SOP 505 Training Requirements, Creating and Maintaining Training Records

For Use in:	Research & Development
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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SOP 505 v1.5

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

Contents

2. Definitions of Terms Used / Glossary

CV	Curriculum Vitae
EU	European Union
GCP	Good Clinical Practice
HRC	Honorary Research Contract
ICH GCP	International Conference on Harmonisation for Good Clinical Practice
JD	Job Description
LoA	Letter of Access
NIHR	National Institute for Health Research
R&D	Research and Development
SOP	Standard Operating Procedure

3. Scope

This SOP describes the training requirements and how training records are created and maintained in order to comply with regulatory requirements of ICH GCP

This SOP determines the minimum training requirements and the process for maintaining training records for NNUH staff and UEA staff and students undertaking healthcare research

4. Introduction

Each individual involved in the conduct of research must be qualified by education, training and experience to perform the tasks of the study.

In order to demonstrate that training has occurred, documentation must be maintained and retained for all staff involved within the research and supporting functions, where applicable. The extent and content of this documentation is a business decision; but for NNUH this SOP describes the minimum requirement.

Persons conducting research must undergo GCP training commensurate with their roles and responsibilities, as described further in SOP 002 Good Clinical Practice (GCP) Training.

Line Managers must ensure that training records are established, maintained and reviewed in accordance with this SOP.

All staff working on healthcare research within the Trust and UEA must ensure that they are familiar with the requirements of ICH GCP and are responsible for maintaining their own training records.

Tailored training matrix should be maintained which describes training for procedures such as SOP's and policy documents.

Additionally, trial specific training must be carried out for each individual involved. There must be documented evidence of the training maintained within the trial documentation for as long as they may be needed, to support historical reconstruction of any trial.

In addition to formal methods of training activities, research teams may use other methods of information sharing:

- Posters
- Newsletters
- Intranet
- Team meetings
- Mentoring

It is good practice to make a journal of such methods with time points; to demonstrate that informal training has been conducted and attended.

It is vital that individuals training records and study specific training is produced maintained and reviewed on a regular basis and must be ready for inspection by R&D, Sponsor and Regulatory Inspectors.

5. Requirements of ICH GCP

Current job description (JD)

- Dated and signed by the post holder and their line manager, to demonstrate the date on which current roles and responsibilities have been agreed

Curriculum vitae (CV)

- To demonstrate current and previous relevent education and experience, signed and dated to confirm the date of the document and ownership by the named individual

Confirmation that GCP training has taken place

- Including clear reference to the framework used in the training, such as UK Statutory Instruments and EU Directives

Role-specific training

- Relevent to the post holders duties and clinincal trial roles and responsibilities

Written procedures training records

- Training Matrix, documents training for specific SOP's and procedures

6. Review timeframe

Job Descriptions

- Job Descriptions (JD) should reflect your current role, if your role changes then the JD should be updated.
- Otherwise a 2 yearly review should be undertaken for accuracy
- Historic JD should be marked as superseded and retained in the historic document section

Curriculum Vitae

- If your role or title changes then your CV should be updated to reflect this
- Otherwise a 2 yearly review should be undertaken for accuracy

GCP Training

- Every two years for the duration of the research project, unless there are changes to legislation, changes will be communicated by R&D

Role Specific Training

- Update for new training procedures on an on going basis

Training Matrix

- Notifications of new versions will be issued to all research staff, where there are training implications then they must be read and understood if the procedures are relevent to your role
- Update the training matrix to reflect that the SOP and new procedure has been understood, recording the version number, signing and dating by postholder and line manager required

Study Specific Training

- The study delgation log must reflect all staff who are working on a project and describe the roles undertaken by each individual
- When an individual leaves the organisation or no longer undertakes work on the project the delegation log for the study should be amended accordingly

All training documentation must reflect your current status; therefore it is best practice to review all training documentation on an on-going basis and document that you have performed a full review at least every two years.

7. Research Passports

Letters of Access (LoA)

- NHS to NHS staff OR applicant is clinical academic with an Honorary Contract with an NHS institution who require access to perform research within NNUH R&D projects, will require a letter of access approved by NNUH R&D
- Proof of workplace, role, identification will need to be verified by their NHS employer before access is granted
- LoA and R&D approval required

Honorary Research Contract (HRC)

- Researcher's substantive employer is a Higher Education Institution or research employer working in partnership with NIHR
- The HRC can be obtained via the Research Passport application system and must be in place before work can commence on a project

Information and Application

- For further information and advice on the application process please email <Office.RD@nnuh.nhs.uk>

8. Approval

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Date:	**09 December 2019**

9. Reason for Update and Training Implication

This replaces SOP 505 v1.5

Update	Reason	Training Implication	Action
• Process updated throughout • Updated to new template	Periodic review required	Yes	Review SOP and update training matrix