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

Providing and Documenting Training for Research Staff

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 and/or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	9th July 2019
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	Signature:	Signed copy held by R&D Unit
	Date:	9th July 2019

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
5.0	6th August 2019	Change of link to R&D website. Update to GCP requirements and identifying training needs, addition of information regarding Research CVs & EDGE (central repository for the key training documents).

Contents

1 Introduction, Background and Purpose

It is a requirement that staff involved in conducting clinical 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 (the relevant trial specific training, therapeutic area training, Good Clinical Practice training appropriate and proportionate to the type of clinical research undertaken, and training in R&D written procedures).

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 study Sponsor, Chief Investigator, the local Principal Investigators, and the Employing Organisation of research staff (R&D staff, members of Research Teams and Support Departments).

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

- The Medicines for Human Use (Clinical Trials) Regulations, 2004 and subsequent amendment regulations
- MHRA/HRA/Devolved Administrations '*Joint Statement on the Application of Good Clinical Practice to Training for Researchers*' 2017
- MHRA GCP Guide, 2012
- The UK Policy Framework for Health and Social Care Research 2017.

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.

This SOP is also applicable to staff within the host organisations that were selected and contracted as Investigator Sites for York Teaching Hospital NHS Foundation Trust's sponsored studies.

3 When this SOP Should be Used

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.
- When a new Investigator Site is contracted for a Trust sponsored study.
- When an amendment to an ongoing Trust Sponsored study has training implications for Investigator Sites' 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 (the therapeutic area and research specific induction, including the R&D Unit and support departments' induction, and the current portfolio of research projects).
- Agree and document training objectives.
- Identify and provide / organise appropriate training: therapeutic area training (where required) and research specific training, including training in the R&D Unit written procedures, and role-specific training relevant to the post holders duties and clinical research role/s and responsibilities that are to be undertaken.
- Request a research Curriculum Vitae (CV) from the staff member to demonstrate their current & previous relevant education and

experiences, signed and dated to confirm the date of the document and ownership by the named individual. Template for a research CV can be downloaded via the following link: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/

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;
- Review the most recent research CV and identify if updates are required;
- Trial specific training must be undertaken and documented prior to commencement of a trial/ or prior to a substantial amendment to a trial being implemented. **Training needs for staff who join a research study team after the trial has started must also be taken into consideration and documented.**

Identifying Good Clinical Practice (GCP) training needs:

The Clinical Trial Regulations require that each individual involved in conducting a clinical trial of an investigational medicinal product (CTIMP) should be qualified by education, training and experience to perform his/her respective task. This applies not only to the study PI, but also to any members of the trial team to whom responsibilities are delegated. A key requirement for anyone involved in the conduct of clinical trials is Good Clinical Practice (GCP) training. GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

- **GCP Training is mandatory** for all research staff involved with clinical trials using investigational medicinal product (CTIMPs).

Both the HRA and the MHRA advocate a **proportionate** approach to the application of GCP to the conduct of clinical trials and the appropriate training of staff involved. However, for **ALL CTIMPs** it is the **high level "conditions and principles" of GCP** (see Appendix A) set out in the UK Clinical Trials Regulations that **must be complied with** and interpreted in proportion to the risks posed to the participants and to the integrity of the results.

It is a requirement set by the York Trust R&D Unit that research staff who are new to clinical research, or who have not been actively involved in clinical research for a period of time, must undertake the face-to-face Introduction to GCP training course provided by the NIHR. Subsequently, GCP refresher training should be undertaken **at least every three years -** this is the minimum requirement for our organisation. However, GCP training might be required to be updated at more frequent intervals if deemed appropriate and proportionate to the complexity of the CTIMP study/or activities undertaken for the trial by the study Sponsor and/or the Trust R&D Unit. This may also depend on any changes in regulations at the time. Therefore,

sometime research staff may be requested by the study Sponsors and /or the R&D Unit to provide evidence of GCP refresher more often than every 3 years.

If a trial related activity is part of a person's normal clinical role and all other protocol activities are undertaken by a member of the research team, then no GCP training may be required for that person (e.g. staff involved in supporting activities such as phlebotomist, chemotherapy nurses or radiology staff where no trial related activities are undertaken outside of their usual role and competencies); however this should be reviewed as part of the risk assessment for a trial and confirmed with the study Sponsor, or R&D Unit contacted for advice. The MHRA strongly recommends training in relevant aspects of GCP for anyone involved in conducting CTIMPs, even if the activities are part of an individual's routine job. In such cases GCP training can be provided in a range of formats, including web-based or as self-directed reading.

On inspection, MHRA GCP inspectors will look for evidence that individuals involved in the conduct of CTIMPs have received adequate training in GCP and appropriate legislative requirements commensurate with their roles and responsibilities.

- **GCP Training is not legally required** for other types of research (i.e. studies which are not clinical trials of investigational medicinal products). Such research should be conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable. Members of the research team in such studies are expected to be qualified by education, training or experience but should not be required or expected to undertake GCP training.

Identifying training needs specific to the assigned portfolio of research studies:

As per the UK Policy Framework for Health and Social Care Research 2017 it is expected that all staff working on any research study (not just CTIMPs) conducted within the York Trust hospitals and/or Sponsored by the York Trust, are appropriately qualified by education, training and experience to perform tasks that they have been delegated.

The key responsibilities here are:

(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 (for CTIPMs), familiarity with the protocol, trial specific Standard Operating Procedures, research methods, informed consent, clinical procedures and specific diseases (see Appendix B). All delegation decisions should be properly considered and recorded in the delegation log (see R&D/S03).

(3) Staff are also responsible for self-directed training in R&D SOPs, and for setting up and maintaining individual research training folders.

(4) 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. See section 4.2 for the requirements of maintaining Training Records.

(5) 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.

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. Training records should be stored securely in a locked cabinet/cupboard. The record should take the form of a separate file and 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) and GCP training Certificate (for CTIMPs only):

- A current certificate confirming GCP training, including clear references to the date & the form of training (on-line or face to face), training provider and the framework used in the training, must be present in the Training File for all staff involved in CTIMP trials.

The NIHR GCP training (on-line & face to face) can be accessed and enrolled on via the NIHR Learn: *https://learn.nihr.ac.uk*
NHS email address is required to be eligible for the NIHR Learn account.

- A current signed and dated research CV demonstrates education, training and prior experience. Research CVs must include evidence of ICH GCP training (when provided for CTIMP trials) and current medical practitioner registration details (where applicable). The relevant education & training should also be referenced in the CV. Research CVs must be updated **at least every three years** to reflect updates to GCP and other research relevant training & experience - this is the minimum requirement for our organisation. However, CVs might be required to be updated at more frequent intervals if deemed appropriate and proportionate to any updates in training, education and

experience at the time. Therefore, sometime research staff may be requested by the study Sponsors and /or R&D Unit to provide updated research CV more often than every 3 years.

All staff with research duties and responsibilities delegated to them should undertake the appropriate training (GCP and/or study specific) and provide current research CV before commencing any work on a research project.

Template for a research CV can be downloaded via the following link: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/. A scanned copy of the current research CV and GCP certificate should be sent to the R&D Unit (via research.governace@york.nhs.uk) to be uploaded to the EDGE *General Documents* central repository.

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 should be maintained in personnel files.

iv) Training while in post

All research related training while in post should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities as set out in relevant legislation and standards. Evidence of training attended should be maintained.

There are no set requirements for the frequency of such training. **Research staff are expected to maintain awareness of current standards** through reference to published guidance and procedures, R&D Unit research QA update emails, the local R&D Research Forums, Quarterly R&D QA meetings, and Trial Management Group meetings for Trust Sponsored studies. Training may need to 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.

Please note:
Trial specific training must be undertaken and documented prior to commencement of a trial/ or prior to a substantial amendment to a trial being implemented. This type of training should be documented within the study Investigator Site File.

Supporting documentation for the relevant research training while in post 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) R&D SOPs training log

An electronic Q-Pulse training record provides evidence of review and understanding of R&D Unit 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 staff.

Self-directed training in York Foundation Trust R&D Unit SOPs on Q-Pulse is detailed in R&D/S22. This training is to be carried out on *'read and understand'* basis. However, certain procedures, such clinical research consent will require 'competency sign-off' as assessed by the R&D Unit Senior Research Nurses.

Please Note:
Appropriate and realistic time should be allowed by individual staff members for written procedures to be *'read and understood'* in order for this type of training to be efficient. It's not acceptable for a large number of written procedures to be listed on the Q-Pulse training record showing as '*read and understood'* within a very short period of time. The extent of the self-directed training will depend on the research activities undertaken by particular members of staff. Upon receipt of an email from Q-Pulse alerting that a new SOP or an updated version of an SOP, or other document has been distributed, recipients should read the document, assess its relevance to their role and responsibilities, and acknowledge confirming they have read and understood the background and purpose of the procedure. For the procedures that are relevant to the job role and undertaken duties, staff members should allow time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification to any of the distributed procedures is needed, the SOP Controller or the SOP Author should be notified.

vi)) 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 should be archived in the R&D Unit, alongside the HR personnel file, Electronic Staff Record as per the Trust policy.

4.2.3 Maintaining track record of research CVs & GCP certificates for York Trust staff

A central repository for research CV's and GCP Certificates is located on the EDGE data base under *General Documents* (www.edge.nhs.uk/GeneralDocument). An active spreadsheet will be maintained by the Research Administrative Co-ordinator and checked monthly. CV/GCP that is within a month of going out of date (three years passed the training day) will be identified and the relevant team/s will be contacted to provide an updated document.

New CV/GCP records will be updated to EDGE regularly and available for all Research staff to download directly from the system. Upload of new documents is limited to EDGE Administrators, if a staff member has a new CV/GCP this should be sent to research.governace@york.nhs.uk and forwarded to EDGE Administrators for uploading on the system.

5 Related SOPs and Documents

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

R&D/S03 Delegation of Tasks for Trust Sponsored Research Studies

R&D/F55 Training Log

R&D/S22 Self-directed training in York Foundation Trust R&D Unit Standard Operating, Procedures on Q-Pulse

6 Appendix A

The Medicines for Human Use (Clinical Trials) Regulations (2004) [as amended]

CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS

Principles based on Articles 2 to 5 of the GCP Directive5

1. The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.

2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.

3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.

4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.

5. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.

7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

Conditions based on Article 3 of the Directive

10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial

7 Appendix B

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. UK Policy Framework for Health and Social Care Research 2017
    e. The Human Tissue Act 2004
    f. The Blood Safety and Quality Regulations (BSQR, 2005)
    g. The Mental Capacity Act 2005
    h. IRMER Regulations 2017

2. Relevant Standard Operating Procedures and instructions/manuals for the study, e.g. Laboratory Manual, Pharmacy Manual, RECIST instructions for oncology trials (Response Evaluation Criteria In Solid Tumours)

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.