Royal Papworth Hospital
NHS Foundation Trust

Document Title: Management of Suspected Fraud and Misconduct in Research

Document Number: R&D SOP052

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Summary of Amendments

Version Number	Modification:
4.0	Updated for clarification on definitions and to align with Papworth DN117.
3.0	Minor administrative changes throughout the document

Key related documents:	Trust Research Policy SOP016: Monitoring Royal Papworth Sponsored Studies Trust Policies: DN203 Corruption and Counter Fraud Policy DN605 Anti-fraud and Bribery Policy and Response plan DN117 Disciplinary Procedure DN259 Whistleblowers Procedure

Key Points of this Document

- This SOP describes the principles, responsibilities and procedures to be followed when fraud or misconduct is suspected in research at RPH.
- This SOP applies to all staff conducting research at Royal Papworth Hospital.
- It aims to provide clear guidance on how suspected fraudulent activity should be reported.
- If Royal Papworth staff suspect fraud at another site, then the issue should be formally raised to the Clinical Director of Research and Development, and appropriate action agreed and implemented.

1 Purpose and Contents

a. The purpose of this SOP is to ensure that RPH fulfil their requirements to identify and manage all reports of suspected fraud and misconduct appropriately, in accordance with UK law and the UK Policy Framework for Health and Social Care Research.

b. Equally, its aim is to create an environment where equal emphasis is placed on accountability and learning, and to ensure there is a mechanism to raise concerns without fear of reprisals and respond with a compassionate approach to reviewing issues involving potential misconduct.

c. RPH values the importance of producing high quality and safe research and rely on the personal and scientific integrity of individuals involved in research. Research misconduct is contrary to this value, places participants at risk, and erodes confidence in the scientific integrity of research as a whole and jeopardises the reputation of RPH and their employees.

d. Fraud and misconduct in research is rare, but it shall be treated as serious. The investigation process for suspected or alleged fraud or misconduct must be managed in accordance with the highest standards of integrity, accuracy and fairness.

e. The monitoring of study data to ensure its validity is outside the scope of this SOP and is described in SOP016: Monitoring Royal Papworth Sponsored Studies.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust.

b. Staff involved in research studies must comply with the requirements set out in section 3a.

c. All research staff are responsible for the quality and safety of the research studies that they are involved in and as such should familiarise themselves with the standards expected of them and the procedures for raising concerns.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Definitions

Research Misconduct

For the purposes of this SOP the definition of research misconduct is taken from the Medical Research Council Policy and Procedure for investigating allegations of research misconduct (V1.4 November 2014).

Research misconduct means the unacceptable conduct, which includes fabrication, falsification, plagiarism, misinterpretation, mismanagement or inadequate management of data and / or primary material, and breach of duty of care.

Fabrication **-** The creation of false data or other aspects of research, including documentation and participant consent.
Falsification - The inappropriate manipulation and/or selection of data, imagery and/or consents.
Plagiarism **-** The misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission.
Misrepresentation - misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data; undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication; misrepresentation of interests,

including failure to declare material interests either of the researcher or of the funders of the research; misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held; misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution.

Breach of duty of care - Whether deliberately, recklessly or by gross negligence: disclosing improperly the identity of individuals or groups involved in research without their consent, or other breach of confidentiality; placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated; not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly and transparently; not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment; improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes.

Improper dealing with allegations of misconduct **-** failing to address possible infringements including attempts to cover up misconduct or reprisals against whistle-blowers; failing to deal appropriately with malicious allegations, which should be handled formally as breaches of good conduct.

Fraud, bribery and corruption

Fraud, bribery and corruption are defined by the Fraud Act 2006 and the RPH Policy DN605 (Anti-fraud and Bribery Policy and Response plan). In addition to the legal obligations, receipt of external funds is frequently governed by contractual arrangements with external funders, which specify purpose and terms of use of the funding. A fraud can occur by deliberate use of external funding for purposes other than for which it was provided. In all cases the financial arrangements for a study must be approved prior to commencement of the study. It is the responsibility of the researcher to ensure that all costs associated with the project have been identified, that funding has been identified, that satisfactory arrangements are in place for the management of income and expenditure and that where there is double funding there is clarity regarding responsibility to ensure that the same elements of a project are not funded twice.

5 Procedure

5.1 Framework

a. The Trust wants to ensure that a culture of openness is fostered, and a research environment exists that encourages high quality research and supports the raising of any legitimate concerns.

b. This procedure should be read in conjunction with Trust wide policies on reporting and investigating fraud and misconduct:

DN605 Anti-fraud and Bribery Policy and Response Plan
DN259 Freedom to Speakup, Raising Concerns (whistleblowing) policy
DN117 Your Behaviour Matters – Disciplinary procedure

c. Where a complaint is made on malicious or vexatious grounds, the appropriate action will be taken against the employee in accordance with the Trust's procedure DN117.

d. All documentation arising from this procedure and its associated policy will comply with the guidance of the Data Protection Act 2018.

5.2 Raising concerns

a. Initially the individual should raise their concern with their line manager. If they feel unable to raise it with their line manager, the concern can be raised directly with the R&D Operational Manager, Senior R&D Manager, or Clinical Director for R&D. Concerns can also be raised with one of the Freedom to Speak-up champions.

b. At this stage the complaint or concern may be resolved informally without the need for referral to the formal stage. Where there is doubt as to the seriousness of the matter, the Medical Director or the Clinical Director of R&D must be consulted.

5.3 Addressing concerns

a. Detailed procedures and responsibilities for the handling of suspected fraud and misconduct as well as sanctions are set out in the Trust Misconduct Policy (DN117).

b. On most occasions, it will not be necessary and/ or appropriate for managers to use the formal stage of the Misconduct Policy, with employee relations advice, and informal discussion may be sufficient to collect sufficient background information, reinforce

standards and support performance improvement. Line managers should keep notes for reference purposes.

c. Normally the informal discussion will be made between employee and their line manager, however individuals addressing concerns should have sufficient expertise to be able evaluate scientific and / or research issues.

d. If the line manager decides that there is a reasonable suspicion that research misconduct/ fraud or bribery has occurred, the formal process within DN117 should be followed. The Senior R&D manager and Clinical Director of R&D should be informed.

e. In cases of substantiated fraud and misconduct, other institutions including professional and regulatory bodies, research journals, funders, sponsor and patients may need to be informed of the incident. Additional actions can be taken by the institutions in response. Criminal prosecution and civil actions are possible sanctions in substantiated cases of fraud and misconduct.

5.4 Research Sanctions

a. In addition to the sanctions described in DN117, research sanctions may include (but are not limited to): removal from the particular project; increased monitoring of future research work; requirements to undertake specified training; withdrawal of funding for the research programme.

5.5 Other Important considerations

a. At any stage of the process consideration should be taken by the manager on the possible impact of allegations and facts ascertained on the rights and safety of the participants as well as integrity of project. In the event of such impact the ***R&D Operations Manager*** and / or ***Senior R&D Manager*** will liaise immediately with the ***Clinical Director*** for ***R&D*** to agree actions. For projects sponsored by other organisations the R&D department will liaise with the sponsor. ***Similarly,*** if ***RPH*** received external funding for a research project, ***the*** R&D department will lead on communication with the funder***.***

6 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved date]
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2023)

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	No	No	No	No	No	No	No
Positive/Negative	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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