

**Document Title: Contract Negotiation and Review**

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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)
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**Version Control**

Version	Date	Author	Status	Comment
1	01/07/2014	Heidi Saunders	Final	New Document
1.1	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2	30/11/2017	Thomas Jenkins	Final	Update to new SOP template. Update from RGF to UK Policy Framework for Health and Social Care (2017). Updates to references to new SOPs. Clarification on harmonisation process

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## 1. INTRODUCTION

This document sets out the procedures to be followed by all Royal Free London staff who are involved in the preparation and / or review of research study contracts or Clinical Trial Agreements (CTAs).

The SOP aims to provide clear guidance on the process of contract review and preparation to ensure compliance with the Trust's policies.

## 2. OBJECTIVE

This document defines the Trust's research procedures for preparing and reviewing contracts pertaining to Research Studies and Clinical Trials by the RF Research & Development (R&D) Office.

The document clarifies the requirements for the establishment of a contract between the two parties so as to comply with the Good Clinical Practice guidelines (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

The document aims to provide clear guidance on who should contribute to, review and approve contracts so as to comply with the Trust's policies on Information Governance and Financial Agreements.

The management of Research Finance is outside the scope of this SOP and therefore will not be discussed in this document.

## 3. DEFINITIONS

**RF** Royal Free London NHS Foundation Trust

**RM&G** - Research Management & Governance

**R&D** - Research & Development

**CTA** – Clinical Trial Agreement

**mNCA** - The model agreement for non-commercial research (mNCA) is a template for documenting the relationship between and the responsibilities of the non-commercial sponsor(s)<sup>1</sup> of a research study and the Health Service organisation where the study takes place.

**mCTA** - model Clinical Trial Agreement (mCTA) is designed to be used without modification for industry-sponsored trials in patients in hospitals throughout the UK Health Service.

**mCIA** - model Clinical Investigation Agreement (mCIA) is designed to be used without modification for company-sponsored commercial research involving medical devices in patients in hospitals throughout the UK Health Service.

**MTA** – Material Transfer Agreement

**CRO mCTA** - The Contract Research Organisation model Clinical Trial Agreement (CRO mCTA) is a tripartite agreement between: the pharmaceutical company sponsoring a trial, the contract research organisation (CRO) managing the trial and the NHS organisation where the trial takes place.

**CRO mCIA** - The Contract Research Organisation model Clinical Investigation Agreement (CRO mCIA) is a tripartite agreement between: the company sponsoring commercial research involving medical device(s), the contract research organisation (CRO) managing the research and the NHS organisation where the research takes place.

**North Thames CRN** – North Thames Clinical Research Network (CRN)

#### **4. SCOPE**

This SOP applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties, those working at the trust under honorary contract or under the remit of a valid research passport, those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

#### **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.

The contracts required for Commercial studies, as well as Portfolio adopted Non-Commercial studies will be reviewed and signed off by the North Thames CRN on behalf of the Trust (see SOP052 Confirmation of capacity and capability for Harmonised Studies).

## 7. PROCEDURE

Person Responsible	Task
Research Costing and Contract Manager with study team	<p><b>7.1 Research Contracts</b></p> <p>Copies of the contract, clinical trials agreement/statement of activities (including details of any finances) between the Trust and the study Sponsor must be sent to the Research Costing and Contract Manager for review. Where applicable, a copy of the protocol and any relevant documentation must also be provided to be reviewed alongside the CTA.</p> <p>Royal Free London NHS Foundation Trust is the legal body with whom all contracts / agreements must be made. Principal Investigators must not enter into agreements with third parties, although they may occasionally be asked to witness an agreement alongside the Trusts legal signatory.</p>
Research Costing and Contract Manager	<p><b>7.2 Reviewing Contracts</b></p> <p>The Trust prefers NIHR Model Agreements to be used, where possible, for applicable contracts.</p> <p>The Research Costing and Contract Manager reviews the draft contracts/agreements for Research Studies and Clinical Trials and carries out all contract negotiations with the Sponsor.</p>
Research Costing and Contract Manager with study team	<p><b>7.3 Costing</b></p> <p>The R&amp;D Office with input from the clinical project team is responsible for ensuring that the study is adequately funded. These costs should include additional staff time, additional procedure time, all test procedures, clinical and administrative activity required by the trial. In addition, the cost of other core departments which may be involved in the trial (e.g. Radiology, Pathology etc.) should be detailed. The costs covered in the contract should be clear and understandable, and should also clearly identify what is not covered.</p> <p>The Research Costing and Contract Manager carries out all finance negotiations for applicable Research Studies and Clinical Trials with the Sponsor.</p>
RF Authorised Signatory	<p><b>7.4 Signatures</b></p> <p>Finalised contracts will be signed by the Director of R&amp;D. In their absence contracts will be signed by the Medical Director. If the Director of R&amp;D is the</p>

	<p>Investigator for the study or involved in the study conduct, then the contract will be signed by the Medical Director.</p> <p>Contracts/agreements for Research Studies and Clinical Trials that are processed through the North Thames LCRN harmonisation route, are signed by the relevant Permission Centre's signatory on behalf of RF.</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 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



**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	(Research) Contract Negotiation and Review
Briefly describe its aims and objectives:	This document sets out the procedures to be followed by all Royal Free London staff who are involved in the preparation and / or review of research study contracts or Clinical Trial Agreements (CTAs).
Directorate and Lead:	Rachel Fay, R&D Manager, R&D Office
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?	<b>Yes</b> 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
<b>Age</b>	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.
<b>Disability</b>	None identified	R&D administrative document	NA	NA	
<b>Gender Reassignment</b>	None identified	R&D administrative document	NA	NA	
<b>Marriage and Civil Partnership</b>	None identified	R&D administrative document	NA	NA	
<b>Pregnancy and maternity</b>	None identified	R&D administrative document	NA	NA	
<b>Race</b>	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			
<b>Religion or Belief</b>	None identified	R&D administrative document	NA	NA	
<b>Sex</b>	None identified	R&D administrative document	NA	NA	
<b>Sexual Orientation</b>	None identified	R&D administrative document	NA	NA	
<b>Carers</b>	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, and 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	13/02/2018
R&D Committee	Royal Free London NHS Foundation Trust	22/02/2018

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