

Document Title: Investigating and Resolving Allegations of Misconduct in Research

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This document supports: <i>Standards and legislation</i>	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
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Version Control

Version	Date	Author	Status	Comment
1.1	24_FEB_2017	Rachel Fay	FINAL	Correction to review date, update to SOP template V2.0
2	03 OCT 2017	Lucy Parker	Final	Update to SOP template 3.0 Replacement of reference from Research Governance Framework to UK Policy Framework for Health and Social Care (2017)

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1. INTRODUCTION

This document sets out the procedures to be followed by all RFL staff who are involved in clinical research within the Trust.

This SOP has been designed to be additional to RFL's existing policies for handling situations where allegations of misconduct are made. It is intended to allow the full and fair investigation of research-related issues and to reach a conclusion on any allegations prior to considering any disciplinary or other non-disciplinary steps that might be required or recommended.

2. OBJECTIVE

This document defines the procedures to be followed by staff involved in Research Studies and Clinical Trials at the Royal Free London NHS Foundation Trust.

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

The SOP aims 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.

3. DEFINITIONS

RF or RFL Royal Free London NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

Misconduct and fraud - RFL has adopted the following, non-exhaustive definition of misconduct and fraud in research that is based on guidance issued by the Wellcome Trust:

“The fabrication, falsification plagiarism or deception in proposing, carrying out or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols or adhere to established ethical principles if this failure results in unreasonable harm to human beings, other living organisms or the environment and facilitating of misconduct in research by collusion in, or concealment of, such action by others. It includes intentional, unauthorised use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings, data hardware or software or any other substance or devices used in or produced by the conduct of research. It includes fraudulent use of research income. It also includes any plan or conspiracy or attempt to do any of the above.”

It does not include honest error or honest differences in the design, execution, interpretation or judgment 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.

Researchers may also wish to follow the United Kingdom Research Integrity Office (UKRIO) guidance – <http://ukrio.org/>

Designated Directors- the designated directors (Director of Planning or Director of Workforce and OD) must ensure their contact details are widely known in order that staff may raise whistleblowing concerns. They must ensure that the issue is clearly understood, taking care to keep the information and arrangements confidential. They should ascertain the type of concern and nominate appropriate contacts if necessary

Designated contact- is responsible for investigating concerns that are brought to their attention. These concerns will be taken seriously, considered fully and sympathetically, recognising that raising concerns can be a difficult experience. As the designated contact, they will provide advice and support, and feedback to the individual/s who has raised concerns.

4. SCOPE

This SOP clarifies the requirements for the reporting, investigating and responding to allegations of research misconduct made against staff undertaking studies at Royal Free London NHS Foundation Trust.

5. EQUALITY STATEMENT

The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the trust's commitment. You are responsible for ensuring that the trust's policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery.

The equality analysis for this SOP is attached at Appendix (2).

6. DUTIES

The Trust is committed to the delivery of world class care and expertise to both staff and patients, and our values of positively welcoming, actively respectful, visibly reassuring and clearly communicating are fundamental to the delivery of this. This policy has been developed with our values in mind, and is intended to be implemented within the spirit of these values.

7. PROCEDURE

Person Responsible	Task
All research staff	<p>7.1 Raising concerns</p> <p>The Trust desires 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.</p> <p>RFL has a Whistleblowing/Raising Concerns Policy and Fraud and Bribery Policy and these should be referred to where allegations of research misconduct and fraud arise.</p> <p>Several channels exist by which an individual may raise their concern either verbally or in writing in line with the Trust's recommended channels for raising concerns (see the Trust's Whistleblowing/Raising Concerns Policy):</p> <ul style="list-style-type: none"> • speaking to the person directly • speaking to your line manager or a more senior manager • speaking to designated directors • contact the Chief Executive • contact the Chairperson <p>Cases of alleged research misconduct and fraud can be dealt with in ways defined below.</p>
All research staff	<p>7.2 Informal Stage</p> <p>A research-related complaint or concern is raised by an individual through one of the channels listed above. At this stage the complaint or concern may be resolved informally without the need for referral to the formal stage.</p>
All research staff/Designated Contact	<p>7.3 Formal Stage</p> <p>The designated contact for research related events is informed of a complaint or concern.</p> <p>The designated contact can be the Director of R&D, Deputy R&D Director or another senior member of staff with knowledge and experience of RFL's research governance procedures. However, in cases where there exists a valid reason why the designated person should not be the Director of R&D or Deputy R&D Director, for example where the Director of R&D or Deputy R&D Director are connected in any way to the research in question, the complaint or concern</p>

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	<p>should be forwarded to another senior member of staff.</p> <p>The designated contact shall lead an initial 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 designated contact will not personally conduct the investigation and will remain separate from it, in order to maintain impartiality and fairness in the investigative process.</p> <p>The designated contact will:</p> <ul style="list-style-type: none"> • decide how an investigation should take place and what form it should take • appoint relevant person/s to investigate the allegation • decide whether there are grounds for proceeding further • In the event of financial implications, inform the Director of Finance • Seek advice from H.R as appropriate • Where the individual holds an honorary contract, inform the individual's employer of the intention to pursue an investigation.
/Designated Contact	<p>7.4 Outcome of initial investigation</p> <p>When the matter has been investigated, the designated contact will decide whether the matter should be taken further and, if so, how it should be handled.</p> <p>The designated contact will provide feedback regarding the outcome of the investigation and the agreed actions following the investigation to the individual/s who had raised the concern or complaint.</p> <p>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 RFL and reference to outside bodies, such as the study Sponsor, MHRA (for studies involving IMPs), Research Ethics Committee, study Funder, or the Chief Investigator's employer (if not the Trust).</p> <p>The outcomes of any investigations shall be reported to relevant senior managers within the Trust who will then consider what disciplinary or other non-disciplinary steps that might be required or recommended.</p> <p>Where the individual holds an honorary contract, the</p>

	designated contact informs the individual's employer of the outcome of the investigation
Designated Contact	<p>7.5 Documentation</p> <p>The designated contact overseeing the investigation will ensure that comprehensive and accurate notes are taken at each stage of the review process.</p> <p>All notes should be stored in a safe and secure environment during the process and should be filed once the matter is concluded. All documentation should be handled in accordance with the Data Protection Act 1998.</p>

8. POLICY

This SOP is mandatory and non-compliance with it may result in disciplinary procedures.

9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- The R&D Office 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).
- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the R&D Manager/Deputy R&D Director 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.
- The R&D Office is responsible for the ratification of this procedure.

10. FORMS/TEMPLATES TO BE USED

None applicable

11. FLOWCHART

None applicable

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APPENDIX 2

Royal Free London NHS Foundation Trust Equality Analysis guide and Tool

An equality analysis is a review of a policy, practice, function, business case, project or service change which establishes whether there is a negative effect or impact on particular social groups. This In turn enables the organisation to demonstrate it does not discriminate and, where possible, it promotes equality to meet the needs of the diverse patients and communities we serve.

This check list is a way to help you think carefully about the likely impact on equality groups and take action to improve services. This is also an opportunity to evidence positive practices in our services and demonstrate strategic integrity to ensure that our services and employment practices are fair, accessible and appropriate for all patients, visitors and carers, as well as our talented and diverse workforce.

Name of the policy / function / service development being assessed	Investigating and resolving allegations of misconduct in research
Briefly describe its aims and objectives:	This SOP provides a process for concerns to be raised, investigated and, where appropriate, acted upon in a fair and transparent manner and in confidence.
Directorate and Lead:	Rachel Fay, R&D Manager, R&D Office
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Is the Trust Equality Statement present?	Yes No if no do not proceed with Equality Analysis (EA)

If you are conducting an EA on a procedural document please identify evidence sources and references, who has been involved in the development of the document, process or strategy, and identify positive or negative impacts. It is the discussion regarding the equality impact of the document that is important.

Equality Analysis Checklist

Go through each protected characteristic below and consider whether the policy, practice, function, business case, project or service change could have any impact on groups from the identified protected characteristic, involve service users where possible and get their opinion, use demographic / census data (available from public health and other sources), surveys (past or maybe carry one out), talk to staff in PALS and Complaints and Patient Experience.

Please ensure any remedial actions are Specific, Measureable, Achievable, Realistic, and Timely (SMART).

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Age	None identified	R&D administrative document	NA	NA	This SOP includes the Trust Equality Statement, as well as the results from the Equality Assessment for this SOP. These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
Disability	None identified	R&D administrative document	NA	NA	
Gender Reassignment	None identified	R&D administrative document	NA	NA	
Marriage and Civil Partnership	None identified	R&D administrative document	NA	NA	
Pregnancy and maternity	None identified	R&D administrative document	NA	NA	

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Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Race	None identified	R&D administrative document	NA	NA	
Religion or Belief	None identified	R&D administrative document	NA	NA	
Sex	None identified	R&D administrative document	NA	NA	
Sexual Orientation	None identified	R&D administrative document	NA	NA	
Carers	None identified	R&D administrative document	NA	NA	

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval committee(s). Add more lines if necessary)	Organisation	Date
SOP Working Group	Royal Free London NHS Foundation Trust	10/11/2017
R&D Committee	Royal Free London NHS Foundation Trust	21/12/2017

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