

**Document Title: Change Management**

**Document Number: 060**

Version:	1
Ratified by:	R&D Committee
Date ratified:	21/12/2017
Name of originator/author:	Lucy Parker
Directorate:	Corporate Services
Department:	Research and Development
Name of responsible individual:	Rachel Fay, R&D Manager
Date issued:	05/02/2018
Review date:	05/02/2021
Target audience:	All research staff
Intranet:	NA
Key related documents:	SOP003 Reporting Amendments SOP016 Protocol Amendments for RL Sponsored Studies
This document supports: <i>Standards and legislation</i>	The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 UK Policy Framework for Health and Social Care (2017)
Date equality analysis completed.	21/12/2017
<b><u>This is a controlled document</u></b>	
Whilst this document may be printed, the electronic version maintained on the RFL website is the controlled copy. Any printed copies of this document are not controlled.	

**Version Control**

<b>Version</b>	<b>Date</b>	<b>Author</b>	<b>Status</b>	<b>Comment</b>
1	09 OCT 2017	Lucy Parker	Final	New document

**Contents**

<b>Section</b>		<b>Page</b>
1	Introduction	
2	Objective	
3	Definitions	
4	Scope	
5	Equality statement	
6	Duties	
7	Details of procedure	
8	Policy	
9	Risk management/liability/monitoring & audit	
10	Forms/templates to be used	
11	Flowcharts	
<b>Appendices</b>		
Appendix (1)	SOP reading log	
Appendix (2)	Equality analysis guide and tool	

## 1. INTRODUCTION

Changes to plans can occur at all stages of a project lifecycle. Most changes can be planned and implemented by the project team independently, but some changes require that the RF R&D Office is informed in order to:

- a) update its records
- b) review and evaluate the institutional risks of the change
- c) inform external stakeholders and approvers.

## 2. OBJECTIVE

This SOP covers general aspects of managing change within research projects. It covers expected pre-planned changes, but also unexpected changes and deviations. Compliance with this SOP is required for all research conducted at Royal Free.

## 3. DEFINITIONS

RF Royal Free London NHS Foundation Trust

**External Approval** - Approval required from an external agency, e.g. a Research Ethics Committee, the MHRA, the Human Tissue Authority or the Funder.

**Internal Approval** - Approvals required by RF's policies. Given by or coordinated via the RF R&D Office including finance-related approvals, NHS R&D approvals (confirmation of capacity and capability), and granting institutional sponsorship

**Documentation** - Documents including but not limited to the Protocol, the Application to a Funder (if not evidently superseded as agreed with the Funder), any forms provided to RF R&D Office or external Agencies, Contracts, and Standard Operating Procedures.

**Assigned Research Portfolio Manager (RPM)** - The RPM assigned to the study. This will normally be in accordance with the Research Theme that the study falls under.

## 4. SCOPE

This SOP covers general aspects of managing change within research projects either sponsored by or hosted at Royal Free London.

## 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.

The Chief Investigator (CI) for a research project has responsibility for ensuring compliance with this SOP for a particular project. In case of joint CI's all CI's are responsible. The Principal Investigator (PI) is responsible for the project at the local site.

The assigned RPM has responsibility for co-ordinating a comprehensive but proportionate review of change requests as communicated under this policy in a timely and responsible manner.

## 7. PROCEDURE

Person Responsible	Task
PI/CI	<p><b>7.1 Temporary (unplanned) Change</b>                      Temporary, intermittent and unforeseen deviation from agreed practices or existing Documentation, where there is no effect to the safety or well-being of subjects or the integrity of the trial data.</p> <p>a) Not in contravention of the terms of Internal or External Approvals, contractual obligations, regulations, guidelines or essential standards (such as GCP).</p> <p>The PI should record such deviations but is not required to inform the RF R&amp;D Office. If the study has an external Sponsor – the PI must check with the Sponsor as to their notification requirements.</p> <p>b) Potentially in contravention of the terms of Internal or External Approvals, contractual obligations, regulations, guidelines or essential standards (such as GCP).</p> <p>The PI should record such deviations and inform the</p>

	assigned RPM.
PI/CI	<p><b>7.2 Planned Change</b></p> <p>a) Change can be implemented as a modification to working practices <b>without an amendment</b> to existing documentation.</p> <p>The PI may implement such changes in accordance with relevant SOPs without notification to the RF R&amp;D Office. If the study has an external Sponsor – the PI must check with the Sponsor as to their notification requirements.</p> <p>b) Change <b>requires amendment</b> to existing documentation that has no significant bearing on internal Approval status.</p> <p>The PI may implement such changes without approval by the RF R&amp;D Office, but must notify the assigned RPM and ensure appropriate internal approvals are sought. If the study has an external Sponsor – the PI must check with the Sponsor as to their notification requirements.</p> <p>A copy of the previous version must be retained within the relevant section in the Trial Master File, clearly dated and marked as superseded, Ensure any new documents approved for use are circulated to the study team(s).</p> <p>c) Change <b>requires amendment</b> to existing documentation (please also refer to the RF R&amp;D SOPs on the management of amendments (SOP016 and SOP 003) and <b>does affect</b> Internal Approvals.</p> <p>The PI must notify the assigned RPM at least 28 days in advance of implementing the change wherever possible. The assigned RPM shall review the change and any associated internal approvals and work with the PI to obtain external approvals to the proposed amendment. If the study has an external Sponsor – the PI must check with the Sponsor as to their notification requirements.</p>
Assigned RPM	<p><b>7.3 RF R&amp;D Office Review</b></p> <p>The RF R&amp;D Office will review the proposed change against two categories of criteria:</p> <p><b>Records management:</b> The RF R&amp;D Office will update records in electronic form to ensure that</p>

	<p>a. the proposed changed status is reflected as such in current records</p> <p>b. reasons for the change are recorded</p> <p>c. the prior status is archived following evidence of appropriate approvals for reference purposes unless, on a risk-based approach, this is not required</p> <p>d. if the change requires further post-implementation review, a note is made to alert the RF R&amp;D Office at such future date</p> <p><b>Risk:</b> All factors of assessment commonly conducted by or via the RF R&amp;D Office should be considered when assessing the potential consequences of the change.</p> <p>This includes but is not limited to considerations of</p> <p>a. finances</p> <p>b. participant safety</p> <p>c. operational challenges</p> <p>d. feasibility of success</p> <p>e. reputation and relationships</p> <p>f. academic excellence</p> <p>g. commercial relevance</p> <p>h. legal &amp; regulatory compliance.</p> <p>Specific expertise should be consulted by the assigned RPM as required on those factors considered potentially relevant.</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





**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	Change Management in Research
Briefly describe its aims and objectives:	This SOP covers general aspects of managing change within research projects either sponsored by or hosted at Royal Free London.
Directorate and Lead:	Rachel Fay, R&D Manager, R&D Office
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 UK Policy Framework for Health and Social Care (2017)
Is the Trust Equality Statement present?	<b>Yes</b> 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
<b>Age</b>	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.
<b>Disability</b>	None identified	R&D administrative document	NA	NA	
<b>Gender Reassignment</b>	None identified	R&D administrative document	NA	NA	
<b>Marriage and Civil Partnership</b>	None identified	R&D administrative document	NA	NA	
<b>Pregnancy and maternity</b>	None identified	R&D administrative document	NA	NA	
<b>Race</b>	None identified	R&D administrative	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
		document			
<b>Religion or Belief</b>	None identified	R&D administrative document	NA	NA	
<b>Sex</b>	None identified	R&D administrative document	NA	NA	
<b>Sexual Orientation</b>	None identified	R&D administrative document	NA	NA	
<b>Carers</b>	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