UNIVERSITY OF LEEDS / NHS The Leeds Teaching Hospitals NHS Trust Standard Operating Procedure	Title	Researcher's Guide to Staff Training Records.				
	Scope	Describes the process that all staff working on LTHT/UoL sponsored CTIMPs must follow when creating and maintaining their own research training record.				
	Version	3.0	Date	09/01/2020	SOP ID	QCRES_06

Details:

Original author:	Daniel Skinner, QA Portfolio Coordinator
Last reviewed by:	Elizabeth Taylor, QA Clinical Trial Monitor
Version no. of replaced SOP:	2.0
Effective date of replaced SOP:	20/12/2017

Approval:

Version no. of SOP	Name of person approving this SOP	Date	Signature of the person approving this SOP
3.0	Clare E Skinner Head of Research Integrity and Governance Secretariat University of Leeds	9.01.2020	Clare E Skinner
	Steph Britt QA Manager (Clinical Trials) University of Leeds / Leeds Teaching Hospitals NHS Trust	09/01/2020	S. Britt

Distribution & Storage:

Distribution to:

Investigators and all members of research teams conducting or assisting with a CTIMP trial sponsored by the University of Leeds or Leeds Teaching Hospital NHS Trust.

Location of document:

Paper: QA Department, Room 5, Research and Innovation Centre, St James' University Hospital

Electronic: http://www.leedsth.nhs.uk/research/information-for-researchers/key-documents
http://lthweb.leedsth.nhs.uk/sites/research-and-development/resources/Sponsored%20CTIMPs%20%28Quality%20Assurance%29

Contents

Please note: *This SOP should be used and followed in conjunction with other UoL / LTHT SOPs developed for researchers to support study set up and management. These can be found on the LTHT website or by contacting R&I / QA directly. For clinical trials where Leeds is not the trial Sponsor, please refer to any Sponsor SOPs for further information.*

Section A: Introduction

1.0. This Standard Operating Procedure (SOP) outlines the procedure for creating and maintaining a training file for staff working on Clinical Trials of an Investigational Medicinal Product (CTIMPs) sponsored by Leeds Teaching Hospitals NHS Trust (LTHT) or the University of Leeds (UoL).

1.1. The completion of a training file is essential to clearly document that all staff working on CTIMPs are appropriately trained and qualified to undertake relevant trial activities.

1.2. The United Kingdom (UK) Clinical Trial Regulations (SI 2004/1031, as amended) state that:

- *"Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks."* (Part 2 (2) of Schedule 1).
- *"No person shall conduct a trial otherwise than in accordance with the conditions and principles of Good Clinical Practice (GCP)"* (Regulation 28).

1.3. The Health Research Authority (HRA) guidance states:

- *"For research, training should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities of researchers set out in relevant legislation and standards",*
- *"Training should be updated when legislation has changed, new policies or practice have been implemented, different research activities are to be undertaken, or a significant period of time has elapsed since research activities have been conducted"* (Health Research Authority, 2013).

1.4. Training records must be made available upon inspection by the Sponsor, regulator and other relevant authorities, and therefore must be kept to an inspection-ready standard at all times.

Section B: Applicability

1. This SOP is applicable to all staff working on CTIMPs sponsored by LTHT or the UoL.

Section C: LTHT / UoL Sponsored CTIMP - Staff Training Records

1. Staff Training Files

1.1. Staff working on LTHT/UoL sponsored CTIMP studies are responsible for ensuring they are trained in accordance with GCP requirements. **For staff working on LTHT/UoL sponsored CTIMPs**, GCP training and Curriculum Vitae's (CVs) must be updated every **2 years**.

1.2. It is the responsibility of individual members of staff to ensure that their training record is updated and maintained on an on-going basis, and that adequate GCP training is evidenced.

1.3. The Sponsor's preferred provider for GCP Training is the National Institute for Health Research (NIHR). If an alternative provider is selected, please consult the Sponsor Quality Assurance (QA) office to confirm that this provider is acceptable.

1.4. All staff working on LTHT/UoL sponsored CTIMP studies should hold their own physical training record file. This should include:

- **Current Job description/Terms of employment** (signed and dated by the individual and their line manager, if available).
- **Previous job descriptions** (if available) relevant to the current post.
- **Current Research CV** (signed and dated by the individual), demonstrating full education, training and qualifications. A template can be obtained from the Sponsor QA Office.
- **Training record logs** demonstrating an individual's training history, including evidence of training on relevant SOPs, and all planned training and learning objectives for the future (please see Appendix A).
- **Confirmation of GCP training** (in the form of a certificate).
- **Certificates of any other relevant course attendance and agendas / details of content covered.**
- **Details of any training received prior to appointment** which may not be covered on the staff members research CV but may be relevant to their position (e.g. therapeutic area training).

1.5. An electronic copy of each staff member's CV and GCP certificate should also be stored on the EDGE database and on the research team's departmental drive.

1.6. When a member of staff leaves their post, they are permitted to take their training file with them, but copies of relevant documents can be retained at the discretion of the individual's line manager.

1.7. These documents can be retained for as long as is needed, in order to demonstrate regulatory and GCP compliance.

2. Staff Delegation Log

2.1 The Chief Investigator (CI)I/Principal Investigator (PI) may delegate trial tasks to appropriate members of the research team, providing this is captured on the trial specific Staff Delegation Log / Staff Authorisation Log (Please see ***QCRES_04_Researchers guide to appropriate Delegation of Duties for UoL/LTHT Sponsored CTIMPs***).

2.2 In order to verify an individual's appropriateness to undertake a specific trial task, the CI/PI may request to review the individual's training file, which should be provided in a timely manner.

2.3 Only individuals that demonstrate appropriate levels of training can be delegated to perform trial activities.

3. Investigator Site File (ISF) / Trial Master File (TMF)

3.1 Staff working on LTHT/UoL sponsored CTIMPs must update their GCP training and CV every **2 years**. Confirmation of staff GCP training and CVs must be held within the ISF/TMF for the entire duration of the trial.

3.2 If CVs and GCP certificates are to be held centrally by a department, a statement of location must be filed in the ISF/TMF.

3.3 If the information included on the current CV remains unchanged when it is due to be updated, it is acceptable for the individual to re-date and re-sign the existing copy.

3.4 Superseded training records should not be removed from the ISF/TMF, but instead marked as superseded and filed behind the current certificate. This demonstrates that staff members were appropriately qualified for the duration that they were undertaking trial duties.

3.5 Evidence of trial initiation visit attendance and any trial specific training logs must also be stored in the ISF/TMF.

Section D: References

Health Research Authority 2013: *Training requirements for researchers.*
MHRA Good Clinical Practice Guide 2012: 11.3.4 Delegation of tasks, pp. 369-370
MHRA Good Clinical Practice Guide 2012: 14.2 Training, pp. 447-448
MHRA Good Clinical Practice Guide 2012: 14.2.1 GCP Training, p. 449.
QCRES_04 Researchers Guide to appropriate Delegation of Duties for UoL/LTHT Sponsored CTIMPs
The Medicines for Human Use (Clinical Trials) Regulations 2004
The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

Section E: Acronyms

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CV	Curriculum Vitae
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigator Site File
LTHT	Leeds Teaching Hospitals NHS Trust
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health Research
PI	Principal Investigator
QA	Quality Assurance
SOP	Standard Operating Procedure
TMF	Trial Master File
UoL	University of Leeds
UK	United Kingdom

Section F: Previous versions of Document

Version no.	Valid from	Approved by	Date approved
1.0	29/09/2016	Clare Skinner Louise Brook	05/10/2016
2.0	20/12/2017	Clare Skinner Louise Brook	20/12/2018

Appendix A: Example SOP Training Log

Please note: the form below is an example of a SOP Training Log and is to be used as a guide only.

UNIVERSITY OF LEEDS / NHS The Leeds Teaching Hospitals NHS Trust	Title:	**SOP Training Log** [Template]

Staff Member Details:

Name:	
Job Title:	

SOP Training Record:

SOP Details:			**Training Requirements:**		**Review Details:**		**Training Details** (*if applicable*):		
SOP Code:	SOP Version:	SOP Date:	Read Only (✓):	Training Req'd (✓):	Date Reviewed:	Staff Signature:	Training Provided by:	Trainer Signature:	Date Trained:
		MM/DD/YYYY			MM/DD/YYYY				MM/DD/YYYY
		MM/DD/YYYY			MM/DD/YYYY				MM/DD/YYYY
		MM/DD/YYYY			MM/DD/YYYY				MM/DD/YYYY
		MM/DD/YYYY			MM/DD/YYYY				MM/DD/YYYY
		MM/DD/YYYY			MM/DD/YYYY				MM/DD/YYYY