Maintaining Training Records

NJRO-GEN-SOP-014

Contents

1. **Background/Introduction**

2. **Purpose**

3. **Scope of Document**

4. **Procedure**

5. **Review and Monitoring**

6. **References**

7. **Appendices**

1. Background/Introduction

1.1   Staff working on research studies must ensure that they are familiar with the requirements of Good Clinical Practice and that they maintain their own training records to show that all members of the trial team are 'qualified by education, training and experience to perform their respective task(s)' (ICH GCP E6 (R2) 2.8).

1.2   All training undertaken by staff within the Research and Development Department must be carried out in conjunction with The Newcastle upon Tyne NHS Foundation Trust policies and procedures.

2. Purpose

This Standard Operating Procedure (SOP) describes the process for maintaining training records and what should be included in an employee's training file.

3. Scope of Document

This SOP relates to all individuals involved in research within The Newcastle Upon Tyne NHS Foundation Trust, Research & Development Department.

4. Procedure
4.1 Creation of Training Record File

4.1.1   All members of staff will ensure they maintain a Staff Training Record and folder. For new members of staff this shall be provided by their Line Manager at Local Induction.

4.1.2   The Staff Training Record will be labelled with the name of the staff member and the date of commencement.

4.1.3   Depending on the role of the individual, the Line Manager will advise on the appropriate Standard Operating Procedure (SOPs) and Working Instructions (WIs) required for the role within the first week of employment. These must be signed off by the individual on the day of completion. The current NJRO SOP

Reading Log should be used to document completion of appropriate SOPs and WIs.

4.1.4   The Line Manager is responsible for informing the individual of any mandatory training/policies/procedures that need to be completed. The individual is responsible for completing all mandatory training as per Trust policy.

4.1.5   The individual must keep their own log of any training/study/conference days that take place throughout their employment within the department.

4.1.6   During the probation period the Line Manager will identify any additional training required together with the individual.

4.2 Updating of Training Record File

4.2.1   It is the responsibility of the individual employee to maintain their own training record and update it as and when appropriate.

4.2.2   The training log should be updated with the name of the particular course, the date it took place, the provider, the duration and the location (Appendix 2).

4.2.3   The training log should always be kept in a safe and secure place to be available for audit when required or review by the individual's Line Manager. The Staff Training Record may be stored electronically by the individual but must be accessible as required. A file note should be placed in the training file explaining the exact location of the Staff Training Record.

4.2.4   If an individual leaves their current employment, the training log will be taken with them and a copy kept by their current Line Manager.

5. Review and Monitoring

5.1   The Line Manager and individual are responsible for reviewing the training records/files annually during the appraisal process and the following documents should be checked for completeness:

- CV – up to date, signed
- GCP – up to date
- Job description
- Copies of certificates from training course undertaken during the year
- Up to date training log (may be stored electronically).

5.2   Line Managers will review their staff training records after the 6 month probationary period and then at yearly appraisals thereafter.

5.3   Future training needs should be discussed during probationary reviews, one-to-one meetings and annual appraisals, and a plan put in place for training needed within the next working year. This will be documented within the individual's Personal Development Records (PDR).

6. References

ICH (2016) *Indexed ICH GCP Guidelines with Integrated Addendum E6(R2),* Canary Ltd, Surrey UK

7. Appendices

Appendix 1: Content of Training Record File

Appendix 2: Staff Training Record

Appendix 1: Content of Training Record File

- Current job description and any previous job descriptions which are relevant to the current post.

- Current CV demonstrating education, qualifications, training and experience

- Current GCP certificate

- Training log – both previous and current. These should list all the training an individual has received in their previous/current role, including mandatory training dates.

- Certificates of course attendance/study days

- SOP Reading Log

Newcastle Joint Research Office

Appendix 2: Staff Training Record

Name:	
Date of Employment:	

The Newcastle upon Tyne Hospitals NHS Foundation Trust Mandatory Training:

	Date completed.	Date completed.	Date completed.	Date completed.
Course Name				

Role Specific Courses/Conferences:

Name of Course	Course Date	Course Provider	Course Location	Course Duration

Staff Training Record, version 1.0, dated 28/11/2017

Maintaining Training Records   NJRO-GEN-SOP-014