

## Glasgow Clinical Trials Unit Standard Operating Procedure

SOP number	50.013	Version	5.0
Title	Setup and maintenance of training files: NHS		

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SOP category	50 NHS GG&C General				
Staff category	<b>Staff Category</b>	<b>R</b>	<b>A</b>	<b>C</b>	<b>I</b>
	Nursing	X			
	Administration	X			
	Principal Investigator	X			
	Clinical Research Fellow	X			
	Site Clinical Trials Pharmacy	X			
	Clinical Research Imaging Facility (CRIF)	X			
	Project Management Unit (PMU)	X			
	GCRF Manager		X		
	GCRF Associate Director				X
	Senior R&I Manager				X

### 1. Scope

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

### 2. Purpose

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

### 3. 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.

#### 3.1 Responsibility

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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.

### **3.2 Setup of a training file**

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

### **3.3 Content of a training file**

Each training file must include a Training file Index Page (Form 50.013F) which lists the minimum requirement.

The documents to be stored within each section are detailed in Form 50.013F appendix 1. Where a section is deliberately empty, an NHS 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.

### **3.4 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.

### **3.5 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.

## **4. Referenced documents**

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

## **5. Related documents**

- The Medicines for Human Use (Clinical Trials) Regulations 2004 and Amendments

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- International Conference on Harmonization - Good Clinical Practice (ICH-GCP) 1996
- Good Clinical Practice Guide, Compiled by the Medicines and Healthcare products Regulatory Agency, 2012

### 6. Document history

Version	Date	Description
1.0	02/07/2012	Release of 1 <sup>st</sup> 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
5.0		Update to SOP template v2.0 Addition of RACI matrix Change of author and approver

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