STANDARD OPERATING PROCEDURE

S26 – Providing and Documenting Training for Researchers

Version	3
Effective Date	5th July 2021
Review Date	4th July 2024
Author & Position	Nicola Jones, Quality Assurance Coordinator
Signature	N. Jones
Date	14/7/21
Approver & Position	Helen Quinn, R&D Director
Signature	
Date	20 July 2021

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
V1.0	25 November 2011	Research Management & Governance Manager	New policy to meet standards
V1.1	16 April 2014	Research Management & Governance Manager	Revision to reflect minor changes to SOP format.
V2.0	23 March 2018	QA Coordinator	Update into Trust template Record change of GCP training frequency
V3	May 2021	QA Coordinator	Update into current version Trust template. Addition of reference to Training Matrix and regular training record reviews.

Associated Trust Policies/ Procedural documents:	Trust Recruitment and Selection Policy Trust R&D Policy
Key Words:	Training Record Log Frequency GCP CV Delegation CTIMP
In consultation with: Quality Assurance Group (March 2018) Quality Assurance Group (May 2021)	

Contents

1 INTRODUCTION

It is a legal requirement that research staff involved in conducting Clinical Trials of Investigational Medicinal Products (CTIMPs) must be appropriately qualified to carry out their role. Evidence of this must be provided.

There are several elements to consider:

i) Ensuring that research staff have appropriate qualifications and experience
ii) Ensuring awareness of regulatory and legal requirements
iii) Providing appropriate training
iv) Providing opportunities for continuous professional development
v) Promoting a quality research culture by supporting staff

The responsibility for meeting these requirements is shared by a number of individuals and organisations such as the employing organisation of research staff, the Chief Investigator (CI) and the Principal Investigators (PI) themselves. The key documents setting out the requirements and /or responsibilities are:

The Medicines for Human Use (Clinical Trials) Regulations, 2004 and subsequent amendment regulations

UK Policy Framework for Health and Social Care Research

Importantly, although it is only a legal requirement for research staff involved in conducting CTIMPs to be appropriately qualified to carry out their role, the principles should still apply for staff involved in ALL research projects within the NHS, which have to meet the UK Policy Framework for Health and Social Care Research and any other clinical research which may have an impact on the safety and wellbeing of human participants.

2. PURPOSE

- To describe the responsibilities of key individuals and organisations with regard to the provision of training / education for research staff
- To list the documentation required to demonstrate education, experience and training of research staff.

3. SCOPE

This SOP should be read and used by all members of a research team, both in the clinical setting and in the Research and Development (R&D) department.

4. DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CV	Curriculum Vitae
GCP	Good Clinical Practice
HR	Human Resources (Department)
PI	Principal Investigator
R&D	Research & Development
SOP	Standard Operating Procedure

5. DUTIES AND RESPONSIBILITIES OF STAFF

This SOP should be used by staff in the member organisations of the Royal Devon & Exeter NHS Foundation Trust (hereafter called 'the Trust') who are involved in research studies and who have responsibility for ensuring that they, and/or any research staff they manage, are appropriately qualified and trained to carry out their research role. This SOP should be referred to:

- When new research staff are appointed

- When a new member of research staff takes up post
- When a new research project begins
- When an amendment to an ongoing research project has training implications for staff
- At annual appraisals (PDR) of research staff
- At regular training reviews

6. PROCEDURES

6.1 Ensuring Relevant Experience and Identifying Training Needs

6.1.1 When new research staff members are appointed: seek evidence that the person concerned has the appropriate qualifications and experience, with reference to the Trust's Recruitment and Selection Policy.

6.1.2 When a new member of research staff takes up post:

- Provide an appropriate induction
- Agree and document training objectives
- Identify and provide / organise appropriate training, to include awareness of and reading the relevant departmental SOPs with reference to the R&D Training Matrix.

6.1.3 When a new research project begins;

6.1.4 When an amendment to a research project has training implications;

6.1.5 At annual appraisals of research staff:

- Agree and document training objectives with staff as appropriate
- Identify and provide / organise appropriate training.

6.1.6 All research staff working on research studies taking place in the Trust must be aware of any applicable regulatory requirements pertaining to the conduct of such trials. Each member of staff must undertake Good Clinical Practice (GCP) training before commencing work on a CTIMP. For interventional non-CTIMP studies it is expected that the CI or PI will undertake GCP training prior to the study opening. The Trust R&D Policy requires GCP training to be updated every three years, unless a Sponsor requires sooner.

6.1.7 Training may also be required on other legal and regulatory requirements, especially when there are changes to existing legislation.

6.1.8 It is the responsibility of the CI /PI to ensure that all staff allocated duties on the Delegation of Responsibility Log are suitably trained in activities linked to those duties. These activities may include training on SOPs, research methods, trial specific procedures, clinical procedures and specific diseases.

6.1.9 The CI/PI and other appropriate departmental staff can initially arrange appropriate training but staff are encouraged to be pro-active with regard to their own training.

6.1.10 The Clinical Trial Regulations require that, "Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s)." There are two responsibilities here:

- All staff engaged in research are responsible for ensuring that they are competent to perform any tasks delegated to them, and for undertaking appropriate training as necessary before agreeing to accept the delegation;
- Anyone authorising delegation of research tasks must take all reasonable steps to ensure the delegate is appropriately qualified for that task. All relevant elements should be considered – not only professional qualifications but also GCP training and familiarity with the protocol.

6.1.11 All delegation decisions should be properly considered and recorded in the Trial Master/Site File Delegation Log.

6.1.12 Training records must be reviewed regularly to identify gaps. If a member of staff feels that he or she requires extra training on procedures, arrangements should be made to provide this training. Refresher courses are to be arranged on procedures where expertise may have lapsed.

6.1.13 The Training Record Review Log will be completed and signed off at each review and if there is any training found to be outstanding it should be documented why it is not up to date and confirmation of the action required to bring it up to date.

6.2 Training Records

6.2.1 Creating and Maintaining Training Records

A training record must be kept for each member of staff involved in running a research study. Each member of staff should create their own training record and keep his/her record up to date. The record may take the form of a separate file, form part of a personnel file (file containing personal information, e.g. performance records, usually held by HR or a line manager) or other format as per Trust or unit/department procedure.

Training records containing confidential documents should be stored securely in a locked room. They may be stored in a central location per unit/department or with individual line managers as per Trust or unit/department procedure. Individuals must be able to gain access to their training files.

Training records must be available for inspection as required by regulatory and other relevant authorities.

6.2.2 Content of Training Record

The following documents make up a training record and shall be maintained as evidence of education, training and experience.

i) Job description - A signed and dated job description confirms the role and responsibilities assigned to an individual. If a person's role or title changes, the new job description shall be signed and dated, and filed. The previous job description(s) shall also be kept.

ii) Curriculum vitae (CV) - A current signed and dated CV demonstrates education and prior experience. CVs should be reviewed annually and updated as appropriate. Current and superseded CVs shall be kept so as to provide evidence of continuity in the Site File for the duration of a study.

iii) Certificate of Higher Education & professional registration, or evidence of education and registration where applicable, should be demonstrated at interview or on appointment. Where this is confirmed, copies are not required for the training file, but may be maintained in personnel files.

iv) Training while in post - Evidence of training attended should be kept. Supporting documentation should include:

- The course / training outline (including trainer's name and title, title of course, objectives, location, date and duration of training)
- Certificate of attendance (copy)
- Where supporting documentation of attendance is not available, whether a course, workshop or one-to-one tuition, the following information shall be provided:
    a. Title of training
    b. Objectives
    c. Location of training
    d. Date training undertaken
    e. Duration of training (e.g. one hour/day/month)

If a certificate confirming attendance / qualification is not available, e.g. in situations where one to one training has been provided, evidence from the trainer should be obtained e.g. an e-mail or the trainer's signature on the

training log. Training information from a previous post may be included in the training record, where relevant.

v) SOP training log: A signed and dated SOP training log provides evidence of review and understanding of SOPs.

vi) Training Record Review Log

6.2.3 Archiving Training Records

On permanently leaving the employment of the Trust concerned, staff members may take their training records with them. However, a full copy must be retained within the Trust until the archiving period of the relevant study / studies on which the person has worked, has expired. Training records of staff who have left the Trust may be archived in the R&D Unit, HR personnel file and/or Electronic Staff Record as per Trust policy.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 *If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.*

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Provide an appropriate induction for new members of staff.	Training Record
2.	It is the responsibility of the CI /PI to ensure that all staff allocated duties on the Delegation of Responsibility Log are suitably trained in activities linked to those duties.	CV and Training Record for members of staff on delegation log.
3.	A training record must be kept for each member of staff involved in running a CTIMP.	Training Record
4.	Training records must be reviewed regularly with a Training Review Log completed each time to document any outstanding training.	Training Review Log within Training Record

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the RDE Research website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

UK Policy Framework for Health and Social Care Research
Trust Recruitment and Selection Policy
Trust R&D Policy