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SOP 505 Training Requirements, Creating and Maintaining Training Records

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
2	30/9/2024	CR268	Review due to removal of matrix NCTU requirements added	Jackie Orford / Lou Coke / NCTU / UEA

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

Copies downloaded from the website are only valid on the day of downloading.

1. Contents

2. Definitions of Terms Used / Glossary

CV	Curriculum Vitae
GCP	Good Clinical Practice
ICH GCP	International Conference on Harmonisation for Good Clinical Practice
NCTU	Norwich Clinical Trials Unit
R&D	Research and Development
SOP	Standard Operating Procedure

3. Objectives

To describe training requirements for those undertaking healthcare research.

4. Scope

This SOP describes training requirements and how training records are created and maintained in order to comply with regulatory requirements of ICH GCP. The SOP determines the minimum training requirements and the process for maintaining training records for NNUH staff, UEA staff and students undertaking healthcare research.

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 will be determined by each organisation, but for NNUH this SOP describes the minimum requirement.

5. Purpose

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

People 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. For trials led by NCTU, staff will need to comply with NCTU requirements.

A tailored SOP training record should be maintained which describes training for procedures such as SOPs 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 record 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 are maintained and reviewed on a regular basis and must be ready for inspection by R&D, the Sponsor and Regulatory Inspectors.

6. Requirements

Records required and review timeframe

- Job description which should reflect the current role.
  - If the role changes, then the job description should be updated. The historic job description should be marked as superseded and retained in the historic document section

- Curriculum vitae
  - to demonstrate current and previous relevant education and experience
  - signed and dated to confirm the date of the document and ownership by the named individual
  - If the role or title changes then the CV should be updated to reflect this. Otherwise, a 3-yearly review should be undertaken for accuracy.

- GCP Training

Confirmation that GCP training has taken place (where required in accordance with SOP 002 Good Clinical Practice Training) – including clear reference to the framework used in the training. Please refer to SOP 002 Good Clinical Practice Training for frequency of undertaking GCP refresher training.

- Role-specific training
  - relevant to the post holder's duties and clinical trial roles and responsibilities.
  - to be updated for new training procedures on an on-going basis.

- Training records
  - Such as a record from Q-Pulse which documents training for specific SOPs and procedures.
  - Notifications of new versions will be issued to all research staff via email.
  - Updated SOPs need to be reviewed by staff if the procedures are relevant to the role and their training record must be updated.

- Study specific training
  - Any study specific training needs to be documented e.g. via completion of training log or minutes from the meeting. Content of training (e.g copy of handouts) should also be saved alongside training log.
  - The study delegation 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 the current status. Therefore, it is best practice to review all training documentation on an on-going basis and document that a full review has been performed at least every three years.

7. References and Related Documents

References	
ICH GCP E6 / SI 2004/1041	
SOP No.	**SOP Title**
SOP 002	Good Clinical Practice Training

8. Approval

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9. Reason for new version and Training Implication

This SOP replaces the previous version number V2

Changes made	
Reason	• New layout • Clarifying procedure
Training Implication	**No**
Actions required	• NA