

## Document Title: Transferring Sponsorship

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<b><u>This is a controlled document</u></b>	
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**Version Control**

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## 1. INTRODUCTION

A Sponsor takes responsibility for the initiation, management and/or financing (EU Directive 2001/20/EC) of research and clinical trials. It is a legal requirement that all Clinical Trials of Investigational Products (CTIMPs) have a Sponsor that is willing and able to take on the responsibilities and liabilities under the Medicines for Human Use (Clinical Trial) Regulations 2004 SI 1031 and subsequent amendments (The Regulations)

The UK Policy Framework for Health and Social Care (2017) sets out the principles and requirements of good governance for all research within the remit of the Secretary of State. According to the policy, all research should have a Sponsor. The Sponsor is defined as an 'the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project'

The Sponsor is usually the company, institution or organisation that is taking responsibility for initiating, financing and/or managing the research or Clinical trial. The Sponsor has the primary responsibility for ensuring that the design of the study meets appropriate standards and that the arrangements are in place to ensure appropriate conduct and reporting.

A Sponsor is required for all NHS research in the UK, including:

- Research concerned with the protection and promotion of public health
- Research undertaken in or by the Department of Health, its non-departmental public bodies and the NHS
- Research undertaken by or within social care agencies
- Clinical and non-clinical research
- Research undertaken by the NHS or social care staff using the resources of health and social care organisations
- Research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. (UK Policy Framework for Health and Social Care (2017) section 9.10)

The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written standard operating procedures (SOPs) to ensure that trials are conducted, data generated, documented (recorded) and reported in compliance with the protocol, Good Clinical Practice (GCP) and the applicable regulatory requirements. The Sponsor is responsible for securing agreement from all involved parties to ensure direct access to all research related sites, source data/documents, and reports for the purpose of monitoring and auditing by the Sponsor and inspection by regulatory authorities.

## 2. OBJECTIVE

This SOP outlines how the Sponsorship of studies can be transferred to or from Royal Free.

### **3. DEFINITIONS**

RF Royal Free London NHS Foundation Trust

### **4. SCOPE**

This SOP is applicable to studies requesting Sponsorship to be transferred to Royal Free or an existing Royal free Sponsored study to be transferred to another organisation.

Royal Free does not currently Sponsor regulated studies. Therefore, this SOP only covers studies being transferred that are non-regulated studies.

### **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) to ensure that the transfer of Sponsorship is done with the full knowledge of both organisations involved.

## 7. PROCEDURE

Person Responsible	Task
CI	<p><b>7.1 Study Transferring into Royal Free</b></p> <p>Once the CI has decided they would like to transfer a study to RF, they should contact the RF R&amp;D Office as soon as possible to see whether the transfer is possible.</p> <p>Once the RF R&amp;D Office has confirmed it is willing in principle to accept the transfer of Sponsorship, the CI must obtain written confirmation from the existing Sponsor that they are willing to transfer Sponsorship to RF. This letter should include any financial arrangements where applicable, such as the transfer of the study grant.</p> <p>A review will be undertaken by the R&amp;F R&amp;D Office to ensure that the study is sufficiently resourced.</p> <p>Once the written confirmation has been received, the CI must then modify all their existing ethically approved documents to reflect change in Sponsorship. For example, changing the insurance statement in the patient information sheet to the RF standard statement. The CI must also produce a substantial amendment form reflecting the change in Sponsor. These documents must be submitted to the RF R&amp;D Office and the existing Sponsor for approval.</p> <p>Once the RF R&amp;D Office has approved these documents, the RF R&amp;D Office will then issue a confirmation of transfer of Sponsorship letter (RFLRDDOC0020).</p> <p>The CI must then obtain the signature of the existing Sponsor and submit the amendment to REC and HRA.</p> <p>Once the amendment has been approved, the RF R&amp;D Office should be notified.</p> <p>The CI will be responsible for informing all sites where the study is active of the change in Sponsor.</p>
Research Portfolio Manager	<p><b>7.2 Studies transferring into Royal Free</b></p> <p>Once the CI has contacted the RF R&amp;D Office, the assigned Research Portfolio Manager will liaise with the different sections of the RF R&amp;D Office as applicable to ensure that RF is able to take on the responsibility of Sponsorship – (follow Sponsorship Working Practice Document RFLRDWPD0001)</p>

	<p>Once the RF R&amp;D Office has confirmed it is willing in principle to accept the transfer of Sponsorship, the CI must obtain written confirmation from the existing Sponsor that they are willing to transfer Sponsorship to Royal Free. This letter should include any financial arrangements where applicable, such as the transfer of the study grant. A review will be undertaken to ensure that the study is sufficiently resourced.</p> <p>Once the change in Sponsorship letter has been received and all the amendment documents, the assigned Research Portfolio Manager must review them as per standard Sponsorship process. Any trial related document must be reviewed by the Research Portfolio Manager contact and approval gained from other sections of the office e.g. contracts and costings.</p> <p>Once the Research Portfolio Manager has approved the documents, the RF R&amp;D Office will then issue a confirmation of transfer of Sponsorship letter (RFLRDDOC0020). At this stage, the Research Portfolio Manager will also inform the investigator what other changes will need to be done e.g. issuing of new contracts to reflect the new Sponsor.</p> <p>The CI must then obtain the signature of the existing Sponsor and submit the amendment to REC and HRA.</p> <p>Once the amendment has been approved, the RF R&amp;D Office should be notified, the CI will be responsible for informing all sites where the study is active of the change in Sponsor.</p>
<p>CI</p>	<p><b>7.3 Studies Transferring outside of Royal Free</b></p> <p>Once the CI has decided they would like to transfer an active RF's study to a different organisation, they should contact their assigned Research Portfolio Manager as soon as possible to see whether the transfer is possible.</p> <p>Once the RF R&amp;D Office has confirmed it is willing in principle to accept the transfer of Sponsorship, the CI must obtain written confirmation from the proposed Sponsor that they are willing to take on Sponsorship. This letter should include any financial arrangements where applicable, such as the transfer of the study grant.</p> <p>Once the written confirmation has been received, the CI must then modify all their existing ethically approved documents to reflect change in Sponsorship. For example, changing the insurance statement in the patient information sheet to their new Sponsor's standard statement.</p>

	<p>The CI must also produce a substantial amendment form reflecting the change in Sponsor. These documents must be submitted to the RF R&amp;D Office and the proposed new Sponsor for approval.</p> <p>Once the RF R&amp;D Office has approved these documents, the RF R&amp;D Office will then issue a confirmation of transfer of Sponsorship letter (RFLRDDOC0020).</p> <p>The CI must then obtain the signature of the RF R&amp;D Office Sponsor Representative and submit the amendment to REC and HRA.</p>
<p>Research Portfolio Manager</p>	<p><b>7.4 Studies transferring outside of Royal Free</b></p> <p>Once the CI has contacted the RF R&amp;D Office, the assigned Research Portfolio Manager will liaise with the different sections of the RF R&amp;D Office (eg costings, contracts) as applicable to ensure that RF is able to transfer on the responsibility of Sponsorship – (follow Sponsorship Working Practice Document RFLRDWPD0001)</p> <p>Once the RF R&amp;D Office has confirmed it is willing in principle to accept the transfer of Sponsorship, the CI must obtain written confirmation from the proposed new Sponsor that they are willing to take on Sponsorship from RF. This letter should include any financial arrangements where applicable, such as the transfer of the study grant.</p> <p>Once the change in Sponsorship letter has been received and all the amendment documents, the Research Portfolio Manager must review them as per standard Sponsorship process. Any trial related document must be reviewed by the Research Portfolio Manager and approval gained from other sections of the office.</p> <p>Once the RF R&amp;D Office has approved the documents, the RF R&amp;D Office will then issue a confirmation of transfer of Sponsorship letter (RFLRDDOC0020). At this stage, the Research Portfolio Manager will also inform the investigator what other changes will need to be done e.g. issuing of new contracts to reflect the new Sponsor.</p> <p>The CI must then obtain the Sponsor representative signature from the assigned Research Portfolio Manager and submit the amendment to REC and HRA.</p> <p>Once the amendment has been approved, the RF RD&amp; Office should be notified.</p>



## **8. POLICY**

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

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

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- The R&D Office will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).
- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the R&D Manager/Deputy R&D Director should be gained before any action is taken.
- SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.
- The R&D Office is responsible for the ratification of this procedure.

## **10. FORMS/TEMPLATES TO BE USED**

None applicable

## **11. FLOWCHART**

None applicable



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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	SOP on transferring Sponsorship
Briefly describe its aims and objectives:	This SOP outlines how the Sponsorship of studies can be transferred to or from Royal Free.
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).

<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 on transferring Sponsorship 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
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

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