

Document Title: Training Records

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This document supports: <i>Standards and legislation</i>	Medicine for Human Use (Clinical Trials Regulations) 2004
Date equality analysis completed.	26/10/2017

SOP 004: Training Records

Version 2.0, 04 OCT 2017

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

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Version Control

Version	Date	Author	Status	Comment
1	01.07.2014	Allison Allen	Final	New document
1.2	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2	04/10/2017	Lucy Parker	Final	New SOP Template used.

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1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the process for maintaining the training records of research staff on ALL research studies at RFH.

2. OBJECTIVE

It is a legal requirement under the EU Clinical Trials Directive 2001/20/EC, EU Good Clinical Practice Directive 2005/28/EC and the Medicines for Human Use (Clinical Trials) Regulations 2004 for clinical trials to be conducted according to the principles of Good Clinical Practice (GCP). All studies should be run to GCP-equivalent standards to ensure consistent practice and scientific quality.

Staff working on all research studies must ensure that they are familiar with the requirements of Good Clinical Practice (GCP) and that they maintain their own training records to show that all members of the study team are “qualified by education, training and experience to perform his or her respective task(s)”(ICH GCP 2.8).

All training undertaken by the study’s staff must be carried out in conjunction with RFH policies and procedures. If RFL sponsored study is taking place at another site, the researchers must also be aware and follow local NHS Trust policies and procedures.

3. SCOPE

This SOP will describe the process for the preparation, review and approval of all training records for staff working on studies sponsored by RFL

4. DEFINITIONS

SOP Standard Operating Procedure

GCP Good Clinical Practice

RFL the Royal Free London NHS Foundation Trust

MDT Multi-disciplinary 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.

Lead Research Nurse – responsible for oversight of this SOP.

Staff member's Line Manager – Induction, Probationary period, Performance Appraisals

Staff member – Maintaining own Training Records

7. DETAILS OF THE PROCEDURE

Training Records

The Training Lead will provide the individual with a training folder. This will serve as a record of the individual's on-going training and professional development. The folder will be kept by the individual and it is their responsibility to ensure it remains up to date.

The suggested contents would be:

1. Training Record Index Page (RFLRDDOC0021)
2. RFH Training Log (RFLRDLOG0017)
3. Trial Related Training Log (RFLRDLOG0013)
4. External Training Log (RFLRDLOG0018)
5. SOP Reading Log (RFLRDLOG0016)

When a member of staff leaves post, they may want to take their training record file with them. A copy of their record should be made and kept in the Trial Master File (TMF – See SOP0054 for TMF management) or site file with the date of leaving noted on the Staff delegation of duties & responsibilities log e.g. RFLRDLOG004.

RFH GCP Requirements

All Principal Investigators, Co-investigators, research staff working on regulated studies within RFH are expected to undergo GCP training. This should then be updated two yearly with issued training certificate filed in the staff members training folder and centrally. See SOP005 GCP Training for further information.

Staff working on non-regulated studies are recommended to have undergone GCP training although it is not mandatory.

Person Responsible	Task
Staff member appointed to a study	<p>All newly appointed members of the Clinical Research Team will be given an individual induction timetable which will include meetings with the Lead Research Nurse or Supervisory lead, other relevant members of the research team, consultants they will be working closely with, relevant members of the MDT, key pharmacy staff and an opportunity to shadow at least one other member of the research team during clinical placement and MDT.</p> <p>As part of their induction into the role the manager will carry out a training needs assessment according to local practice. This will be documented according to local procedures. The purpose of this is to establish the individual's baseline skills and competencies and identify gaps in their knowledge that need to be filled, with the aim of highlighting what training sessions should be attended over the coming months. The supervisory lead will identify and discuss possible training sessions to be attended which will help with the individual's professional development. The supervisory lead will write a summary of the assessment as detailed in the RFH probationary policy and procedure. A copy of this and the training needs assessment will be sent to the individual for filing in their training file.</p> <p>As part of their induction to the unit, the manager who will explain about the arrangements for standard operating procedures (SOPs) and explain the procedure for SOPs within the unit.</p> <p>Following the initial assessment, the Line Manager will assess, review and support staff as required. A minimum requirement is to follow the RFH Appraisal Policy and Procedure. Individual Objectives and Personal Development Plan will be documented using the RFH probationary and Appraisal Policies and procedures. All on-going training should be recorded on the staff member's Personal development plan. Details of study specific training (eg Investigator meetings, site initiation visits, other specialist training) should be recorded according to local practice, certificates of attendance should be collected whenever possible. Where they are not provided then the staff member should sign their name alongside the respective training course as proof of attendance</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 Directorate is responsible for the ratification of this procedure.

10. FORMS/TEMPLATES TO BE USED

RFLRDDOC0001 CV Template
RFLRDDOC0021 Training Record Index Page
RFLRDLOG004 Staff delegation of duties & responsibilities log
RFLRDLOG0013 Trial Related Training Log
RFLRDLOG0016 SOP Reading Log
RFLRDLOG0017 RFH Training Log
RFLRDLOG0018 External Training Log

11. FLOWCHART

NOT 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	Standard Operating Procedure Training Records
Briefly describe its aims and objectives:	This Standard Operating Procedure (SOP) describes the process for maintaining the training records of research staff on ALL research studies at RFH.
Directorate and Lead:	Medical Directorate, Alison Allen, Lead Research Nurse
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicine for Human Use (Clinical Trials Regulations) 2004
Is the Trust Equality Statement present?	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.

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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	
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	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
		document			
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	27/09/2017
R&D Committee	Royal Free London NHS Foundation Trust	26/10/2017