Standard Operating Procedure			**50.013**
Setup and maintenance of training files: NHS			
Version	**4.0**		
Prepared by	Shona McDermott	Signature	Date
Approved by	Chloë Cowan	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category

NHS GG&C General

2. Staff Category

GCRF Clinical and Administration
Research & Development
Chief Investigators
Principal Investigators

3. Scope

This procedure applies to the Glasgow Clinical Research Facility (GCRF) and Research & Development.

4. Purpose

The purpose of this Standard Operating Procedure is to describe the procedure for the setup and maintenance of training files.

5. Procedures

All members of staff require a training file to provide a record and evidence that they are appropriately trained and qualified to perform their role. A paper copy of the training file will be held by the staff member in their relevant functional area.

5.1 Responsibility

Each member of staff is responsible for setup and maintenance of their own training file. The line manager or designee will check the training file for completeness on a regular basis as part of Personal Development Reviews and any audits.

5.2 Setup of a training file

A training folder will be provided by the appropriate line manager or designee for this purpose.

5.3 Content of a training file

Each training file must include an Index Page Form 50.013F which lists the minimum requirement.
The documents to be stored within each section are detailed in GUI 50.013F appendix 1. Where a section is deliberately empty, a Training Folder File Note (Form 50.013A) must be inserted. This should direct the reader to the location of the relevant documents or detail why it is empty.

5.4 Maintenance of training file

The training file will be maintained on an on-going basis. A training record (Form 50.013E) must be completed following attendance at any training or study events.

Training records can be maintained and updated either electronically or in paper form. However a paper copy of all documents must be held in the training file for the purposes of inspection and audit. The training file (paper copy) will be stored in a secure and accessible designated area in the relevant functional area.

Should a member of staff take up a new position in the Clinical Trials Unit (CTU) this should be recorded in the training file and a new job description and CV included in the file. Superseded records, job descriptions and CVs must be retained in the training file for audit and inspection.

5.5 Archiving

When a member of staff is leaving, a copy of their training file must be retained in the appropriate functional area for the purposes of inspection and audit. The required retention period will be determined by the line manager or designee. The staff member should take the original file with them to their new post.

6. Referenced documents

- Form 50.013A: Training Folder File note
- Form 50.013E: Training Record
- Form 50.013F: Training File Index

7. Related documents

- The Medicines for Human Use (Clinical Trials) Regulations 2004 and Amendments
- International Conference on Harmonization - Good Clinical Practice (ICH-GCP) 1996
- Good Clinical Practice Guide, Complied by the Medicines and Healthcare products Regulatory Agency, 2012

8. Document History

Version	Date	Description
1.0	02/07/2012	Release of 1st Version
1.1	28/08/13	Minor changes, new forms
1.2	30/06/14	Minor changes to form and transferred to new template
2.0	14/07/16	SOP restructure Update to file index Minor admin changes Update to approved and released by
3.0	19/12/2018	Staff category updated
4.0	11/12/19	Staff category update to include PIs