York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S25

Providing and Documenting Training for Researchers

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit's website: www.northyorksresearch.nhs.uk/sops.html

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	Date:	8th May 2017
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	Signature:	Signed copy held by R&D Unit
	Date:	8th May 2017

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	1st February 2008	Issued as Guidance Document
2.0	8th March 2010	Document updated and reissued as SOP. Other SOPs cross referenced.
3.0	14th June 2013	Change of SOP Controller. Removal of North and East Yorkshire R&D Alliance references. Extension of SOP to all research not just CTIMPs. Removal of detail about Clinical Trials Regulations and RGF.
4.0	5th June 2017	Change of author

Contents

1 Introduction, Background and Purpose

It is a requirement that staff involved in conducting research must be appropriately qualified to carry out their role. Evidence of this must also 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 and members of research teams.

The key documents setting out the requirements and /or responsibilities are:

- The Medicines for Human Use (Clinical Trials) Regulations, 2004 and subsequent amendment regulations[1]
- The Research Governance Framework (RGF) for Health and Social Care (2nd edition, 2005).

The purpose of this SOP is to:

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

2 Who Should Use This SOP

This SOP should be used by staff within York Teaching Hospital NHS Foundation 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.

3 When this SOP Should be Used

This SOP should be referred to:

[1] The Medicines for Human Use (Clinical Trial) Regulations 2004 and the Medicines for Human Use (Clinical Trial) Amendment Regulations 2006 (SI 2006 No. 1928), the Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 (SI 2006 No. 2984), the Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (SI 2008 No. 941), and the Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 (SI 2009 No. 1164).

- 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 of research staff

4 Procedure(s)

4.1 Ensuring Relevant Experience and Identifying Training Needs

When new research staff are appointed:

- Seek evidence that the person concerned has the appropriate qualifications and experience, with reference to the Trust's HR policy

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

When a new research project begins
When an amendment to a research project has training implications
At annual appraisals of research staff:

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

It is the responsibility of the CI/PI to ensure that all staff allocated duties on the Delegation of Duties Log are suitably trained in activities linked to those duties. These activities may include training on Standard Operating Procedures, research methods, informed consent, trial specific procedures, clinical procedures and specific diseases (Appendix A).

All research staff working on research studies taking place in York Teaching Hospital NHS Foundation Trust must be aware of any applicable regulatory requirements pertaining to the conduct of such trials. Each member of staff should undertake GCP training before commencing work on a clinical trial of an investigational medicinal product (CTIMP). GCP training should be updated as deemed appropriate by the study Sponsor and/or York Teaching Hospital NHS Foundation Trust. Training may also be required on other legal and regulatory requirements, especially when there are changes to existing legislation.

The CI/PI and other appropriate departmental staff may arrange initial training for members of research teams but individuals are also encouraged to be pro-active with regard to their own training needs.

The Medicines for Human Use (Clinical Trials) Regulations and the Research Governance Framework require that each member of a research team is qualified by 'education, training and experience' to perform his / her role in a particular study. There are two responsibilities here:

(1) 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 if necessary before agreeing to accept the delegation;

(2) anyone authorising delegation of research tasks must take all reasonable steps to ensure the delegate is appropriately qualified for each delegated task. All relevant elements should be considered – not only professional qualifications but also GCP training and familiarity with the protocol.

All delegation decisions should be properly considered and recorded in the delegation log (see R&D/S03).

Training records must be reviewed regularly to identify gaps. If a member of staff thinks 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.

4.2 Training Records

4.2.1 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 or other format as per Trust or unit/department procedure.

Training records containing confidential documents should be stored securely in a locked cabinet/cupboard. They may be stored in a central location per unit/department or with individual line manage 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 monitors, regulatory and other relevant authorities.

4.2.2 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. Previous CV(s) shall also be kept.

iii) Certificate of higher education & professional registration

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:
  - Name and title of trainer
  - Title of training
  - Objectives
  - Location of training
  - Date training undertaken
  - Duration of training (e.g. 1 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.

A suggested Training Log (R&D/F55) can be found on the R&D Unit's website

v) SOP training log

An electronic Q-Pulse training record provides evidence of review and understanding of SOPs. Q-Pulse can be used to generate a list of the SOPs and versions which have been acknowledged by relevant research staff. This list may be used to update personal training files or to prepare for an audit or MHRA inspection. When required, this list can be provided by the R&D unit SOP Controller or Research Quality Assurance Officer.

V1) Archiving Training Records

On permanently leaving the employment of the Trust, 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, Electronic Staff Record as per Trust policy.

5 Related SOPs and Documents

R&D/S01 Preparation, Review and Approval of Standard Operating Procedures for Research

R&D/S03 Delegation of Roles and Responsibilities for Trust Sponsored Research Studies

R&D/F02 SOP Training Log

R&D/F55 Training Log

6 Appendix A

Suggested Topics for Training Related to Clinical Trials

1. Regulatory and legal requirements

    a. The Medicines for Human Use (Clinical Trials) Regulations 2004
    b. The principles of Good Clinical Practice (GCP) as set out in EU Directive 2005/28/EC; the 'GCP Directive' (implemented in the UK as Statutory Instrument (SI) 2006 No 1928)*
    c. Other Amendments to the Medicines for Human Use (Clinical Trials) Regulations, as appropriate
    d. The Research Governance Framework for Health and Social Care (2nd edition), 2005*****
    e. The Human Tissue Act 2004
    f. The Mental Capacity Act 2005

    * Mandatory for all clinical trials of investigational medicinal products

2. Relevant Standard Operating Procedures for the study

3. Research Methods
   e.g. understanding research protocols, randomisation procedures

4. Trial Procedures and Documentation
   e.g. taking informed consent, completing case report forms, reporting adverse events, data management

5. Clinical Procedures
   e.g. taking blood, carrying out ECGs, preparing and dispatching specimens

6. Disease Specific Training
   e.g. aetiology, pathology, signs and symptoms and treatment.