

Document Title: Escalation Procedure

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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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<u>This is a controlled document</u>	
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Version Control

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1. INTRODUCTION

All research conducted at Royal Free will be in accordance with the key principles of ICH GCP to ensure that

- The rights and wellbeing of the human participants are protected
- The reported trial data are accurate, complete and verifiable from source documents
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirements

Investigators will have agreed to follow and abide by the approved protocol, Sponsor standard operating procedures (SOPs) and the research compliance policies of Royal Free at the point of receiving confirmation of capability and capacity (formerly known as Host Site approval) and/or Sponsorship by Royal Free.

Monitoring is an integral role in the Quality Control (QC) of a clinical trial and is designed to verify the quality of the study. Should the findings detailed in the monitoring report not be corrected, this could have an impact on the QC of a study. Therefore, it is important to have in place, an escalation procedure should there be non-compliance in relation to monitoring reports.

Auditing is an integral role in the Quality Assurance (QA) of a clinical trial and is designed to verify the quality of the study. Should the findings detailed in the audit report not be corrected, this could have an impact on the study. Therefore, it is important to have in place, an escalation procedure should there be non-compliance in relation to audit or inspection reports.

Investigators may be contacted by members of the RF R&D Office during the lifecycle of the study and documentation or evidence of required documentation, study progress reports can be requested. Following receipt of such requests the investigator will be expected to respond with an acceptable time frame dependant on urgency of the request. Failure to reply will be seen as non-compliance.

2. OBJECTIVE

This SOP describes the procedure for suspending studies that are persistently non-compliant.

3. DEFINITIONS

RF Royal Free London NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

TROIKA - is a sub-committee of the Research and Development (R&D) Committee and comprises of the Dean of the Royal Free campus of UCL Medical School, the Director of the R&D Office and the RF's Medical Director

4. SCOPE

This SOP covers the escalation procedure of persistently non-compliant studies that are hosted and/or Sponsored by the Royal Free.

This SOP does not cover the escalation process of serious breaches of Good Clinical Practice (which is covered in SOP033). It should be read in tandem with SOP032 Non-compliance.

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.

This SOP should be read and followed by the Principal Investigator and their team. It should also be read and followed by the R&D team and the Research and Development (R&D) Committee.

7. PROCEDURE

Person Responsible	Task
PI	<p>7.1 Investigator Procedures</p> <p>The investigator and their team must respond promptly to any communications from the RF R&D Office. This means that responses must be timely and within any given deadlines which may be set.</p> <p>If the investigator persistently does not respond to requests from the RF R&D Office or correct findings from previous monitoring visits or respond to Audit findings, this could bring doubt on the reliability of the data produced, the possible safety of participants, the ability of the investigator to manage his/her agreed responsibilities which could increase the risk borne by RF, therefore it is vital that investigators respond to written requests by the R&D Office in a timely fashion.</p> <p>Should the R&D Office decide that the study is to be closed to new recruitment (see section 7.2), then:</p> <p>7.1.1 RF Sponsored Studies</p> <p>It is the investigator's responsibility to complete a substantial amendment form and send it to their assigned RPM for approval. The amendment form will be to suspend the study to new recruitment until the findings have been corrected. The investigator will then be authorised by the RPM to complete another substantial amendment opening the study to new recruitment when all the findings have been addressed.</p> <p>7.1.2 Hosted Studies not Sponsored by RF</p> <p>The R&D Office will inform the Sponsor /CRO of the decision to suspend recruitment and the related circumstances. The R&D Office may be required to assist the Sponsor in the identification of an alternative PI.</p> <p>The study team must endeavour to communicate efficiently with the R&D Office and respond quickly to any request or query.</p> <p>If the study team are still not communicating or responding within the stated timelines, then the investigator will be expected to appear before the R&D Committee or Troika in order to discuss the</p>

	<p>future of the study. Researchers must be aware that host site approval maybe revoked by the Committee(s) for non-compliance.</p> <p>If there are issues which result in the requests being unanswered/unresolved within the given timeframe, the researcher must discuss this with their assigned RPM as soon as possible.</p> <p>Recruitment following suspension will constitute a Serious Breach of GCP.</p>
<p>R&D Office/Assigned Research Portfolio Manager (RPM)</p>	<p>7.2 R&D Office Procedures –Suspension</p> <p>The assigned RPM will discuss any concerns regarding audit findings or Monitoring report findings or consistent communication problems by a study team with the RF R&D Manager detailing the given deadline for expected resolution.</p> <p>The RPM will repeat the written request for resolution of outstanding issue(s) addressed to the Principal Investigator. Reference to this escalation procedure (SOP061) will be made and the date when the response is required – this will dependant on the possible perceived risk to patients/ trial data/institution. The RPM will ensure that the R&D Manager is cc'd into the communication, clearly stating that the study will be suspended to new requirement if a satisfactory response is not received by the date stated.</p> <p>If the study team fails to respond adequately within the requested timeline, the study will be suspended to new recruitment until the R&D Manager is satisfied the study is compliant. The suspension will be notified to the REC by completion of a substantial amendment form if the study is sponsored by RF or the suspension notified to the Sponsor if the study is hosted by RF.</p> <p>Support departments such as pharmacy and any other participating sites (if a Royal Free Sponsored study) will also be informed that the study is suspended to new recruitment until further notice.</p> <p>Recruitment following suspension will constitute a Serious Breach of GCP.</p>
<p>Assigned Research Portfolio Manager</p>	<p>7.3 R&D Office Procedures – Post-Suspension</p> <p>When the CI states that the study audit or monitoring findings have been corrected, the assigned RPM will perform a visit to assess whether the corrections are</p>

	<p>appropriate.</p> <p>7.3.1 Sponsored studies</p> <p>If the corrections are appropriate, the RPM will authorise the investigator to notify the REC that the study is reopened through submitting an amendment (see SOP003 and SOP016). Support departments such as imaging and all participating sites will be told that the study is re-opened to new participants.</p> <p>If the study is still not compliant within one calendar month of suspension, this will be escalated within 2 working days of the deadline passing to the Research & Development (R&D Committee) or Troika (where awaiting R&D Committee scheduled meeting would be impractical) for possible revoking of RF Sponsorship.</p> <p>7.3.2 Hosted Studies</p> <p>If the changes are appropriate, the RPM and study team will liaise with the Sponsor Representative to re-open the study for recruitment at RF.</p> <p>If the study is still not compliant within one calendar month of suspension, this will be escalated within 2 working days of the deadline passing to the Research & Development (R&D Committee) or Troika (where awaiting R&D Committee scheduled meeting would be impractical) for possible revoking of RF Host Site Approval (Confirmation of Capability and Capacity).</p>
RPM/Theme Lead	<p>If closing the study at RF or revoking Sponsorship would pose a risk or adversely affect the ongoing patient management then identifying an alternative Principal Investigator should be considered. All responsibilities by the non-compliant team members should be revoked. The Delegation of Responsibilities log should be updated with end dates for those team members.</p>
Assigned RPM	<p>A simple report of the reasons leading to escalation procedure – actions taken by whom, should be placed in the site file. Sponsors in the case of hosted studies and funders in the case of funded RF Sponsored studies should be kept fully informed at each stage of the process.</p>
Troika	<p>When the Troika has been consulted between scheduled R&D Committee meetings, the membership will ensure that a summary of the consultation/escalation circumstances and any actions taken are summarised for discussion at the next</p>

	scheduled R&D Committee meeting.
R&D Committee	<p>The R&D Committee will include in the committee minutes, the subjected study's RD R&D Ref number, the study team member(s), the issues raised and the recommended actions. The R&D Committee will also note the details of the issue(s) raised and members will be invited to vote on any further action to be taken. The R&D Committee should also consider risk to any other research studies noted as active on the RF R&D Office database and possible actions to be taken. Troika will be contacted in between scheduled R&D Committee meetings to raise issues or to communicate follow up actions.</p> <p>The Committee's opinion will be sought to allow future research activity for non-compliant investigators.</p>
Assigned Research Portfolio Manager	Will add a note on the RF R&D database against the investigator entry of <i>non-compliance with Royal Free policies and procedures</i> .

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

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?	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 33%;">Yes</td> <td style="text-align: center; width: 33%;">No</td> <td style="text-align: center; width: 33%;">if no do not proceed with Equality Analysis (EA)</td> </tr> </table>	Yes	No	if no do not proceed with Equality Analysis (EA)
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	

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, and 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