this procedure. Those entitled to report allegations of research misconduct are not restricted to BSUH employees and can include for example external collaborators. Complaints from research participants should be dealt with in accordance with SOP/RD/011 Managing Research Participant Complaints.

The HRD/QAL and Investigation Panel are responsible for carrying out investigations of alleged research misconduct with integrity and sensitivity.

The BSUH Research Governance & Quality Assurance Committee is responsible for maintaining an oversight of research governance matters including reports of research misconduct and fraud either by self reporting, whistling blowing or as a result of monitoring, inspection or audits. Trends and hotspots for research-related Datixs will be monitored, discussed and actioned by the committee.

4.0 Procedure

4.1 Reporting Allegations of Research Misconduct

Allegations of research misconduct should be made in writing with any supporting evidence to the HRD immediately. The initial approach may be made informally but should always be followed up with a written submission. This information will remain confidential. If a potential fraud case is identified, the Local Counter Fraud Specialist will under taken the investigation. A confidential discussion with the subject will only take place following liaison with the Local Counter Fraud Specialist.

Allegations which are in any way linked to the HRD or which raise the potential for conflict of interest should be reported to the QAL instead.
Upon receipt of an allegation of research misconduct, the HRD should formally acknowledge receipt of the complaint and advise him/her of the procedure that will be followed.

The HRD will ensure all relevant information and evidence in relation to the allegation is secured to ensure a proper investigation can be conducted if required.
The complainant should record the issue on the online Datix reporting system and highlight it as research-related. If the issue is of a sensitive nature i.e. involving named individuals, the matter should be discussed with the HRD beforehand.

4.2 Initial Investigation

The HRD will review the nature of the allegations and, where they concern situations where a serious breach of GCP or the protocol is suspected then the SOP/RD/003 Notification of Serious Breach of GCP or the Trial Protocol will be implemented immediately to prevent any further risk or harm to those involved.

If the allegations relate to issues of fraud, bribery or anti-corruption then the HRD should ensure the Local Counter Fraud Specialist is made aware of the allegations

so investigations can commence. For issues relating to patient safety, a member of the Patient Safety Team should be contacted and involved as appropriate.

If the allegation falls within the definition of research misconduct and does not require notification to the regulatory bodies then the HRD will inform the Head of the Organisation, the Head of Human Resources (HR), and the Head of Finance of these received allegations.

They should be provided with information of identity of respondent and complainant as well as any relevant details in relation to the research in question e.g. funding sources or external collaborators. It should be stressed that the allegations have not yet been proved and that the information is confidential.

Investigation into the contractual status of the respondent and the research project related to the allegations should commence. If the organisation is not the respondent's primary employer, the primary employer should be contacted and informed of these allegations and the Trust should be reassured that an appropriate investigation will be instigated. The HRD should confirm whether there are any contractual/legal obligations with e.g. external sponsors, funding organisations or collaborators in relation to research misconduct to ensure that any obligations are fulfilled in the appropriate timelines.

A confidential meeting with the HRD, respondent and a representative from the Human Resources department will be arranged to inform the respondent of the allegations and to ensure the respondent has the opportunity to respond to the case against him/her. If allegations are being made against more than one respondent, the HRD should inform each individual separately and not divulge the identity of any other respondent. The respondent will be given a summary of the allegations in writing and a copy of the procedure being used in the investigation. All allegations will be investigated fully even in the event of the complainant withdrawing the allegation or the respondent admitting the alleged misconduct.

The HRD will perform an initial investigation to determine whether the allegations are mistaken, frivolous and/or malicious. If this is the case then all parties will be informed in writing and no further investigation will be required. Appropriate support should be provided to those involved if deemed appropriate. As per the Trust policy for raising concerns (whistle-blowing) independent advice can be sought from their trade union/staff representative or the independent authority 'Public Concern at Work'.

If the allegations of research misconduct do not appear to be mistaken, frivolous and/or malicious then a formal investigation will be conducted. The UKRIO may be consulted by the HRD or any other party involved in the allegations for advice and guidance.

4.3 Formal Investigation

If after the initial investigation, the HRD requires a formal investigation to be performed, an Investigation Panel should be convened. This should be clearly communicated to all those previously notified of the allegations.

The Investigation Panel should consist of at least two individuals who do not have conflicts of interest in the case and have the appropriate expertise to evaluate the issues. If possible, the Investigation Panel should include external members.

The Investigation Panel will review all the relevant evidence collated, investigating further if required, interviewing the respondent and concluding whether the allegations of research misconduct are:

1) Upheld in full
2) Upheld in part
3) Not upheld

The respondent has the right to be accompanied by a work colleague or trade union representative if desired when being interviewed.

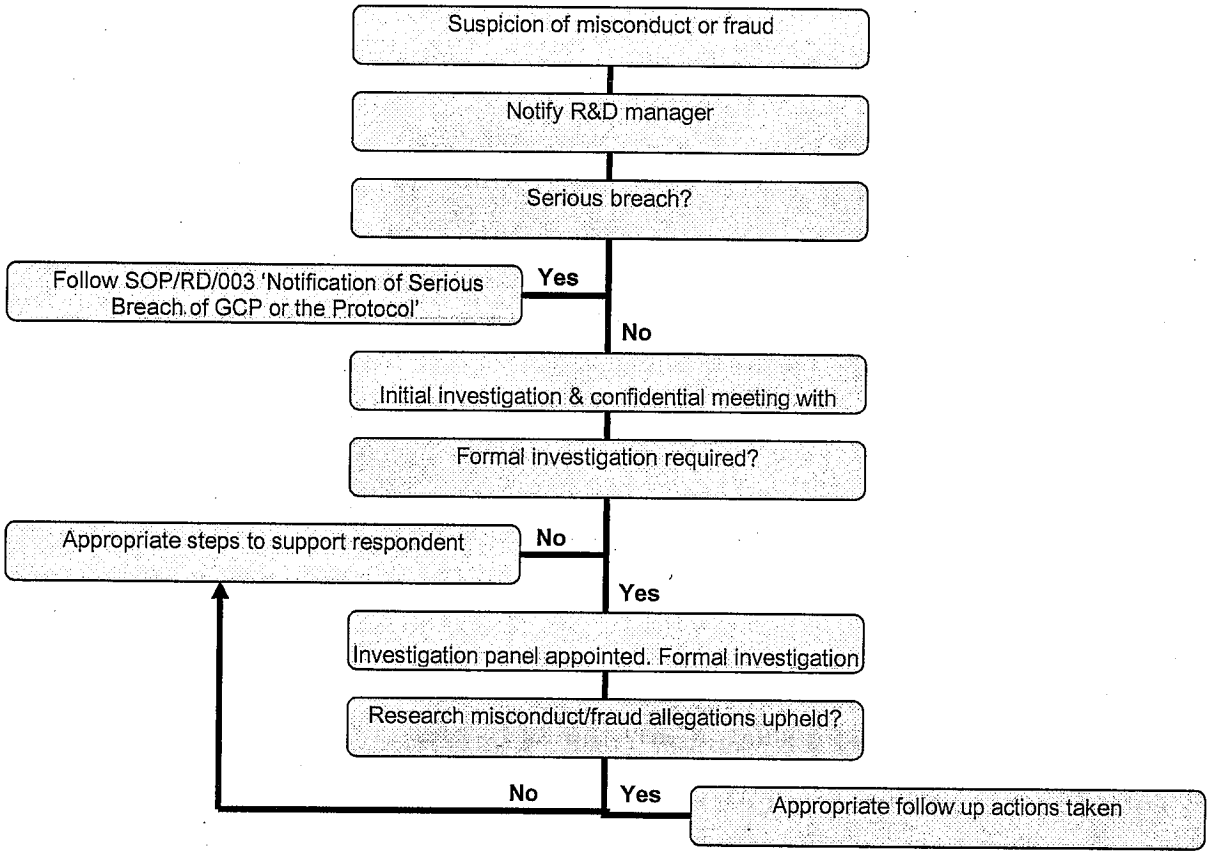
A report will be produced by the Investigation Panel summarising the conduct of the investigation, whether the allegations are upheld giving reasons for the decision and making recommendations relating to any matters in relation to any other research misconduct identified.

If the allegations are upheld in full or in part then the HRD should decide with appropriate staff whether the matter should be referred to the Trust's disciplinary process or any other formal action taken. If the allegations have not been upheld then the HRD should take appropriate steps to support the reputation of the respondent and any associated research.

All involved parties should be informed of the conclusions of the formal investigation. An after action review should be performed and any corrective and preventative actions should be clearly communicated and implemented accordingly.

All associated documentation in relation to research misconduct and fraud should be stored securely and confidentially in a location separate to the trial master file.

4.4 Process Flow Diagram



4.5 Research Governance & Quality Assurance Committee

The BSUH Research Governance & Quality Assurance Committee is responsible for reviewing and maintaining an oversight of research governance matters. The Committee will be notified of all allegations of research misconduct by the HRD and provided with the formal investigation report from the Investigation Panel for review ensuring confidentiality of all parties involved is maintained. The Committee will also monitor research-related Datix reports for trends and hotspots. These will be discussed and remedial action implemented as decided by the Committee.

5.0 Training

This is a 'read and understand' SOP. To evidence that you have read and understood this SOP, please complete your SOP Training Matrix.

Please note that the R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the Trust website.

6.0 Cross referenced SOPs

SOP/RD/003 Notification of Serious Breach of GCP or the Trial Protocol
SOP/RD/011 Managing Research Participant Complaints

7.0 References

'Procedure for the Investigation of Misconduct in Research' August 2008, UK Research Integrity Office
'Raising Concerns (Whistle-Blowing) Policy and Procedure' BSUH NHS Trust, v3 19/May/2014