Plymouth Research and Development

NHS University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	Suspected research fraud		
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1. Purpose

Most research staff conduct research projects entirely honourably and satisfactorily. However, occasionally data may be encountered which appear to be suspect. It is vitally important that fraudulent research is identified and exposed. The purpose of this SOP is to outline the steps to be taken by University Hospitals Plymouth NHS Trust (UHP) if research fraud is alleged or suspected to be occurring in research studies being performed by UHP personnel, and to define the disciplinary procedures to be undertaken in dealing with such a situation.

The Disciplinary Procedure is designed to ensure that employees are aware of and maintain the standard of conduct and performance required by the Trust. The procedure is also designed to ensure that employees are treated fairly and consistently.

The UHP will not tolerate any harassment, victimisation or other disadvantage – including disciplinary action – of employees who raise concerns in good faith which are subsequently shown to be unfounded. There is, of course, a need to ensure that any investigation process is not misused. Any abuse such as raising unfounded, malicious allegations may be dealt with as a disciplinary matter.

2. Scope

This SOP relates to all staff engaged in research within UHP (this includes researchers with Letters of Access and Honorary Research Contracts).

3. Responsibilities

It is the responsibility of the Clinical Trial Investigators and UHP research staff to:

- Notify the Trust if fraud is suspected or has been identified

It is the responsibility of the sponsor:

- When fraud has been identified to take appropriate action

The Trust Local Counter Fraud Specialist (LCFS) is:

Tracy Wheeler

3rd Floor, Elsie Margaret House, William Prance Road, Derriford, Plymouth PL6 5ZD

Telephone: 01752 431378

Mobile: 0778 986 8568

Email: tracy.wheeler2@nhs.net

Contact the LCFS is you have any suspicions or concerns. All referrals will be treated in the strictest of confidence.

If staff wish to report any suspicions or concerns and feel that it cannot be done internally they can contact the NHS Fraud and Corruption reporting line on 0800 028 40 60 (Freephone 24/7) or *via* the online fraud reporting form at www.reportnhsfraud.nhs.uk Please give as much information as possible.

4. Related documents

- UK Research Integrity Office (UKRIO). Code of practice for research; Promoting good practice and preventing misconduct.
- UK Research Integrity Office (UKRIO). Procedure for the investigation of misconduct in research.
- UHP - TRW.RAD.POL.150.9 Research and Development Policy
- UHP - Fraud, Bribery & Corruption policy.
- UHP - Raising Concerns Policy.
- UHP – TRW.HUM.LEA.84.7 Speaking Up Leaflet (Raising Concerns Policy)
- UHP – Conduct Policy
- UHP – Standards of Business Conduct Policy
- SI 2004-1031 The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.

5. Acronyms

ABPI: The Association of the British Pharmaceutical Industry

ACAS: The Advisory, Conciliation and Arbitration Service

CI: Chief Investigator

CRF: Case Report Form

CTIMP: Clinical Trial of an Investigational Medicinal Product

GCP: Good Clinical Practice

GMC: General Medical Council

HRA: Health Research Authority

LCFS: Local Counter Fraud Specialist

LoA: Letter of Access

LSMS: Local Security Management Specialist

MHRA: Medicines and Healthcare products Regulatory Agency

UHP: University Hospitals Plymouth NHS Trust

R&D: Research and Development

REC: Research Ethics Committee

RO: Research Office

Research Misconduct: “Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards” (Royal College of Physicians Edinburgh, 2000).

Research Fraud: “The generation of false data with the intention to deceive” (Royal College of Physicians Edinburgh, 2000).

5. Process map

Action to be taken if YOU discover or suspect FRAUD, BRIBERY/CORRUPTION or THEFT

<table>
<tr><th></th><th>This includes:</th><th>What to do:-</th></tr>
<tr><td>FRAUD</td><td>When a person knowingly or recklessly obtains money or property to which they have no entitlement – it is theft through using deception.

In research fraud may also be defined as the generation of false data with the intention to deceive</td><td rowspan="2">You must discuss your suspicions or what you have discovered with one of the following:-

• The Director of Finance on 01752 439085.

• Directly with the Trust's Local Counter Fraud Specialist on 01752 431378/0778 986 8568/ or via e-mail: tracy.wheeler2@nhs.net

• NHS Fraud & Corruption Reporting line Free Phone 0800 028 40 60 or www.reportnhsfraud.nhs.uk

<u>For Research Fraud or misconduct</u>:-
• R&D Director of Operations on 01752 (4) 31046 or the Research Governance Manager on 01752 (4) 31045 or the Deputy Research Governance Manager 01752 (4) 32195.</td></tr>
<tr><td>BRIBERY/ CORRUPTION</td><td>Where someone is influenced by bribery, payment or benefit in kind to unreasonably use their position to give some advantage to another.</td></tr>
<tr><td>THEFT</td><td>Any misappropriation, stealing, malicious damage and actual or attempted break-in.</td><td>This MUST be reported immediate to your line manager and an incident report raised via the Datix incident reporting system. The incident must then be reported to the Police via the non-emergency reporting systems either by telephone or on-line and the subsequent crime number should be added to the Datix report. Any damage, such as to electronic access control systems, door locks etc., must be reported via the Estates reporting system on Staffnet. The incident must also be reported directly to the Trust Local Security Management Specialist, Jo Woolley: (4)37004 or Jwoolley@nhs.net

For incidents where a break in is in progress, an emergency call should be placed via Switchboard on 3333 requesting security and police.</td></tr>
<tr><td rowspan="4">DO'S AND DON'T'S</td><td colspan="2">If you are suspicious or have concerns DO report it - confidentiality will be respected</td></tr>
<tr><td colspan="2">DO NOT confront the individual with your suspicions</td></tr>
<tr><td colspan="2">DO NOT contact the police directly – go via one of the contacts above first</td></tr>
<tr><td colspan="2">DO Keep or copy any document that arouse your suspicions</td></tr>
</table>

6. Procedure

Step	Action	Responsibility
1	Notify the Trust if fraud has been identified . When fraud has been identified to take appropriate action. Contact the LCFS is you have any suspicions or concerns. All referrals will be treated in the strictest of confidence. If staff wish to report any suspicions or concerns and feel that it cannot be done internally they can contact the NHS Fraud and Corruption reporting line on 0800 028 40 60 (Freephone 24/7) or *via* the online fraud reporting form at www.reportnhsfraud.nhs.uk . Please give as much information as possible.	Clinical Trial Investigators UHP research staff. Research Governance team and the study sponsor.
2	Prevention of Fraud. GCP guidelines are designed, in part, to prevent the generation of fraudulent data in clinical research, whether academic or commercially sponsored. Monitoring and auditing procedures are of paramount importance. There are several reasons why research staff may become involved in fraud: • Financial - such research staff are likely to undertake too many trials with the patient population at their disposal and may be tempted to invent patients or to invent data attributed to genuine patients. • Pressure to publish – research staff and physicians in training need to enhance their list of publications, which will be vital when applying for a career post. Also, academics may believe that an extensive publication list will help when applying for extra staff or scarce research grants. The quality of research may not be of as much interest as the quantity. • Boredom - Research staff may become bored and as a result have difficulty maintaining standards and will need to be monitored with care. • Work Pressure – Demands on a researcher's time may be large and a temptation to take short cuts becomes appealing to solve short term problems.	All research staff.

Step	Action	Responsibility
3	When the Trust is acting as Sponsor. In this case a monitor (either a Trust employee or external consultant) will be visiting the Clinical Trial Investigator as a representative of the Sponsor. Monitors will ensure they are familiar with the signs and or indications of potential research fraud. Concerns may be raised by the monitor which initially may be nothing more than intuitive. The procedures and any concerns regarding potential research fraud should not be discussed with the Clinical Trial Investigator/s who might become forewarned of suspicion.	Research Governance team
4	External Sponsors should be made aware of the need to notify the Trust in writing of any “for cause” audit of Trust personnel or on Trust premises.	Commercial companies, universities, charities other NHS Trusts
5	Trust policy and SOPs includes the performance of monitoring of all Trust sponsored research by a Trust research monitor. Such monitoring is designed to identify non-compliance with Research Governance requirements, including potential research fraud.	Research Governance team.
6	On suspicion of fraud no independent action will be taken by a Monitor or Auditor acting on behalf of the Trust. The Directors of R&D and the Trust Counter Fraud Specialist will be immediately informed. Where an incident occurs, which could be regarded as fraud, the Directors of R&D and the Local Counter Fraud Specialist must take the following step: In cases of suspected research fraud, the Local Counter Fraud Specialist must be consulted prior to the commencement of investigations. Such investigations may subsequently need to be completed by the Counter Fraud Specialist team. If the research study in question is a Clinical Trial of an Investigational Medical Product (CTIMPs) or Medical Devices study that falls under the remit of the MHRA. The MHRA must be informed as soon as possible of grounds to suspect an incident of research fraud has occurred (i.e. more than just alleged). The MHRA may choose after discussion with the Directors of R&D and the Local Counter Fraud Specialist (LCFS) to investigate. The LCFS will liaise with the MHRA to ensure they have the access they require and to offer any other assistance that maybe required.	All Research staff

Step	Action	Responsibility
	At no stage should any member of staff speak or write to representatives of the media or any third party about a suspected fraud. Confidentiality is of paramount importance in any fraud investigation.	
7	For research studies which do not come under the auspices of the MHRA. At the discretion of the Directors of R&D and the Local Counter Fraud Specialist (LCFS), a suitably experienced and qualified independent auditor may be requested to undertake a “for cause” audit. If there are grounds for suspicion of a person’s involvement in an offence, then they will be invited by the NHS Counter Fraud Service to attend an interview under caution. The interview will be conducted in line with the Police and Criminal Evidence Act 1984. The investigation will have been conducted in line with the Criminal Procedure and Investigation Act 1996. Any person invited to attend an interview is entitled to have a legal representative present in a professional capacity. Any potential disciplinary matters will be dealt with by the Trust whilst criminal cases will be progressed by the NHS Counter Fraud Service. If civil action is necessary to recover the lost funds this will be taken by the Trust with the assistance of NHS Counter Fraud Service. At this point when there is a case to answer: The Director of People shall advise those involved in the investigation in matters of employment law and other procedural matters, such as disciplinary and complaints procedures as requested. It is important that the Directors of R&D, Director of People and the LCFS liaise closely during an investigation to ensure that all the relevant sanctions are explored and that the individual is not notified too early which could jeopardise the investigation. All staff have a duty to protect the assets of the Trust. Assets include information and goodwill as well as property. If documentary evidence shows beyond all reasonable doubt that fraudulent data has been submitted, the Directors of R&D should immediately inform the study	Research Directors and Local Counter Fraud Specialist

Step	Action	Responsibility
	Sponsor (if appropriate). Furthermore, in the case of research Investigator involvement, the matter should be referred to the appropriate professional body responsible for their registration, examples of which are the General Medical Council (GMC) and the Royal College of Nursing for possible consideration by the Professional Conduct Committee. If the Trust is acting as Sponsor submission to the GMC should be made directly. Cases submitted to the GMC, relating to commercial interventional studies, may be mediated by the Association of the British Pharmaceutical Industry (ABPI). Submissions to the GMC must be submitted the form of a Statutory Declaration. This should be accompanied by a report setting out details of the case, including: A description of the study. The method of recruitment of the Investigator concerned. The monitoring processes. How suspicions were first raised. How suspicions were investigated. How the conclusion was reached which led to GMC reporting. Supporting documents required later are: Study protocol. Recruitment letter(s) to the doctor concerned. The formal agreement with the doctor (including details of financial arrangement). Copies of all Case Report Forms (CRFs), laboratory and/or other reports and diary cards which may be suspect.	
8	Internal Disciplinary Procedure. Trust procedures follow the principles of both the ACAS Discipline and grievance at work handbook and is in accordance with the relevant legislation. In determining the disciplinary action to be taken, managers should be aware of the need to satisfy the test of reasonableness and must ensure that each case is investigated thoroughly, and all relevant facts are considered. To ensure this, managers must consult with the appropriate Human Resource lead. In circumstances of alleged gross misconduct or gross incapability, dismissal may be considered without the issue of prior formal warnings.	Senior managers and Human Resources

Step	Action	Responsibility
	If it is decided that no further action will be taken following the investigation, a letter to this effect will be sent to the employee concerned. No record of the investigation will be kept on the employee's personal file.	

7. Changes from last revision

Updated to revised SOP template, reviewed, edited text, named individuals roles confirmed.