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<i>Standards and legislation</i>	amendments. UK Policy Framework for Health and Social Care Research (2017)
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Version Control

Version	Date	Author	Status	Comment
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1. INTRODUCTION

This SOP is a comprehensive document which sets out the roles, responsibilities and procedures to be followed by all research staff involved in the Royal Free London NHS Foundation Trust's (RFL) sponsorship pathway.

The document will underline the steps that need to be undertaken by all investigators and researchers who wish to develop their proposals to obtain RFL Sponsorship en route to HRA and Ethics Committee submissions, for research studies that fall under the remit of the Department of Health's UK Policy Framework for Health and Social Care Research (2017). In addition this SOP will act as a reference point and policy document for R&D staff that assess research proposals and carry out sponsorship reviews on behalf of the trust.

This document has been published along with complimentary guidance tools, appendices and templates which will facilitate all stakeholders to complete their relevant tasks during the sponsorship process.

The Health Research Authority (HRA) sets out guidance on the expectations of Sponsors. This includes that Sponsors should satisfy themselves that the trial meets the relevant standards and that arrangements are put and kept in place for management; appropriate peer review; all supporting information is supplied to the regulators for their consideration; defined roles and responsibilities for the duration of the trial; monitoring and audit; a risk assessment processes; public and participant involvement in the trial; ensuring the training and suitability of the research team; public registration of the trial; dissemination of the results; project oversight; guidance for academic supervisors and providing on-going quality assurance

At the outset it is important to highlight, the Trust does not sponsor high risk studies (e.g. CTIMP's), studies for which adequate resources and risk management structures are not in place to satisfy safety or regulatory requirements (see 'Risk Management' section for more details). In instances where a submitted proposal is deemed to be a high risk study, the RFL R&D office will advise the researcher on alternative routes for sponsorship.

Further details about how the definition and categorisation of risk has been derived, along with the details of complimentary guidance tools and key definitions can be found in sections further down and within associated documents which are linked to this SOP. There is a step by step explanation of the sponsorship pathway and process in the 'Procedure' section later on, however all research staff are required to read this document in its entirety.

In addition researchers are reminded that all projects sponsored by the trust would also need to go for review at the Trials Feasibility Committee (TFC) before 'Confirmation of Capacity and Capability' is issued for the study to open. The purpose of the TFC is to ensure that a study can be delivered safely and to time and target. In light of this all researchers are strongly advised to familiarise themselves with the SOP related to the TFC as well ensuring early engagement with the key stakeholders which will minimise any barriers to their study opening.

2. OBJECTIVE

In 2017 the RFL Trust Board ratified and published its inaugural R&D strategy. Amongst other key objectives, the strategy commits the trust to substantially growing its NIHR portfolio research activity with the aspiration of breaking into the top ten NHS trusts for recruitment into portfolio studies by 2020. NIHR adoption for a trial is

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normally an indicator that a study has had appropriate scientific peer review, offers value to the NHS, and is adequately funded. In addition, NIHR adoption carries with it national recognition and opportunities for the researcher to access additional delivery support as well as reputational and potential financial benefits for the host institution. These benefits are designed to incentivise the research community to seek NIHR adoption for studies where possible, it's also one of the cornerstones in the Trust's research strategy; as such it will be at the forefront of R&D policy for sponsorship of studies.

All research studies that are submitted to the R&D office for sponsorship consideration will undergo rigorous review to ensure that the proposal meets the criteria for high quality research. In practice this means that all avenues will need to be exhausted by the researcher, with help from the R&D office where possible, in an effort to identify and secure appropriate funding, and by extension NIHR adoption, before RFL sponsorship is confirmed for a study.

If funding and NIHR adoption is not secured, the investigator or researcher would need to provide a compelling reason(s) for study sponsorship to continue and evidence of independent peer review. Further review and approval may be needed from the relevant clinical R&D theme director for the sponsorship review process to continue. As a final step, the R&D Contracts & Costs Manager will perform a costing review of the full research proposal using the HRA Schedule of Events template after which the investigator needs to provide evidence of how all the research costs or costs above routine clinical practice that have been identified will be met (e.g. letter from relevant clinical division or service support department confirming costs will be absorbed internally etc.). If a study is to be funded directly from an Investigator(s) account, then the Investigator(s) will need to confirm in writing to Research and Development their acknowledgement that the cost of the study (including all amendments) will be derived from their own account(s).

Further details about funding, the process of costing research proposals and the timelines associated with this, including grant applications can be found SOP049 'Assessing costs of RFL research studies'.

3. DEFINITIONS

RFL/Trust - Royal Free London Hospital NHS Foundation Trust

Research/Study/Trial/Proposal – As per the definition of the Health Research Authority, 'research' means "the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods". Throughout this document the terms 'research', 'study', 'clinical health research study', 'trial' and 'proposal' will be used interchangeably to denote those projects and endeavours which fall under the remit of the UK Policy Framework for Health and Social Care Research (2017) and require review by RFL R&D.

GCP – Good Clinical Practice is an international ethical and scientific quality 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.

UK Policy Framework for Health and Social Care Research (2017) – National standard and framework for Health and Social Care research in England, outlines the principles of good governance that applies to all research undertaken

NIHR – National Institute for Health Research; a Department of Health body which funds and supports research across the UK

NIHR CRN Adoption – National accreditation and confirmation that a clinical health research study has been adopted onto the NIHR Clinical Research Network Portfolio. Detailed eligibility criteria for NIHR adoption can be found on the NIHR website (link), but in summary, the key determining factor for eligibility is securing independent funding through a competitive process

HRA – Health Research Authority; an executive non-departmental public body of the Department of Health in the United Kingdom. The HRA oversees ethics committees and provides a unified system for governance of health research

HRA Approval – A centralised national approval for a clinical health research study

EC Approval – Ethics committee approval for a clinical health research study

Confirmation of Capacity & Capability (C&C) – An assurance issued in writing by a local institution which confirms that the study is feasible to run within the organisation. C&C will be issued once sponsorship is confirmed and the researcher has obtained HRA/EC approval, thereafter the study may be activated at the local institution

R&D - Research & Development

RM&G - Research Management & Governance

TFC – Trials Feasibility Committee; all interventional/complex studies require review and approval by the RFL TFC before the study can open at site. The role of the TFC is to ensure that the study can be delivered safely and to time and target. Low risk and simple studies are exempted from formal TFC review and are usually issued with a TFC waiver at the discretion of the TFC chair and Lead Research Nurse for the R&D theme

Sponsor - Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and/or finance a clinical health research study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.

Funder – Organisation/or institution that provides funding to cover the costs/or some of the costs for a clinical health research studies. The sponsor and funder can be the same institution, but in many instances are separate entities

CI - Chief Investigator (CI) is the authorised health care professional who takes primary responsibility for the conduct of the trial in the UK. There can only be one CI within the nation where the study is conducted There is only one Chief Investigator per Member State.

PI – Principal Investigator (PI) is the authorised health care professional who takes primary responsibility for the conduct of a trial within a specific research site. There should only be one PI per research site, but the PI maybe supported by Co-Investigators within the institution. The CI will act as the PI for their local institution where the study is conducted; they can also delegate the role of PI to another individual within the organisation

IRAS - The Integrated Research Application System (IRAS) is a single on-line system for applying for the permissions and approvals for health and social care / community care research in the UK. At the conclusion of sponsorship review, the researcher/CI will make a submission to the HRA and EC through the IRAS system. The online system can be accessed via www.myresearchproject.org.uk

Troika – An independent panel composed of the R&D Director, Research Clinical Director and Vice-Dean of the UCL Medical School

4. SCOPE

As per the definition of the HRA, ‘research’ means “the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods”. Throughout this document the terms ‘research’, ‘study’, ‘clinical health research study’, ‘trial’ and ‘proposal’ will be used interchangeably to denote those projects and endeavours which fall under the remit of the UK Policy Framework for Health and Social Care Research (2017) and require review by RFL R&D. If a proposal is submitted to the R&D office and it is deemed to be a Clinical Audit or Service Evaluation, R&D staff will re-direct the researcher to the RFL Clinical Audit & Effectiveness Team.

Student studies and studies which are undertaken as part of a researchers’ educational program (MSc etc.) will be exempt from these measures, but opportunities for NIHR adoption may still be pursued in these cases (e.g. where a student’s research project is funded by an overseas government, it would potentially qualify for NIHR adoption). In the first instance, the expectation is for the researchers’ academic institution to sponsor their project, but if this is not possible then RFL will consider sponsorship for these educational projects on a study by study basis.

To be eligible to request sponsorship from RFL, the chief investigator should hold a substantive or honorary contract (for clinical academic with clinics at RFL) with RFL. If RFL is the only research site, the PI and CI will be the same person

Flexibility can also be shown when there are valid reasons for not pursuing funding options or NIHR adoption, e.g. pilot studies, research conducted by service support departments (Pharmacy, Imaging etc.). The R&D office will take a pragmatic approach based on the merits of the proposal in such instances. However, for RFL to take on sponsorship the study funding will need to be awarded/held and managed by RFL. R&D will request a copy of the funding award letter and cost centre if applicable.

RFL will not consider entering into co-sponsorship arrangements for any research projects; it will only support proposals for sole sponsorship. This also applies to any academics – based in RFL – who seek sponsorship through the RFL R&D office, for such projects RFL will not accept any co-sponsorship arrangements with their academic institution. There may be instances where projects, which are going through early development under academic sponsorship, will be conducted primarily at RFL (lead site), in such instances the onus is on the researcher to ensure early engagement with the RFL R&D office to ensure that all NHS/RFL site costs are captured correctly. Failure to do so may result in the study being rejected at the RFL TFC.

There may be occasions where the sponsor for a research study is based outside the UK/EU, in such instances RFL will consider taking on the role of ‘Legal Representative’ on a study by study basis. Requests for legal representative will need

to be made to the R&D manager and if agreed RFL will enter into an agreement with the third party.

As stated earlier, if a proposal is submitted to the R&D office and it is deemed to be a Clinical Audit or Service Evaluation, R&D staff will re-direct the researcher to the RFL Clinical Audit & Effectiveness Team.

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.

7. RISK MANAGEMENT

R&D staff and researchers should refer to the 'Risk Matrix' for a detailed guide on risk factors and to assess the risk categorisation for a proposed study. Please note that the appendix is an extensive but not exhaustive list, all risk assessments will be carried out on the merits of a research proposal, on a study by study basis and the principles around risk management as described below will be applied to all proposals.

There are numerous ways to rationalise and categorise risk within clinical research, for the purpose of this SOP and as R&D policy, risk has been defined in the following way:

Risks are those factors arising from the conduct of research, which if left unmanaged or insufficiently managed, can potentially lead to one, more than one or all of the following breaches:

1. Harm caused to the patient/or participant
2. Breach of research governance regulations/NHS/Trust/R&D policies

3. Diminished integrity of research data
4. Damage to institutional reputation

In broad terms, these risk factors can arise from four overlapping areas within the conduct of research:

- a. Interventions, study procedures and assessments (e.g. device study/CT or efficacy scans etc.)
- b. Study design and management (e.g. Multicentre trial, randomisation/blinding, central data management etc.)
- c. Patient safety (e.g. Medical exposure, ionising radiation etc.)
- d. Study delivery (e.g. Suitability and experience of research team/CI/PI, resources for PI or sponsor oversight etc.)

For each risk or potential hazard, the sponsor will consider the following:

- a) The associated risks to the particular trial
- b) The potential consequences of each hazard occurring

Reasonable steps must be taken to reduce the risks by:

- 1) Reducing the probability of the hazard occurring
- 2) Minimising its adverse consequences.

The sponsor has the responsibility for the initiation and management of a clinical research study, as such it is the responsibility of the sponsor to ensure that there are adequate risk management measures in place complimented with the resources and infrastructure to manage and mitigate all risks that are identified within a clinical research study. This is the key consideration for the Trust before it makes a final decision to act as sponsor for a study. Based on the above definitions and considerations the following risk categories have been established:

Low Risk: Risk presented by this category of studies is less than or equivalent to those observed in standard and routine clinical practice. Adequate resources and structures already in place at RFL, to comfortably manage and mitigate the risks which would arise from the conduct of such a study. In principle RFL can sponsor low risk studies; e.g. Questionnaire study, tissue collection study etc.

Medium Risk: Risk presented by this category of studies is equivalent to or above those observed in standard and routine clinical practice. Adequate resources and structures already in place/or additional measures will be needed at RFL, to manage and mitigate the risks which would arise from the conduct of such a study. In principle RFL can sponsor medium risk studies; e.g. Basic science study with assessments and procedures, Randomised surgical study etc.

High Risk: Risk presented by this category of studies is above those observed in standard and routine clinical practice. RFL does not have the adequate resources and structures in place to manage or mitigate these risks, conducting such studies

will inevitably lead to one of the four (1-4) breaches as highlighted above. RFL cannot sponsor high risk studies; e.g. CTIMP's, ATIMP's, First in man studies, Device studies without CE marking etc.

The R&D office will closely review studies which involve CE-marked devices, surgical interventions, research involving vulnerable patient groups and research which utilises the collection and transfer of tissue samples to third parties (UCL Biobank etc.).

After an upfront review of a study proposal, if it is deemed to be high risk, R&D staff will notify the researcher of this decision and will advise them on alternate routes for seeking sponsorship (UCL CCTU etc). If a researcher is not happy with the initial risk assessment, they can appeal in writing to the R&D Manager. If the researcher is not happy with the decision taken by the R&D manager then they have the option of appealing to the RFL troika, please see the escalation SOP for more details. For all other studies (Low/Medium risk) the sponsorship process will continue as described in the next section.

Researchers are reminded that they cannot submit their studies to the REC and HRA before sponsorship sign off which is documented on the IRAS form.

8. PROCEDURE

In summary the following three chronological steps need to be completed for a research proposal before it can open to recruitment:

1. Sponsorship review & sign off
2. HRA & EC submission & approvals (NIHR CRN Submission if applicable)
3. Confirmation of Capacity & Capability (Site Activation)

The R&D office will aim to complete an initial review of a proposal within 7 days of a full submission. Researchers should note that as a minimum a full submission encompasses a research proposal, draft IRAS form, and a Patient Information Sheet (if applicable). It is anticipated that a minimum of 30 days will be required for Sponsorship review and sign off, for complex studies it may take longer. HRA and EC reviews can also take up to 60 days once a submission is made to them, again this will vary and may take longer if the HRA and EC request changes to be made and provide provisional opinion respectively. Once HRA, EC, and TFC approval are in place (see step 15 below regarding TFC), the R&D office will issue a 'site activation' and 'confirmation of capacity & capability' e-mail within 5 days. Researchers are encouraged to keep these timelines in mind when planning their proposals and ensuring they get in touch with the R&D office well in advance of any deadlines that might be stipulated for their projects. There is no guarantee that the R&D office can turnaround reviews at short notice so early engagement with our team is crucial.

These three milestones have been broken down into detailed steps and tasks in the process table below, the table also underlines the responsible individual for a given step/task ('Who').

Process Table

Roles:

CI – Chief Investigator

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RPM – R&D Portfolio Manager

CM – Costing Manager

RDM – R&D Manager

RDD – R&D Directors

R&D Office – General R&D Office

	Who	Activity	Comment
1	CI	<p>First Contact – The CI/Researcher should get in touch with the R&D office at the earliest possible opportunity to discuss their research proposal or any potential grant applications which they are interested in. They can drop into the R&D office to speak to one of the coordinators or RPM's, alternatively they can submit their draft proposal and request for Sponsorship review via e-mail to rf.randd@nhs.net</p> <p>If a study is deemed to be a Service Evaluation or Clinical Audit, the R&D team will re-direct the researcher to the RFL Clinical Audit and Effectiveness Team</p>	<p>Please note we advise at least 4 weeks' notice for reviewing and signing off on grant applications before submission to the funder. RFL R&D need to perform a risk assessment and costing review before agreeing to Sponsorship in principle, so there is no guarantee that the R&D office will sign off on any funding applications which are submitted at short notice</p>
2	RPM	<p>Initial Review – A dedicated RPM will perform an initial risk assessment on the CI/researcher's proposal and clarify any queries they have. Ensure that a suitable CI has been identified for the study and, for interventional studies, identify a suitable deputy PI for clinical management in the absence of the CI. Thereafter the RPM will confirm whether or not RFL can in principle Sponsor the proposed study; this would be a provisional decision pending comprehensive Sponsorship review and risk assessment before final sign off.</p> <p>If a study is deemed to be a Service Evaluation or Clinical Audit, the R&D team will re-direct the researcher to the RFL Clinical Audit and Effectiveness Team</p>	<p>If study is high risk, the R&D office will advise on alternate routes for Sponsorship.</p> <p>Where a study proposal is rejected; please see escalation SOP for more details</p>
3	CI CM RPM	<p>Start of formal review – The first step of the formal Sponsorship review will primarily look at three areas:</p> <ol style="list-style-type: none"> 1. Developing a research protocol/identifying costs/identifying the research team (CI/PI) 2. Funding opportunities 3. NIHR Adoption 	

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		<p>If the CI/Researcher have already identified a funding stream or grant, please see step 7</p> <p>If no funding has been identified to begin with, see step 6</p> <p>It may be necessary at this stage to hold an initial meeting with the CI is to discuss all the support functions, governance issues, potential study costs</p>	
4	CI	<p>Write the protocol using the sponsor approved template</p> <p>The CI must write a protocol using the current version of the RFL R&D Protocol Template. This is available on our website or from the RPM. Special attention should be given to ensuring that no template wording or guidance remains in the submitted protocol, and that it is consistent, accurate and proof read before it is submitted to R&D. All protocol writing guidance must be taken into consideration. R&D is not responsible for the scientific development of the protocol but will ensure it is compliant with GCP, REC, HRA and other regulatory requirements and guidance. If R&D receives a protocol that is not on the R&D's approved template they will ask the CI to transfer to the approved template to ensure it complies with all R&D SOPs.</p>	
5	CI CM RPM	<p>Categorising the study as a non-CTIMP</p> <p>If there is any ambiguity as to whether a trial is a CTIMP or a non-CTIMP, the CI must discuss this with the RPM. The CI should consider if the trial uses any of the following: drugs; vitamins; nutritional supplements; food supplement; devices that deliver drugs e.g. stents; probiotics; or imaging tracers OR patients who were previously on an advanced therapy trial (ATMP). Please refer to the MHRA website for guidance on determining a CTIMP/ATMP. If it is still unclear R&D will send a scoping query to the MHRA by sending a copy of the protocol to the MHRA clinical trials helpline, retaining documented evidence to support the MHRA's decision (i.e. the email from the MHRA and version of the protocol sent). It may be necessary to confirm the status of the trial with the MHRA at the grant stage to ensure that sufficient funds are secured to support a successful CTIMP. The MHRA's opinion as to whether a trial is a CTIMP is final. If the MHRA's opinion is unforeseen</p>	

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		<p>it is the CI's responsibility to comply with the applicable regulations of a CTIMP classification or to revise the protocol or grant proposal so that it is no longer classified as a CTIMP. The R&D, as Sponsor, reserves the right to re/submit a funding proposal or protocols for scoping review with the MHRA, including following revisions to the proposal or amendments to the protocol</p>	
<p>6</p>	<p>CI CM RPM</p>	<p>Assessing Costs - The CI/Researcher will be asked to complete and submit a research protocol using the appropriate RFL protocol template.</p> <p>The CI is responsible for ensuring that CTIMPs are accurately and realistically costed in the formative stages to ensure that it has adequate funding to be deliverable, successful and compliant. It is the CI's responsibility to ensure that a study is adequately resourced. R&D cannot guarantee the approval of any Sponsorship application for studies that are considered to have insufficient funds to support the trial design or its management. The R&D office may ask the CI to seek further funding or to reduce the scope of the trial design to meet the secured budget. Contacting R&D at the early stage can prevent unnecessary delays in the set-up process.</p> <p>Before agreeing to any milestones with funders, the CI should discuss their feasibility with the RPM. This is to avoid agreeing to milestones such as deadlines for REC approval, first patient recruited or for reporting results that may not be realistic or take into consideration the regulatory and site approval timelines or protocol design.</p> <p>They will also work with the Costing Manager to populate the 'HRA Schedule of Events' document. Both of these documents will allow the Costing Manager to identify and assess the overall cost attached to running the study.</p> <p>The R&D office will strongly advise the CI/Researcher, and support them where possible, to find a funding stream which will allow for costs to be met and allow the project to be considered for NIHR adoption. If funding is identified, go to step 5.</p> <p>If funding isn't forthcoming after all options have been exhausted, the R&D office will then ask the CI/Researcher to provide evidence of independent scientific peer review for their proposal as well as providing evidence of how any costs will be absorbed internally. The R&D office will defer the proposal to the troika for a final decision on whether the Sponsorship review should continue.</p>	

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		<p>The CI/Researcher will also have the opportunity to provide justification for why their proposal should be exempted from this rigorous process.</p> <p>If approval is issued, please go to step 9</p>	
7	CI CM RPM RDD	<p>Assessing Costs (cont.) - Where a funding stream or appropriate grant has been identified; the CI/Researcher will be asked to complete and submit a research proposal (if not done so already). They will also work with the Costing Manager to populate the 'HRA Schedule of Events' document. Both of these documents will allow the Costing Manager to identify and assess the overall cost attached to running the study. The finalised costs will then be appended to the bid which is submitted to the funder. If the funding application is successful, the Costing Manager will work with the funder to formalise a funding agreement which will be signed off by the RFL R&D Director once ready</p>	See Costing SOP
8	CI	<p>NIHR CRN Adoption Submission – If the study is eligible for NIHR Adoption (secured funding/decision pending); the RPM will advise the CI to complete and submit the Portfolio Application Form (PAF) which can be found on the IRAS online system (see IRAS guidance document).</p>	<p>Not applicable to studies which have no funding and are not eligible for NIHR adoption. Where a study is submitted and adoption is rejected, further R&D review required to see if study Sponsorship can continue</p>
9	CI	<p>Feasibility – multisite RFL sponsored studies</p> <p>See 026 SOP Site Selection and Initiation for RF Sponsored Studies for guidance on site and PI selection</p>	
10	CI RPM	<p>Finalising Sponsorship Review - Whether internal funding/other arrangements have been made (as per step 6) or the decision is still pending on the grant application or the grant has been secured from the funder (as per step 7), the RPM will continue to work closely with the CI/Researcher to further the Sponsorship review process. The RPM will liaise with the CI/Researcher to finalise the following:</p> <ul style="list-style-type: none"> - Research Protocol (using appropriate RFL Template) - IRAS form 	<p>CI/Researchers are advised to read the IRAS guidance document for help in completing the IRAS form and other study documents</p>

		<ul style="list-style-type: none"> - Patient Information Sheet and Consent Form (using RFL Template) - Any other required documentation for ethics eg GP letter, patient diaries - Risk Assessment Form (Risk Matrix) - Assessment that the study complies with the regulatory requirements, according to the study type, including but not limited to the Human Tissue Act, The Data Protection Act (1998) and subsequent amendments, the mental capacity act (2005) and IRMER (2000). - Ensure that the study is a regulated study i.e. a CTIMP, ATMP, non-CE marked device. Where there is doubt R&D will send the study to the MHRA for scoping. - HRA Schedule of Events (this would be complete already from step 6 & 7) - HRA Statement of Activities (if there are other research sites) - Provide signed and dated CV for CI - Provide evidence of GCP training for CI - Adequate independent peer review (see SOP 055 –Peer Review for further guidance) <p>These documents will be reviewed to ensure they meet all governance requirements before a submission to the HRA/REC can be made.</p> <p>For studies not requiring REC review:</p> <ul style="list-style-type: none"> • Investigators should submit the protocol, IRAS and associated documents as part of the valid sponsorship submission and follow the same process as above, but not submit the IRAS form to REC <p>Investigators should submit the IRAS form with all supporting documents to the HRA.</p>	
11	CI	<p>Service Support Requirements - During the course of the Sponsorship review and depending on the nature of the study, early engagement may be needed with the relevant research nursing/delivery team and service support departments (Radiology, Nuclear Medicine, Labs etc.). This would be the case in particular for studies which will have a high volume of patients as well as complex non-routine study procedures; in such instances early support and agreement with collaborative partners is needed to ensure that the study can recruit to time and target. The RPM will facilitate these discussions between the CI and</p>	<p>Note: Where there are support implications for service departments (Radiology etc) and delivery support (nursing/data management), any associated costs would need to be considered at an early stage particularly for the grant/funding</p>

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		support departments as is appropriate, but ultimately it is the responsibility of the CI to secure agreement for support. Studies involving ionising radiation will need a local IRMER review and sign off (on the IRAS form), the RPM will refer the CI onto the Research Imaging Coordinator who will work with the CI and imaging guardians for IRMER sign off.	application as per step 7
12	RDM	QA Check - Once all the study documents have been finalised and funding arrangements have been confirmed the R&D Manager will perform a final QA check	
13	CI RPM RDM RDD	Confirming Sponsorship - Upon completion of the QA check, the following documents will be signed off: <ul style="list-style-type: none"> - Conditions of Sponsorship & CI Agreement - IRAS Form <p>At this point, Sponsorship is officially confirmed for the study</p>	
14	CI	HRA & EC Submission - The CI/Researcher can now submit their IRAS form and study documents to the HRA and REC. This submission is made via the IRAS online system, the HRA will review the study remotely but the CI will need to schedule an REC review meeting. Details for booking REC meeting can be found on the IRAS online system: <p>www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-central-booking-service-cbs/)</p>	
15	CI	TFC Review/Approval - Whilst HRA and REC approvals are pending, the R&D office will advise the CI to take the study to the relevant RFL Trials Feasibility Committee (TFC). <p>The role of the TFC is not to assess the scientific value, Sponsorship aspects or merits of the study. Rather the TFC's role is to ensure that a study can be delivered safely and to time and target. If the study in question is deemed to be a low risk trial, then a TFC waiver will be issued by the R&D office.</p>	For interventional/medium risk studies; TFC review is essential. TFC approval would be easier to obtain if the CI ensures there is early engagement with support teams and departments as per step 11. See TFC SOP
16	R&D Office	Site/Study Activation – Once the CI has obtained HRA/REC approvals, funding arrangements are confirmed, NIHR CRN Adoption is confirmed (if applicable) and TFC approval is in place; all	See C&C SOP See SOP 026 Site Selection and initiation

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		contracts including SLA fully-executed (see SOP 014 Contract Negotiation and Review), the R&D office will issue a formal confirmation of C&C e-mail to the CI. This will in effect act as the local green light for the study to commence locally; if the study is multi-centre it will be the responsibility of the CI to ensure that the study is setup appropriately at other sites	of RFL sponsored studies to activate sites
17	CI R&D Office	<p>Post Activation – As per the Sponsorship agreements the CI will take responsibility for study activities including submission/notification of amendments, EDGE uploads, annual progress reporting, safety reporting and all other relevant reporting/notifications during the course of the study. The R&D office will also fulfil its responsibilities as highlighted in the conditions of Sponsorship agreement.</p> <p>The escalation SOP and policies highlighted in the escalation section of this SOP will be applicable throughout the duration of the study.</p>	
18	CI R&D Office	End of Study – Please see end of study and archiving SOP's	

9. POLICY

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

10. 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 Department 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.

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- The Research and Development Directorate is responsible for the ratification of this procedure.

11. FORMS/TEMPLATES TO BE USED

SOP 006 Roles and Responsibilities for the Conduct of Research Studies

SOP 019 Investigator site file

SOP 022 Case Report Forms Design for RFL sponsored studies

SOP 025 sponsor files

SOP 042 Research data management for RFL sponsored studies

SOP 048 Submitting Clinical Research Studies for Review at a TFC

SOP 049 Assessing costs of RFL research studies

SOP055 Peer Review

RFLRDDOCO42 – Risk Matrix

Research Protocol RFL Template

IRAS form

Risk Assessment Form (Risk Matrix)

HRA Schedule of Events (this would be complete already from step 4 & 5)

HRA Statement of Activities (if there are other research sites)

RFL IRAS Guidance Document for Researchers

12. FLOWCHART

N/A

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				
Briefly describe its aims and objectives:				
Directorate and Lead:				
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback				
Is the Trust Equality Statement present?	<table border="0"> <tr> <td style="text-align: center;">Yes</td> <td style="text-align: center;">No</td> <td style="text-align: center;">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					
Disability					
Gender Reassignment					
Marriage and Civil Partnership					
Pregnancy and maternity					
Race					
Religion or Belief					

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
Sex					
Sexual Orientation					
Carers					

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