

**Document Title: Production, Approval and Review of  
 SOPs**

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Name of originator/author:	Neil Hubbard
Directorate:	Corporate Services
Department:	Research and Development
Name of responsible individual:	Rachel Fay, R&D Manager
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<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>
1.0	29.04.2014	Heidi Saunders	Final	Original Document
1.1	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2.0	07 SEPT 2017	Lucy Parker	Final	Update to New SOP template Change from reference to Research Governance Framework for Health and Social care (2005). to UK Policy Framework for Health and Social Care (2017)
2.1	01 Dec 2018	Neil Hubbard	Final	Update to remove references of ReDA to EDGE Database. Remove references to SOP working group and replaced with QMS group. Clarification of the approval process for non-substantial changes to SOPs.

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## 1. INTRODUCTION

This document defines the Trust's procedures for preparing, managing and reviewing Standard Operating Procedures (SOPs) that describe the standard activities used in Research Studies and Clinical Trials at the Royal Free London Hospital NHS Foundation Trust.

It aims to provide clear guidance on the steps involved in the preparation of SOPs to ensure compliance with RFL policies and procedures.

## 2. OBJECTIVE

This document sets out the procedures to be followed by all RFL Staff who are involved in the preparation, review, dissemination and implementation of SOPs for the core activities of clinical research.

The document clarifies the requirements for written SOPs to provide quality assurance 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').

All core clinical trial activities need to be supported by appropriate SOPs. This document provides guidance on the preparation and review of these departmental SOPs so as to comply with the Trust's policies on document preparation and control.

## 3. SCOPE

This SOP will describe the process for the preparation, review and approval of all new SOPs as well as revision of existing SOPs that are produced by RFL R&D Office for trials sponsored by RFL.

This SOP will cover the numbering of SOPs, but not numbering of other associated R&D Office documents. Numbering of other documents is covered in the working practice document (WPD) "Document control for important R&D Office documentation" (RFLRDWPD0005)

This SOP will not cover training of Investigators or the R&D Office personnel on SOPs produced by the R&D Office.

Training Records are covered in other R&D Office SOPs (Training Records SOP004 and GCP Training SOP005)

## 4. DEFINITIONS

<b>NIHR</b>	National Institute for Health Research
<b>RFL</b>	Royal Free London Hospital NHS Foundation Trust
<b>RM&amp;G</b>	Research Management & Governance
<b>R&amp;D</b>	Research & Development

**SOP** Standard Operating Procedure. ICH GCP (1.55) defines SOPs as *'Detailed, written instructions to achieve uniformity of the performance of a specific function.'* Section 2.13 of ICH GCP goes on to state that 'systems with procedures that assure quality of every aspect of the trial should be implemented.'

**Date Issued** Defines the date when the SOP is authorised for training and implementation. The authoriser should not be the person writing the SOP. It defines the date when the SOP is finalised and signed off by the person authorised to sign off the SOP. Authorised signatories are the following : the R&D Committee.

**Review Date** This defines the date the SOP is due for review by the author and/or a person designated to review the SOP. The review date will be set by default, 3 year from the effective date. If there is a justification for an earlier review (such as a change in process or regulation)

## 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 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, those working at the trust under honorary contract or under the remit of a valid research passport, those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

Staff involved in the preparation, review and dissemination of SOPs must comply with the requirements set out in section 7.

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It is the responsibility of the department's personnel to ensure that they are familiar with and adhere to all current SOPs, and have signed the relevant log in their training record.

This SOP is to be followed by the R&D Office and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the R&D Manager of the RFL R&D Office to ensure that this SOP is updated by the review date or as necessary.

Any SOPs produced by the RFL R&D Office must be used in conjunction with any other RFL policies and procedures. The SOPs are designed to be used as a template for individual departments and will require amending by researchers and their teams to meet the requirements of their individual projects.

### 6.1 Quality Management Systems Group

The Quality Management Systems Group (QMS Group) consists of Research Nurses, Lead Research Nurses, R&D Portfolio Managers, R&D Costing and Contracting, R&D Research Data and Performance Analyst, R&D Manager, and R&D Director, Clinical Trials Pharmacist. Terms of Reference (ToR) for this group are available from the R&D Office.

The Quality Management Systems Group are responsible for identifying the need for a new SOP and arranging its production, review, ratification and implementation.

The Group is responsible for identifying and organising further representation from the specialists/staff groups for the inception/review of a SOP where they may be particularly affected by the implementation of that SOP.

The task of preparing the SOP may be delegated to R&D personnel who are deemed to have the appropriate knowledge and experience.

The Group is responsible for identifying and arranging provision of any training that the introduction of a new SOP will require for staff to be able to perform their role in compliance with the SOP.

## 7. DETAILS OF THE PROCEDURE

Person Responsible	Task
Quality Management Systems Group	<u>7.1 Writing SOPs</u> <ul style="list-style-type: none"><li>• A review of the background context, including statutory or regulatory requirements, should be undertaken as part of the development of a new SOP. Stakeholders should be consulted as required including those who will carry out the SOP in practice.</li><li>• Before an SOP is produced for a clinical trial activity, the activity will be mapped to describe the process in a</li></ul>

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	<p>stepwise fashion. This will be used to draft the SOP using the standard SOP template.</p> <ul style="list-style-type: none"><li>• Updates to the SOP template will be managed by the Chair of the QMS Group and all versions will be stored on the R&amp;D shared drive.</li><li>• All SOPs should include a version control history that must be updated with each change to the SOP. All SOPs will have a review date and version number in the footer to ensure the most recent is used, and numbered pages in the page x of y format. The preferred numbering system is: version 1.0 (initial approved document); versions 2.0, 3.0 etc (subsequent updated documents which have been approved).</li><li>• Unapproved draft versions for review will be marked with version 1.1, 1.2 etc. The “DRAFT” watermark should be printed diagonally on the page.</li><li>• New SOPs should be generated in MS Word from the current SOP template.</li><li>• New SOPs will be given the next sequential number (SOPXXX) according to the Complete Current Listing controlled by the Chair of QMS Group. Changes to the title of an SOP, when preparing a new version, will not require a new number.</li><li>• On completion, the draft SOP will be reviewed internally by the relevant members of staff (relevance according to the purpose of the SOP). This review will look at compliance with the regulations, readability and accuracy of information.</li><li>• A formalised training needs assessment will be carried out for each new/revised SOP by the QMS Group. The type and level of training should be appropriate the roles and responsibilities of specific members of staff and the procedure concerned. Class-room based training may be required when competency sign-off is required, where complex processes or concepts are involved, or for staff new to the role or task. Realistic timeframes for the completion of training should be set.</li><li>• The training requirement i.e. read only or class-room training will be minuted and indicated on the SOP matrix. The arrangements for any training will be delegated by the QMS Group to an R&amp;D or other member of staff as most appropriate and logged according to Training Records SOP.</li><li>• The QMS Group will assess whether an amendment to a SOP is a substantial or non-substantial and whether the version needs to be ratified by the R&amp;D committee. Non substantial changes are defined as corrections or</li></ul>
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	<p>clarifications that have no impact on the process and require no staff training. Non-substantial amendments to SOPs can be ratified by the QMS chair and released and distribution with a version 1.1 or 2.1 to indicate a non-substantial change has been made.</p> <ul style="list-style-type: none"> <li>• QMS Group will approve the final draft for submission for approval by the Trust R&amp;D Committee.</li> <li>• When the SOP is approved by the Trust R&amp;D Committee: the watermark should be removed; the version number should be updated to the next whole number and planned review date added to the footer, front page and version control section of the SOP.</li> <li>• Once the SOP has been authorised, the chair of SOP Working group will update the SOP Training Matrix.</li> <li>• The impact of new or revised SOPs will be reviewed by the SOP Working group.</li> </ul>
R&D Committee	<p><u>7.2 Authorising SOPs</u></p> <ul style="list-style-type: none"> <li>• The new or substantially changed SOP will be ratified by the Trust R&amp;D Committee.</li> <li>• Non-substantially changed SOPs will be ratified by the QMS Group, at the discretion of the QMS chair and be record of the decision. Date of the QMS meeting will be added to the relevant section of the document history</li> <li>• Approval of an SOP by the Trust R&amp;D Committee must be minuted so as to provide written evidence of its approval.</li> <li>• The date of the Committee approval will be added to the relevant section of the document history.</li> </ul>
R&D Office	<p><u>7.3 Distribution and Implementation</u></p> <ul style="list-style-type: none"> <li>• All SOPs will have an effective date four weeks after authorisation by the trust R&amp;D committee so as to allow any required training to be performed prior to its implementation.</li> <li>• Whilst SOPs may be printed, the electronic version maintained on RFL's internet page is the controlled copy. Any printed copies are not controlled.</li> <li>• Local Chief and Principal Investigators will be notified of new and forthcoming SOPs via email.</li> <li>• All R&amp;D personnel and study support staff will be made aware of new versions of SOPs via email news bulletin and on the RFL internet page.</li> </ul>
Research Staff	<ul style="list-style-type: none"> <li>• Any existing clinical trial documentation, or departmental written and electronic material that refers in any way to a superseded version of an SOP, should be updated to</li> </ul>

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	<p>reflect the new SOP.</p> <ul style="list-style-type: none"> <li>• Staff should record that they have read and completed any required training in the SOP in the relevant section of their training record. SOPs should be read within two weeks of release, and required training completed before the member of staff performs the particular activity the SOP refers to.</li> </ul>
<p>Research Staff, R&amp;D Office and Group Quality Management Systems Working Group</p>	<p><u>7.4 Deviations and Waivers from SOPs</u></p> <ul style="list-style-type: none"> <li>• The RFL has an open policy to encourage declaration of deviations from SOPs.</li> <li>• It is the responsibility of staff to report SOP deviations to the RM&amp;G Manager/Deputy R&amp;D Director and record these deviations.</li> <li>• Deviations or waivers to active SOPs (including continued implementation of superseded SOPs) will be agreed according to section 9 of the SOPs.</li> <li>• A log of authorised deviations or waivers will be maintained and stored on EDGE. Review of the deviations or waivers will be included in the three-yearly review of the affected SOPs by the QMS Group in line with section 7.5.</li> <li>• The QMS Group will be responsible for ongoing and continued review of the logged deviations and waivers to initiate any remedial action required prior to the SOP review date.</li> </ul>
	<p><u>7.5 Review of SOPs</u></p> <ul style="list-style-type: none"> <li>• The designated review date of a particular SOP will be detailed on the SOP itself.</li> <li>• SOPs should be reviewed at least every three years or in response to changes in practice, regulations or legislative requirements.</li> <li>• The QMS Group will keep a log of the effective dates of all the departmental SOPs. SOPs should be flagged for review within the department three months prior to the specified review date to enable a new version to be prepared and ratified if necessary.</li> <li>• The QMS Group identifies any SOP requiring review, circulate the SOP and arrange a meeting, under the direction of the management, for its evaluation.</li> <li>• Where no new changes are deemed necessary, the existing version will be approved for up to a further three years by Chairman's Action at the R&amp;D Committee.</li> <li>• Where an SOP requires updating, the procedures</li> </ul>

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	<p>detailed in 7.1 will be followed.</p> <ul style="list-style-type: none"><li>• Superseded (approved and implemented) versions of SOPs will be archived and retained on the R&amp;D system (EDGE).</li></ul>
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## 8. POLICY

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

## 9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The QMS 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

SOP Template version 3.0 will be used to create or revise any SOPs.

**11. FLOWCHART**

Not Applicable

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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).

<b>Equality Group</b>	<b>Identify negative impacts</b>	<b>What evidence, engagement or audit has been used?</b>	<b>How will you address the issues identified?</b>	<b>Identifies who will lead the work for the changes required and when?</b>	<b>Please list positive impacts and existing support structures</b>
<b>Age</b>	None identified	R&D administrative document	N/A	N/A	This SOP for the Production, Approval and Review of SOPs introduces a requirement to include the Trust Equality Statement in all SOPs that describe the standard activities used in Research Studies and Clinical Trials at the Royal Free London Hospital NHS Foundation Trust.
<b>Disability</b>	None identified	R&D administrative document	N/A	N/A	
<b>Gender Reassignment</b>	None identified	R&D administrative document	N/A	N/A	
<b>Marriage and Civil Partnership</b>	None identified	R&D administrative document	N/A	N/A	
<b>Pregnancy and maternity</b>	None identified	R&D administrative document	N/A	N/A	
<b>Race</b>	None identified	R&D administrative document	N/A	N/A	

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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
<b>Religion or Belief</b>	None identified	R&D administrative document	N/A	N/A	It also introduces a new Equality Analysis Template for the SOPs, that requires the presence of the Equality statement.  These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
<b>Sex</b>	None identified	R&D administrative document	N/A	N/A	
<b>Sexual Orientation</b>	None identified	R&D administrative document	N/A	N/A	
<b>Carers</b>	None identified	R&D administrative document	N/A	N/A	

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
QMS Group	Royal Free London NHS Foundation Trust	27/09/2017
R&D Committee	Royal Free London NHS Foundation Trust	26/10/2017

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