

Document Title: Peer Review

Document Number: 055

Version:	1.2
Ratified by:	R&D Committee
Date ratified:	19/11/2018
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Directorate:	Corporate Services
Department:	Research and Development
Name of responsible individual:	Rachel Fay, Research & Development Manager
Date issued:	01/12/2018
Review date:	05/02/2021
Target audience:	All Research Staff
Intranet:	NA
Key related documents:	RFLRDDOC0028 Simple Peer Review Form RFLRDDOC0029 Peer Review Cover Form RFLRDDOC0030 Peer Review Feedback Form
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)
Date equality analysis completed.	21/12/2017
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Version Control

Version	Date	Author	Status	Comment
1	16 OCT 2017	Lucy Parker	Final	New document
1.1	09 May 2018	Rachel Fay	Final	Correction to SOP number on first page
1.2	01 December 2018	Neil Hubbard	Final	Update from ReDA to EDGE Database. Removal or references to SOP Working group and replacing with QMS Working Group. Deletion of Reading log.

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1. INTRODUCTION

All proposed research should be subject to a process of independent scrutiny outside the research team during the development phase. For most research, independent scientific peer review is likely to have been undertaken during the development of the study and therefore will not need to be repeated in order to confirm Sponsorship. This applies to research funded by the Research Councils, major charities (especially members of the Association of Medical Research Councils), National Institute of Health Research (NIHR) and main government agencies, as well as many industry-funded studies, in particular those industry-initiated clinical trials which are adopted onto the NIHR portfolio.

Research which is wholly or largely funded from Royal Free's own funds, studies that form part of a programme grant, investigator-initiated studies funded by industrial partners and studies funded by smaller charities (including those which are considered as 'closed' charities funding research only or mainly at Royal Free) or studies that are unfunded are less likely to have been subject to a robust process of peer review during the development phase and it is this research which this SOP is intended to cover.

If the study is to be put forward for NIHR portfolio adoption, NIHR criteria must be followed. That is, the study **must** have two peer reviews conducted, with both reviewers external to the host organisation.

Please see Appendix One: Peer Review Algorithm, which should give a definitive answer as to whether a particular study requires formal peer review, by the RF R&D Office.

2. OBJECTIVE

The purpose of this SOP (Standard Operating Procedure) is to affirm that all research sponsored by Royal Free London should be subject to a process of peer review prior to sponsorship being granted.

The standards and processes for peer review are set out, and vary according to the expected risks and burdens the research carries for the Sponsor.

3. DEFINITIONS

Peer Review

Peer review is a cornerstone principle of academic research, a means of assessing the quality of research as presented in proposals, presentations or papers.

Proposals and papers are subject to critical evaluation by experts independent of the research, usually appointed by the party to which the work has been submitted (e.g. funding body, journal editors), often taking into account reviewers suggested by the originator. Peer review is increasingly promoted within research organisations as a formal approach for assuring and improving research quality before a proposal is submitted for funding or a paper for publication.

Whilst there are debates on the (cost-) effectiveness, subjectivity and transparency of the peer review process, especially in relation to novel and innovative (including

multi- and transdisciplinary) research, it is generally accepted to be the best available mechanism to assess and affirm the quality of planned research.

Good Clinical Practice

Good Clinical Practice (GCP) is an international quality standard that was agreed by the International Conference on Harmonisation (ICH), an international body that defines standards, which governments have transposed into regulations for clinical trials involving human subjects. The European Clinical Trials Directive (EUCTD) 2001/20/EC was transposed into UK law by The Medicines for Human Use (Clinical Trials) regulations 2004 (SI 2004/1031) on 1st May 2004

Troika

The 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 applies to all research carried out by staff employed by RF in the course of their employment, where research is funded or part-funded through a contract held by RF or funded or part-funded from institutional funds, and where RF is requested to act as Sponsor.

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 (3).

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 and/or Principal Investigator is responsible for identifying the peer review process to be used, factoring this into planning timetables and completing documentation as required, (see Appendix One).

CIs/PIs will be expected not to refuse unreasonably to act as reviewers of others' proposals.

The Theme Lead will review the completed peer review and amended documents and make decisions or recommendations as a result.

Reviewers must allow adequate time to complete the task, seek to be objective, be aware of the limits of their own competence, and complete the agreed form within 2 weeks of the request. Peer reviewers' anonymity will be respected at all times unless they express a preference to be identified (by indicating this on Appendix Two).

The Troika will have oversight of the process and will act as the arbitrator of any final decisions relating to the research following peer review and the Theme Lead's recommendations if required.

7. DETAILS OF THE PROCEDURE

Person Responsible	Task
Chief Investigator (CI)	<p>Liaises with assigned R&D Office Research Portfolio Manager to develop protocol, supporting documents etc. and to complete the ethics application form. This form is known as the IRAS form (Integrated Research Approval System) .The method of peer review will be identified through the IRAS form</p> <p>The CI must check the algorithm to see what peer review process must be used. (see Appendix 1)</p> <p>If the funder will be undertaking the peer review as part of the funding application, and sponsorship in principle is required prior to the funding application being submitted, otherwise, peer review should normally take place as part of the risk assessment prior to sponsorship being issued.</p> <p>If funder-organised peer review is to be used, the CI must complete the cover sheet (RFLRDDOC0029) and include copies of written feedback from peer reviewers where received.</p> <p>Reviewers to be sent the peer review feedback form by the CI and returned to the assigned Research Portfolio Manager</p>

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	(preferably within 2 weeks).
Research Portfolio Manager (RPM)	<p>Will assess the completed peer review forms once received.</p> <p>If the study is fully funded or RFLRDDOC0030 has been completed with a ranking of 'A' (Acceptance), then the RPM does not have to refer the study onto the Theme Lead.</p> <p>If RFLRDDOC0030 has been completed and given a ranking of 'C' (Rejection), then the protocol must be re-designed taking into account recommendations made. The study cannot progress for Sponsorship but must be re-submitted for peer review.</p> <p>If RFLRDDOC0030 has been completed and given a ranking of 'B' (Revision and review), then the CI must revise the documentation in line with the reviews and submit the revised documents to their assigned RPM. The RPM will forward the peer review and the revised documents to the investigator's Theme Lead.</p>
Theme Lead	The investigator's Theme Lead will review feedback when required and the revised documents and recommend whether the trial should proceed.
Troika	If required, will review the peer review forms and recommendations from the peer reviewers and act as the arbitrator of any final decisions relating to the research following peer review and the Theme Lead's recommendations.
Research Portfolio Manager	The assigned Research Portfolio Manager will then record information about the peer review process and outcome in the EDGE study record.

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

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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

RFLRDDOC0029 Peer Review Cover Form

RFLRDDOC0030 Peer Review Feedback Form

11. FLOWCHART

None applicable

Appendix 1: Peer Review Algorithm

Study Type	A	Funding	B	NIHR	C	D	E		
<p>If you answer no to the question in Column A, go to column D</p> <p>If you answer yes to the below – move onto column B</p>	<p>If you answer yes to any of the below – move to column C</p> <p>If you answer no to all of the below, formal peer review through the RF R&D Office is needed.</p>	<p>If you answer yes to any, move to column E</p> <p>If you answer no to all, move to column D</p>			<p>A study that is potentially eligible for NIHR portfolio adoption ^</p>	<p>Funded by a Research Council ^^</p> <p>Funded by NIHR ^^</p> <p>Funded by a main Government Agency ^^</p> <p>Funded in open competition by an industry partner ^^</p>	<p>Study has undergone two independent Peer Reviews.</p> <p>Study is not eligible for NIHR portfolio adoption</p>	<p>Complete RFLRDDOC0029 Peer Review Cover Form and arrange for two independent peer reviews to be completed (RFLRDDOC0030) Available to down load at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops</p> <p>and send to your assigned RPM</p>	<p>Complete RFLRDDOC0029 Peer Review Cover Form. Available to down load at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops</p> <p>and send to your assigned RPM with evidence.</p>
<p>Notes</p> <p>^ A study is potentially eligible for NIHR Portfolio adoption if it is fully funded (from awarded funding)</p>									
<p>^^ The funds must be awarded to the specific study i.e. not awarded as part of a programme grant.</p>									

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APPENDIX 2

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APPENDIX 3

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	Peer Review
Briefly describe its aims and objectives:	SOP describes when Peer review is needed and the process
Directorate and Lead:	Rachel Fay, R&D Manger, 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?	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

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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).

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	
Race	None identified	R&D administrative	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
		document			
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
QMS 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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