Royal Papworth Hospital
NHS Foundation Trust

Document Title: Dealing with Misconduct and Fraud: Good Research Practice

Document Number: R&D SOP052

Staff involved in development: *Job titles only*	RM&G Manager, R&D Administration Manager, Research Officers
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Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
All	Minor administrative changes throughout the document

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who record data for the purpose of research.

- 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. This document defines the procedures to be followed by staff involved in Research Studies and Clinical Trials at the Royal Papworth R&D Unit (the 'Unit').

b. The document clarifies the requirements for the reporting and investigation of misconduct and fraud so as to ensure the integrity and quality of clinical trials as described in Good Clinical Practice (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

c. The document aims to provide clear guidance on the how concerns of misconduct and fraud should be raised and dealt with so as to comply with the Trust-wide policies on Corruption and Fraud.

d. The procedures described aim to ensure the safety of those involved in research, and that any research that takes place in the Trust is conducted in a fair and equitable manner.

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 including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties including those within CUHP AHSC and those seconded to and providing consultancy to the Trust, and to students undertaking training 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 Procedure

a. This procedure details the systems that are in place to detect and deal with research misconduct and fraud; a necessary part of the Trust's Research Governance strategy. The Trust's Research Governance Framework constitutes systems and processes to ensure that all research performed on Trust premises, or by Trust employees, is:

1. Safe
2. High quality
3. Contributes to improving the treatment and care of patients

b. Patients and healthcare users are seen as active participants in the research process, and this procedure contributes to the systems and processes that are in place to protect their rights and wellbeing.

c. Research Misconduct and Fraud is defined as:

1. Acts of fabrication, falsification, plagiarism or deception at any point in the process of proposing, performing or reporting the results of research or the deliberate, dangerous or negligent deviation from accepted practices in performing research.
2. It includes failure to follow established protocols, including those of the National Research Ethics Service (NRES) or Tissue Bank Committee, if this results in unreasonable risk or harm to humans, other vertebrates or the environment, and facilitating misconduct in research by colluding in, or concealing, such actions by others.
3. It also includes intentional, unauthorised use, disclosure or removal of, damage to, research-related property of another, including apparatus, material, writings, data, hardware or software, or any other substance or device used in, or produced by, the conduct of research.
4. It does not include honest errors 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.

d. The principles of good research practice are:

1. An important first step in good research practice is an awareness of the existence of this policy and procedure. All staff involved in research will be made aware of this policy and procedure and their responsibilities under it.
2. The Trust places considerable emphasis on prevention of misconduct and fraud.
3. The Medical Director has responsibility for informing the R&D Research Governance Team of any matters raised under this policy which require their consideration and/or action. In turn, the Research Governance Team has a responsibility to report to the Clinical Governance Committee where appropriate.
4. The Trust will seek to ensure that all concerns raised are dealt with in the timescales set out in the procedure.
5. The Trust will seek to ensure that due consideration is given to safeguarding the confidentiality and professional reputation of members of staff regarding whom concerns are being raised.
6. All research undergoes appropriate peer review and is submitted to the Research Ethics Committee in line with National Guidelines for approval as appropriate.
7. Approval by the Trust's R&D Office must be sought for all research that involves patients, patient samples, patient data and Trust infrastructure (e.g. research equipment, staff).
8. As stated in the Research Governance Framework, the Principal Investigator is responsible for the conduct of his or her research team. If an Investigator is unsure of the processes in relation to any of the above points then they should seek advice from the Trust's R&D Department.

4.1 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. Several channels exist by which an individual may raise a concern:

   1. Clinical Directors
   2. Research and Development Managers
   3. Medical Directors
   4. Clinical Directorate Managers
   5. Through the Trust's recommended channels for raising concerns (see the Trust's policy DN259)

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 1998.

e. Cases of alleged research misconduct and fraud are dealt with in several stages as defined below.

4.2 Informal Stage

a. A complaint or concern is raised by an individual to one of the following:

1. Clinical Directorate Manager
2. Head of Department
3. Clinical Director of R&D
4. Medical Director
5. Any other appropriate person as identified in the Trust Policy DN259

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.

4.3 Formal Stage

4.3.1 Stage 1: Raising the Complaint / Concern

a. The Clinical Director of R&D or Medical Director receives communication of the complaint / concern.

b. The reporter must provide a detailed written statement in support of the allegation.

c. The researcher is informed by the Director that an anonymised complaint or concern has been made and that an assessment panel will be set up to review it.

4.3.2 Stage 2: Assessment of the Complaint / Concern

a. An assessment panel is set-up consisting of a minimum of two members:

1. The Clinical Director of R&D, Clinical Directorate Manager, or a nominee of the Medical Director

2. A representative of the lead employer if not Royal Papworth Hospital (e.g. Medical Research Council, University etc)

b. The assessment panel should inform the medical director of its findings within 7 days of receipt of the complaint / concern, under one of the following headings:

1. No case to answer
2. No case, but malicious intent
3. Minor concern
4. Major concern

c. Actions to be taken. The following actions should be taken:

1. No Case: the researcher and complainant are informed
2. No Case, but malicious intent: the researcher is informed. The relevant human resources departments are informed and the relevant action is taken in respect to the reporter.
3. Minor Concern: the panel recommends actions to be taken to resolve the concern. The Medical Director approves these plans, if appropriate. The Medical Director then communicates these plans to the necessary parties
4. Major concern: Stage 3 of the process is undertaken

4.3.3 Stage 3: Formal Investigation

a. An investigation team is appointed consisting of two members as a minimum:

1. The Clinical Director of R&D, a Directorate Manager, or a nominee of the Medical Director
2. A representative of the lead employer if not a Royal Papworth employee (e.g. University or Medical Research Council)

b. Actions to be taken. The following actions are taken:

1. The researcher is advised of the detail of the complaint / concern in order to prepare
2. The researcher is given written notice of the requirement to assist fully in the formal investigation process
3. The researcher is informed of the membership of the Investigation Team
4. A written report of the findings is prepared by the Investigation Team and presented to the Medical Director

4.3.4 Stage 4: Outcomes of Investigation

a. The Medical Director receives a report of the findings and recommendations of the Investigation Team.

b. Actions to be taken. The Medical Director will recommend one or more of the following actions, and will communicate the recommendations to the relevant parties:

1. Implementation of all or some of the Investigation Team's recommendations
2. Referral to lead employer recommending action under appropriate disciplinary procedures
3. Report to the Research Governance Team
4. Report to an external regulatory body
5. Report to the Trial Sponsor (if not Royal Papworth R&D)

4.4 Appeal Process

a. Only in the case of a referral to the lead employer with recommendations for actions under the appropriate disciplinary procedures, would the researcher have access to a right of appeal through his or her lead employer's disciplinary procedure.

b. If no disciplinary action has been invoked and the researcher wishes to appeal against the process of the investigation, then an appeal should be submitted under the lead employer's appropriate appeals or grievance procedure.

4.5 Procedural Notes

a. Individuals are to be advised of their right to representation during the above processes.

b. Where appropriate, the overall aim of the procedure is to try and solve any concerns at an informal level. There may however, be occasions where a formal investigation is required.

c. Anonymity and confidentiality of both the reporter and the researcher are vital to the proper conclusion of all cases. Information will be exchanged only for the proper conduct and conclusion of any case, and disclosure of any information will be only to those individuals that need to know.

d. The Trust may seek the involvement of an external adviser on any occasion it is deemed necessary.

4.6 Reporting

a. The levels of reporting are governed by the following criteria:

1. The outcome of a particular stage of the review process
2. The main employer status
3. The conditions set by the funding body
4. The regulations set by the professional body

4.7 Documentation

a. Comprehensive and accurate notes should be taken at each stage of the review process.

b. All notes should be stored in a safe and secure environment during the process and should be filed in the Medical Director's Office once the matter is concluded.

c. All documentation should be handled in accordance with the Data Protection Act 1998.

d. Anyone of the following may grant access rights to the notes:

1. The Clinical Director of R&D
2. The Medical Director
3. The Chief Executive

5 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. Research Governance Framework for Health and Social Care (2005)
Key related documents:	Trust Research Policy SOP016: Monitoring Royal Papworth Sponsored Studies Trust Policies: DN203 Corruption and Counter Fraud Policy DN117 Disciplinary Procedure DN259 Whistleblowers Procedure

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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Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0	01 August 2012	June 2014	RDD	13 July 2012
2.0	12 March 2015	March 2018	RDD	10 April 2015
3.0				

I certify the contents of this SOP has been reviewed and ratified

..... 2nd March 2018

Signed by Dr Ian Smith, Clinical Director of R&D — Date

SOP release date: 5th March 2018