

Document Title: Delegation Log

Document Number: 021

Version:	2
Ratified by:	RF R&D Committee
Date ratified:	30/11/2017
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Department:	Research and Development
Name of responsible individual:	Rachel Fay, R&D Manager
Date issued:	04/12/2017
Review date:	04/12/2020
Target audience:	All research staff
Intranet:	NA
Key related documents:	SOP004 Training Records SOP005 GCP Training SOP006 Roles and Responsibilities for the Conduct of Research Studies RFLRDLOG004 Staff Delegation of Duties log.
This document supports: <i>Standards and legislation</i>	Medicines for Human Use (Clinical Trials) Amended Regulations 2006 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Date equality analysis completed.	30/11/2017
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SOP 021: Delegation Log

V2 04 OCT 2017

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<https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

Version Control

Version	Date	Author	Status	Comment
1	03.06.2014	Heidi Saunders	Final	New document
1.1	03 OCT 2017	Lucy Parker	Final	SOP Review Date Time Extension
2	04 OCT 2017	Lucy Parker	Final	New template. Addition of references to standard documents/logs.

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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 management or running of clinical trials and research studies at, or sponsored by, Royal Free London NHS Foundation Trust.

It aims to provide clear guidance on how research specific duties and tasks should be delegated so as to ensure compliance with the Trust's policies, Good Clinical Practice and the UK Policy Framework for Health and Social Care (2017).

2. OBJECTIVE

This document defines the Trust's research procedures for the delegation of duties and responsibilities in clinical trials and research studies being performed at, or sponsored by, Royal Free London NHS Foundation Trust.

This SOP clarifies the requirements for the allocation of responsibilities so as to conform with Good Clinical Practice (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').

3. DEFINITIONS

RF - Royal Free London Hospital NHS Foundation Trust

R&D - Research & Development

Clinical Trial of Investigational Medicinal Product (CTIMP) - Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal products(s) and/or Study absorption, distribution, metabolism and excretion of one or more investigational product(s) with the object of ascertaining its (their) safety and/or efficacy.

PI – Principal Investigator

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/letter of access, 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.

Staff involved in the conduct of clinical trials and research studies performed at or sponsored by RF must comply with the requirements set out in section 7.

The Principal Investigator (PI) for each study within the Trust carries the primary responsibility for the conduct of the trial at RF and as such they should ensure that tasks are only delegated to those who are deemed sufficiently competent.

7. DETAILS OF THE PROCEDURE

Person Responsible	Task
PI	<p>7.1 Requirements</p> <p>As mandated by GCP, an Investigator should be qualified by education, training and experience to assume responsibility for the proper conduct of a trial. They should meet all the qualifications specified by the applicable regulatory requirements and should provide evidence of such qualifications through up-to-date curriculum vitae (CVs should be dated and signed and no more than 2 years-old) and/ or other relevant documentation requested by the sponsor and regulatory authorities.</p> <p>Delegation Logs are an essential document; identifying which individuals the Investigator has delegated study specific tasks.</p> <p>The delegation log must reflect the current situation, showing who is delegated what, with start and end dates. The log</p>

	<p>should be read and signed by the PI, with the original stored in the Investigator Site File. The Pharmacy Department delegation log is stored in the Pharmacy site file. A copy will be supplied to the Sponsor and both the original and the copy will be kept up to date throughout the study.</p> <p>PIs are responsible for ensuring that anyone in their team that they have delegated tasks to is appropriately qualified to carry out that task. The PI needs to be familiar with Roles and responsibilities for the conduct of research studies (SOP006)</p> <p>For CTIMPS CVs and GCP certificates must be available for everyone on the Delegation Log. Each CV must be current (within two years), signed and dated by the individual. (SOP005 GCP Training)</p> <p>Evidence of appropriate training must be available in the personal training file. New staff must be added to the delegation log prior to completing any study related activities or a new one prepared, but the old versions must not be destroyed.</p>
<p>PI</p>	<p>7.2 Delegation logs</p> <p>During the set up phase, the PI and the appropriate staff members involved in the clinical trial, must discuss and agree on the study requirements with the Sponsor (or their delegated representative). The types of tasks that can be delegated will depend on the suitability of the individuals to accept the tasks.</p> <p>The allocation of tasks should be recorded clearly in the Delegation Log. The PI should review the delegation log for each study and should ensure that all individuals are:</p> <ul style="list-style-type: none"> ○ Competent to perform the tasks that they have been delegated e.g. Provision of training records (SOP004: Training Records) ○ Adequately informed about the protocol and investigational product(s). ○ Informed of their involvement and what duties they are expected to perform. <p>Each individual whose name is on the Delegation Log needs to sign and date their entry to acknowledge their given responsibilities for the trial. The Delegation Log must be countersigned and dated by the PI.</p> <p>Further added responsibilities or changes to the above must be agreed by the PI and the Delegation Log must be updated accordingly. Corrections made with a single strike through, date and initials. This must be countersigned by the PI.</p> <p>A template delegation log is available from the R&D Office website RFLRDLOG004 Staff Delegation of Duties log.</p> <p>If there are research team members listed on the delegation</p>

	log that are not employed by the RF, evidence of their research passport or letter of access should be filed within the ISF.
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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

RFLRDLOG004 Staff Delegation of Duties log.

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	Standard Operating Procedure for Roles and Responsibilities /Delegation Log
Briefly describe its aims and objectives:	<p>This document sets out the procedures to be followed by all Royal Free London staff who are involved in the management or running of clinical trials and research studies at, or sponsored by, Royal Free London NHS Foundation Trust.</p> <p>It aims to provide clear guidance on how research specific duties and tasks should be delegated so as to ensure compliance with the Trust's policies, Good Clinical Practice and the Research Governance Framework.</p>
Directorate and Lead:	Medical Directorate, Liba Stones, R&D Manager
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	<p>Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments.</p> <p>UK Policy Framework for Health and Social Care (2017)</p> <p>New process for handling amendments to NIHR CSP studies (NIHR, 2013).</p>
Is the Trust Equality Statement present?	<p style="text-align: center;">Yes X No if no do not proceed with</p>

	Equality Analysis (EA)
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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 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
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	

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
Pregnancy and maternity	None identified	R&D administrative document	N/A	N/A	and promote equality compliance within the Trust.
Race	None identified	R&D administrative document	N/A	N/A	
Religion or Belief	None identified	R&D administrative document	N/A	N/A	
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