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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) ICH Harmonised Tripartite Guideline for Good Clinical Practice E6(R2)
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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	04/10/2017	Tolu Williams	Final	Update to booking of GCP training. Clarification of training requirements for the CI/Lead team RFL Sponsored Projects. Clarification of the need for CI/lead team to review SOPs and RFL requirements. Addition of standard document references Change from reference to Research Governance Framework for Health and Social care (2005). to UK Policy Framework for Health and Social Care (2017)
2.1	28/06/2021	Lucy Parker	Final	Moved onto new SOP template. Correction of audit SOP reference number to correct number Clarification that staff outside the R&D department are not required to undertake GCP training.

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1. INTRODUCTION

This document sets out the procedures to be followed by all Royal Free London NHS Foundation Trust Staff who are involved in, or undertaking, clinical research.

It aims to provide clear guidance on the GCP training requirements so as to ensure that personnel involved in clinical research studies are aware of, and have an understanding of, the principles of GCP and the law on which they are based.

2. OBJECTIVE

This document defines the Trust's requirements with regards to GCP training of staff involved in Research Studies and Clinical Trials across RFL. Specifically, this includes Investigators and researchers involved in any part of the research process that lies outside of the normal pathway of care.

This SOP clarifies the requirements for staff to be aware of the principles of 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').

This document aims to provide clear guidance on the frequency and type of GCP training that is required so as to comply with the Trust's policies.

3. DEFINITIONS

ATMPs: Advanced-therapy medicinal product

CTIMPs: Clinical Trial of Investigational Medicinal Products (drug trials)

Clinical Investigations: is defined as that segment of clinical research for which an investigator directly interacts with patients in either an outpatient or inpatient setting. This definition excludes studies for which material of human origin is obtained through a third party and for which an investigator has had no direct interaction with the patient.

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.

MHRA - Medicines and Healthcare Products Regulatory Agency

NIHR – National Institute of Health Research

North Thames CRN – North Thames Comprehensive Research Network

Non-CTIMPs: Non - Clinical Trial of Investigational Medicinal Products (non-drug trials).

RFL Royal Free London NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

TROIKA - is a sub-committee of the Research and Development (R&D) Committee and comprises of the Dean of the Medical School, the Director of the R&D Office and the RF's Medical Director

4. SCOPE

This SOP applies to ALL staff undertaking research at Royal Free, including clinical and non-clinical staff.

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 applies to all personnel that are conducting clinical 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.

Staff involved in research within the Trust must comply with the requirements set out in section 7.

Staff outside the scope of the R&D team directly delivering the research who are carrying out their clinical routine work, such as phlebotomists or radiographers, are not required to undertake GCP training. Supervisors or team leaders in such areas are encouraged to undertake GCP training in order to gain an understanding of the standards governing the conduct of clinical research at the Trust. The R&D office can provide further guidance should this be required.

7. PROCEDURE

Person Responsible	Task
All research staff	<p>Studies sponsored by RFL</p> <p>It is recommended although not mandatory for the CI and lead team to attend the GCP training course prior to being delegated responsibilities on any clinical research project.</p> <p>There are a number of organisations which offer GCP training. Some of these are free, and some the research team member may have to pay for.</p> <p>CTIMP Trials Hosted at RFL (externally sponsored studies)</p> <p>All staff who work on 'hosted' studies i.e. sponsored by organisations other than RFL, should receive GCP prior to commencing work on any project at the any RFL location. The type and extent of the clinical research training is at the discretion of the external Sponsor. It is the responsibility of the research team to establish with the external Sponsor what training they require.</p> <p>Non CTIMP Trials Hosted at RFL (externally sponsored studies)</p> <p>It is not mandatory for staff working on non CTIMP 'hosted' studies to undergo GCP Training, All staff who work on non CTIMP 'hosted' studies i.e. sponsored by organisations other than RFL, should check with the external Sponsor as to whether they require GCP prior to commencing work on any project at the any RFL location. It is the responsibility of the research team to establish with the external Sponsor what training they require</p>
All Researchers (Site , Co-ordination and central facility staff)	<p>Individual researchers working on a research project should ensure an up to date CV is present in the trial file (TMF or ISF as applicable). It is advised that researchers use the R&D CV template RFLRDDOC0001 to ensure relevant information is captured.</p> <p>CVs should be updated at least on a 2 yearly basis or when a new role or training is undertaken. (See SOP 0004)</p>
Chief Investigator	<p>The CI of RFL sponsored trial is overall responsible for coordinating and ensuring site personnel are appropriately trained prior to working on a study.</p> <ul style="list-style-type: none"> • The CI is responsible for ensuring that all co-

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	<p>ordination personnel have had appropriate* training and an up to date CV is present in the trial master file prior to commencing work on the project. CVs should be updated on a 2 yearly basis, when undertaking a new role, when training is undertaken or for sites external to RFL as per local site Institutional procedures.</p> <ul style="list-style-type: none"> The CI should also ensure that at site initiation all site personnel have had appropriate training prior to activating the site. <p>Evidence of training needs to be filed as per SOP004 (Training Records). It is advised that all research personnel maintain a training record. The suggested contents would be:</p> <ol style="list-style-type: none"> 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) <p>When researchers leave, they should take the original copies of training with them but a copy should be retained by the team leader.</p>
Principal Investigator	<p>The RFL PI is to ensure that all site personnel have had appropriate* training prior to commencing work on the project.</p> <p>Evidence needs to be filed as per SOP054 (Trial master file). This should be reviewed as part of routine monitoring (see SOP0047 Research Audit and Inspection)</p>
All researchers	<p>All researchers should ensure that they are appropriately* trained prior to commencing work on any research project, trial or study.</p> <p>Training should be proportionate to the researcher's role within the study team.</p> <p>*Appropriate training should include</p> <ul style="list-style-type: none"> • Topic specific. <p>This should include an understanding of the research area or disease. The researcher's level of knowledge should enable them to accurately perform their allocated role.</p> <ul style="list-style-type: none"> • Study and protocol specific <p>This should include: review of protocol, study specific SOPs and manuals, any training in and allocated study producer (e.g. randomisation, unblinding or CRF completion).</p> <p>This can be delivered as part of a site initiation visit but should also be carried out for all new staff.</p>
All Researchers	Researchers should work in compliance with RFL

	<p>research polices and the R&D standard operating procedures.</p> <p>Staff should maintain a reading log (see Associated Document RFLRDLOG0016) to show SOPs have been read and understood. All R&D SOPs are available on the RFL R&D website.</p> <p>www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops</p> <p>Further information and guidance can be provided by the R&D Manager</p>
Line managers of research staff	<p><u>Evidence of Training</u></p> <p>A copy of the certificate should be retained in the individual's personal training file and made available for monitoring, audit and inspection purposes (See SOP047)</p> <p>Copies of the certificate should be included in the site files of the research studies that the staff member is involved in, or a file note should be present in the site file to explain where the certificate is held (See SOP004)</p>
R&D Coordinator, R&D office staff	<p>Send all queries regarding bespoke GCP training course to the Trust Lead Research nurse and onsite GCP trainer to coordinate.</p>
PI/ Managers of staff undertaking GCP training	<p>Enrolment of staff</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 and as part of the agreed R&D Audit programme. 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.

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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 GCP Training for Research Staff			
Briefly describe its aims and objectives:	This SOP aims to provide clear guidance on the GCP training requirements so as to ensure that personnel involved in research studies are aware of, and have an understanding of, the principles of GCP and the law on which they are based.			
Directorate and Lead:	Medical Directorate – Professor Adele Fielding, 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. Research Governance Framework for Health and Social care (2005). New process for handling amendments to NIHR CSP studies (NIHR, 2013).			
Is the Trust Equality Statement present?	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 33%;">Yes</td> <td style="text-align: center; width: 33%;">No</td> <td style="text-align: center; width: 33%;">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.

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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	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.
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 document	N/A	N/A	
Race	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	
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