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Version Control

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1. INTRODUCTION

The National Institute for Health Research (NIHR) commissions and funds NHS, social care and public health research that is essential for developing research evidence to support decision making by professionals, policy makers and patients, making this evidence available, and encouraging its uptake and use which provides clinical and non-clinical evidence and best practice, to make informed decisions. The NIHR's key objective is to improve the quality, relevance, and focus of research in the NHS and social care by distributing funds in a transparent way after open competition and peer review.

The National Institute for Health Research Clinical Research Network (NIHR CRN) Portfolio is a database of high-quality clinical research studies that are eligible for support from the NIHR Clinical Research Network in England. In order to be considered for NIHR Clinical Research Network (CRN) support a research study must be identified as being 'Eligible'. In England, the Department of Health has established the eligibility criteria for CRN support. The CRN Portfolio team assesses eligibility for CRN support on behalf of the Department of Health (in England). Studies that are eligible for consideration for CRN support are included in the NIHR CRN Portfolio.

Applications to be considered for CRN support are made through the NIHR Coordinated System for gaining NHS Permission via the Integrated Research Application System (IRAS).

Studies that are eligible must be fully funded through a grant that was awarded in open competition. For further information on eligibility, please see www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support

although as the eligibility criteria may be amended from time to time and the Portfolio Adoption Form (PAF) must now be submitted prior to HRA/REC submission, Investigators are encouraged to apply for adoption. NB. You cannot apply for adoption after you have received your HRA initial assessment.

All studies applying for RF Sponsorship must consider portfolio adoption.

2. OBJECTIVE

This SOP describes the procedures to be followed by all RF staff if a study is potentially eligible for NIHR portfolio adoption. NIHR adoption is a key component of RF R&D accepting a Sponsorship request. All RF Sponsored studies must be submitted for portfolio adoption if potentially or eligible for adoption.

3. DEFINITIONS

Clinical Research Network (CRN) There are 15 Local Clinical Research Networks (CRN) that cover the whole of England. Each local CRN delivers research across 30 clinical specialties including cancer, cardiovascular disease and children, for example. Typically, Local Research Network teams comprise a clinical director and senior manager who oversee a range of research support staff including nursing and

other health professions, life-sciences backgrounds, RM&G, data managers and administrative staff. The Local CRN for RF is North Thames.

CRN Portfolio This is a database of clinical research studies taking place in the NHS that are funded by the life sciences industry, charities, central and overseas governments, and commercial collaborating bodies. All studies funded by the NIHR, and some studies that meet certain criteria, will be eligible for adoption onto the Portfolio, and thus eligible for free support from the CRN. 'Support' may be in the form of network funded staff to facilitate identification and consenting of participants. Should a study potentially fulfil portfolio adoption, the Network Study support service may assist in completion of the HRA Schedule of Events by attribution of costs to study activities in line with ACoRD guidelines.

Regulatory Checks The Health Research Authority (HRA) was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research. HRA Approval is the new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments' Research Ethics Service. The HRA has taken over the responsibility for ensuring that each new study complies with all applicable regulatory requirements in England. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study (www.hra.nhs.uk).

In question A68 on the Integrated Research Application System (IRAS) form, the Investigator states which will be the lead NHS Trust site for the study. This question obviously determines which R&D office will lead the study and which Local CRN will be involved if the study is eligible or applying for Network Support, whether commercially sponsored or not. That CRN will offer support services to help study feasibility, set up and delivery to time and target www.nihr.ac.uk/funding-and-support/study-support-service/study-support-service-contacts e.g. completion of the Schedule of Events –attribution of associated costs in accordance with the ACoRD guidelines.

RF Royal Free London NHS Foundation Trust

UK Central Portfolio Management System (CPMS) This database has replaced the UKCRN Portfolio database, which used to comprise the four CRN portfolios from England, Northern Ireland, Scotland and Wales. It is open to public search on the Clinical Trials Gateway website on www.ukctg.nihr.ac.uk

4. SCOPE

This SOP outlines the role of the RF R&D Office in the review process for all RF sponsored regulated research that is to be considered for adoption onto the NIHR CRN Portfolio. The SOP will also outline the submission procedure for the

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Investigator when a research project is potentially eligible for adoption onto the Portfolio.

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 is to be followed by the RF R&D Office

It is the responsibility of the R&D Manager to ensure that the SOP is updated and audited where necessary.

It is the responsibility of the Chief Investigator (CI) or local Principal Investigator (PI) to ensure that the completed documentation is submitted through the Integrated Research Application System and to respond to subsequent requests from the CRN, HRA, REC, and/or the RF RD& Office and follow the procedure listed in Section 7 of this SOP.

It is the responsibility of the assigned Research Portfolio Manager to ensure review of all relevant documents in accordance with this SOP prior to Sponsorship being issued.

7. PROCEDURE

Person Responsible	Task
CI	7.1 Investigator Procedure

	<p>If it is ascertained (either from consultation with personnel from the NIHR, the IRAS website, the HRA website, the local CRN or the RF R&D Office) that a study may be potentially eligible for NIHR adoption, the CI or delegated research team member, should answer yes to the following question in the IRAS Project Filter questions:</p> <p><i>5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio?</i> The CI and/or delegated research team member will need to complete the NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) and submit the form through IRAS before the IRAS form is submitted.</p> <p>The CI and/or delegated research team member will then need to follow the Sponsorship process (Applying for Royal Free Sponsorship SOP029)</p> <p>The CI and/or delegated research team member should respond to requests from the NIHR Portfolio team if further information regarding the funding for the study is required. This normally entails providing the grant award letter to the CRN.</p> <p>The CI should also ensure that appropriate peer review for the study has been undertaken (SOP055)</p>
<p>Research Portfolio Manager</p>	<p>7.2 RF R&D Office Procedure</p> <p>On receipt of a new study application for Sponsorship, it is the Research Portfolio Manager's responsibility to review the application in order to ascertain whether the study may be eligible for NIHR CRN Portfolio adoption.</p> <p>The assigned Research Portfolio Manager will review the financial section of the IRAS form. Eligibility criteria for the NIHR CRN Portfolio can be found on the NIHR website : www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support</p> <p>Studies fall into three categories: automatically eligible, potentially eligible and not eligible. If it is deemed by the Research Portfolio Manager that the study is eligible or potentially eligible for NIHR CRN Portfolio Adoption, they will advise the CI or delegated research team member to submit the NIHR CRN Portfolio Application Form through IRAS.</p> <p>The assigned Research Portfolio Manager will then advise the CI and/or delegated research team member to complete the Sponsorship process (Applying for Royal Free Sponsorship SOP029)</p>

	<p>The CI, as stated in the IRAS form and as agreed with RF R&D Office and the Sponsor’s Representative will receive notification from the NIHR Portfolio team regarding the eligibility of the study. On receipt of notification from the NIHR portfolio team that the study is not eligible the CI will need to go back into IRAS and unselect yes on the project filter question 5b. The CI should discuss the financial feasibility of the study with their assigned Research Portfolio Manager.</p> <p>On receipt of notification from the NIHR Portfolio team that a study is potentially eligible for NIHR Portfolio adoption, the Research Portfolio Manager should advise the CI and/or delegated research team member to submit the HRA/REC submission through IRAS once ready.</p> <p>The Research Portfolio Manager must request a PDF copy of the PAF that was submitted through IRAS from the CI and retain within the study e-folder.</p> <p>Upon submission of the project through IRAS, notification will be received from the NIHR Portfolio team to the CI as well as the Sponsor’s representative as stated on the IRAS form. The notification will confirm NIHR Portfolio adoption for the study, which is proceeding through HRA, or will advise that the study cannot be adopted. The Portfolio Adoption team may also require further information within a given timeline and it is very important to make sure that the timeline is met.</p>
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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 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 RM&G 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	Applying for NIHR Adoption
Briefly describe its aims and objectives:	This SOP describes the procedures to be followed by all RF staff if a study is potentially eligible for NIHR portfolio adoption
Directorate and Lead:	Rachel Fay, R&D Manager
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 X 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	N/A	N/A	This SOP on applying for NIHR adoption 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.
Disability	None identified	R&D administrative document	N/A	N/A	
Gender Reassignment	None identified	R&D administrative document	N/A	N/A	
Marriage and Civil Partnership	None identified	R&D administrative document	N/A	N/A	
Pregnancy and maternity	None identified	R&D administrative document	N/A	N/A	
Race	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
Religion or Belief	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.
Sex	None identified	R&D administrative document	N/A	N/A	
Sexual Orientation	None identified	R&D administrative document	N/A	N/A	
Carers	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
SOP Working Group	Royal Free London NHS Foundation Trust	20/10/2017
R&D Committee	Royal Free London NHS Foundation Trust	30/11/2017