




SOP Number **004**
SOP Title **Training for Clinical Research**

	Name	Title	Signature	Date
Author on behalf of the QA Focus Group	Clare Riddle	Senior QA and Compliance Manager, Clinical Trials and Research Governance		06 SEPT 2019
Reviewer on behalf of the QA Focus Group	Elaine Chick	Deputy Head of Clinical Trials and Research Governance		19.9.19
Authoriser	Heather House	Head of Clinical Research Support (University Lead of the Joint Research Office)		19/09/2019

Agreed by QA Focus Group	7 August 2019
Effective Date	25 Nov 2019
Review Date	24 Nov 2022

1. PURPOSE

This SOP describes the processes which units will put in place to ensure that those involved in clinical research are demonstrably qualified by education, training and experience to perform their respective study roles and responsibilities.

2. INTRODUCTION

The principles of Good Clinical Practice (GCP) state that each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s). Such training should be proportionate to need, in line with GCP principles, and meet applicable legal and contractual requirements.

3. SCOPE

The scope of this procedure is for all CTIMPs and device trials sponsored by the University of Oxford, but may also be used for other clinical research studies at the discretion of the unit.

4. DEFINITIONS

Curriculum Vitae (CV)

A CV written, signed and dated to provide clear, comprehensive, concise evidence of education, qualifications, experience and training relevant to the researcher's current role and responsibilities.

Training record

A record of training completed by those involved in clinical research in terms of GCP, general training, study-specific and role-specific training.

5. RESPONSIBILITIES

Relevant Manager

Responsible for implementing and maintaining processes and documentation that ensures that staff receive and record relevant training.

Chief Investigator/Principal Investigator (CI/PI)

Responsible for ensuring that the Study Team have received all necessary training to allow formal delegation of responsibilities.

All staff

Ensure that SOP, GCP, study-specific and role-specific training are up-to-date and adequately recorded in training records.

6. SPECIFIC PROCEDURE

6.1 SOP training

All staff should be trained prior to undertaking any clinical research activity unsupervised.

All staff will read and familiarise themselves with the necessary SOPs, and document this in a training record. Additional training may be required on certain procedures, and this will be planned and recorded when performed.

A system should be in place to identify when training or retraining is required, for example following changes to a SOP and/or a member of staff taking on a new role, and this process should ensure that anyone carrying out a particular duty receives the same level of training.

6.2 GCP training

GCP training may be face-to-face or online, and should be appropriate and proportionate to the role and the activities undertaken by the member of staff. This will be determined by the CI, PI or a relevant manager.

Training should be refreshed as necessary e.g. following a significant change in GCP, on returning to research following a prolonged break, or upon a change in role. Refresher training may also be required at periodic intervals, the frequency of which may be determined by unit or external policy.

Training undertaken must be recorded in a training record.

6.3 Study-specific training

The CI/PI is responsible for ensuring that study-specific training is delivered, which will be documented.

All staff will ensure that they receive relevant training on the protocol, and other study-related documents, to a level that enables them to perform their delegated duties appropriately, and that they have read and understood the content. They must complete the required training before starting study-specific activities, and training must be maintained as necessary throughout the study.

If required, retraining will be delivered following an amendment to the protocol or other changes to study procedures.

6.4 Training records

Staff training records should contain at least the following:

- A current signed and dated CV
- Evidence of GCP training appropriate to their role
- Evidence of SOP training
- A current job description/role outline
- Evidence of any relevant internal and external training
- Evidence of study-specific training

Any of the above may be stored separately so long as their location is recorded in a file note. Training documentation must be stored securely and be easily accessible for update by individuals, and review by authorised parties. Obsolete records should be archived.

7. RELATED DOCUMENTS

University of Oxford Core SOP 005 - Archiving of Essential Documents

University of Oxford Core SOP 006 - Trial Master File and Investigator Site File

8. REFERENCES

ICH Harmonised Tripartite Guidelines for Good Clinical Practice (ICH GCP) 1996

Joint Statement on the Application of Good Clinical Practice to Training for Researchers: HRA, MHRA, Devolved Administrations for Northern Ireland, Scotland and Wales (v1.1 12/10/17)

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
1.0	01 Jan 2014	First version of SOP	N/A
1.0-rev01	01 Jan 2017	SOP text unchanged – effective and review date updated	1.0
2.0	see page 1	Introduction and Scope updated Clearer guidance on requirements for GCP, SOP and refresher training Change in job title on page 1	1.0-rev01