# SOP02: Standard Operating Procedure for Staff Training & Records

**Authorship team:** Hayley Hutchings and Marie Thomas for Joint SOP Group (viz Angela Evans, Sarah Gaze, Kathy Malinovszky, Anne Seagrove, Ian Russell)

**Approved by WWORTH JMG (Ian Russell in chair)**

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1 Table of Contents

0 Version Record ........................................................................................................ 1
1 Table of Contents .................................................................................................... 2
2 Glossary ................................................................................................................... 3
3 Introduction ............................................................................................................... 3
4 Purpose ..................................................................................................................... 3
4 Roles & Responsibilities ............................................................................................. 4
6 Procedure .................................................................................................................. 5
6.1 Creation and maintenance of training records ....................................................... 5
6.2 Training flow Chart- For WWORTH staff with University Appointments .......... 6
6.2 Annual training cycle – Swansea University ......................................................... 7
6.3 Training Cycle - for staff external to Swansea University ..................................... 7
6.4 Training principles ................................................................................................. 7
6.5 Trial-specific training principles ........................................................................... 8
7 Training plan ............................................................................................................. 9
8 References ............................................................................................................... 10
9 Related SOPs ............................................................................................................ 10
10 Appendices ............................................................................................................. 10
   Appendix 1 Training log for Training SOP ............................................................... 11
   Appendix 2 Staff training log ................................................................................... 12
2 Glossary

The full Glossary is in Swansea University H drive/Documents/526 – WWORTH/Development Group/Glossary.

3 Introduction

Standard Operating Procedures (SOPs) are succinct formal documents designed to achieve consistency in specified trial functions by specifying standard practice in performing those functions (GCP 1.55 & 5.1.1 – EMeA, 2002). While SOPs should cite relevant legislation & regulations, and key references & evidence, they need not expound theory.

This document forms part of the standard operating procedures (SOPs) of the West Wales Organisation for Rigorous Trials in Health (WWORTH). This SOP sets out the ways in which WWORTH trains people paid to conduct trials and other rigorous research. It identifies the roles, responsibilities and actions of those engaged in training clinical trial staff and keeping records of this.

WWORTH SOPs are written in compliance with regulatory requirements – notably EU Clinical Trial Directive¹, ICH Good Clinical Practice (GCP)² and the NHS Research Governance Framework³. Where appropriate they distinguish regulatory requirements between Clinical Trials of a Medicinal Products (CTIMPs) and other research.

This SOP also advocates the principles of adult education, in particular the ‘learning cycle’. This cycle encourages trainers and trainees to identify learning needs, to plan training that meets those needs, to assess the success of that training, and to initiate the next cycle by evaluating outstanding or further learning needs and developing corresponding training plans.

4 Purpose

To describe the process to ensure clinical trial staff involved in trials and other rigorous studies receive appropriate training to comply with the requirements and guidance of regulatory authorities, employers and WWORTH. It aims to contribute to fulfilling: WWORTH’s need continuously to improve the knowledge and performance of trial and associated staff; the needs of individual staff to enhance their formal qualifications and operational skills; and the perceptions and experience of trial participants.
4 Roles & Responsibilities

The WWORTH Director is responsible for ensuring that WWORTH staff receive training that is: appropriate to their job descriptions; effective, efficient & equitable; and accords with relevant regulations & guidance.

A. The WWORTH Manager is responsible to the WWORTH Director for:

B. checking that WWORTH staff and those associated with WWORTH are up to date with training;

C. ensuring that new staff receive training in using WWORTH’s current SOPs during their induction;

D. informing staff about available and appropriate training, notably from NISCHR CRC, National Institute for Health Research (NIHR), UK Trial Managers Network (UKTMN), etc;

E. developing a general training plan for WWORTH staff and staff working with WWORTH on adopted studies;

F. checking that Trial Managers or Coordinators (TMs/TCs) attend a Clinical Trials (CT) management course recognised by the UKCRC; and

G. checking that other professionals comply with CPD requirements of their professions and employers.

CI/PIs are responsible for ensuring that all staff associated with a trial receive training that is:

- appropriate to their trial & job descriptions;
- effective, efficient & equitable;
- accords with relevant regulations & guidance;
- centred on the needs of users (see WWORTH-SOP09Userinclusion)

They will also ensure that adequate cover during training is readily available. PIs are responsible to their CI(s) for ensuring that local trial staff also receive training that is appropriate, effective, efficient, equitable, valid and user-centred.

TMs/TCs are responsible to their CIs for arranging trial-specific training and ensuring all trial staff keep their training logs up to date, including CVs and certificates of attendance. They should include adequate funding for trial-specific training within the trial budget, and ensure that it is spent appropriately.
and to the full. They should also ensure that trials appear in the research portfolios of UKCRC and NISCHR CRC (and any other relevant body, eg Clinical Study Groups) and access the corresponding resources (both for training and more generally) to which they are entitled, both appropriately and to the full.

**WWORTH core staff, Trial Statisticians and / or Trial Data Managers (TDMs)** are responsible for ensuring that their TMs/TCs arrange for training of staff associated with trials in technical issues like randomisation and use of databases both in coordinating centre and on site.

It is the responsibility of all WWORTH staff to ensure their GCP and professional training is up to date. In particular staff should attend GCP training at least once every two years.

WWORTH staff may request specialist training from their CI or, from the WWORTH Manager should they feel that something is appropriate.

## 6 Procedure

### 6.1 Creation and maintenance of training records

The training file should be developed within the first two months of employment. It should contain an up-to-date CV (signed and dates), job description and training record logs. These documents should be reviewed as part of the staff annual review process.

These training logs should list external and internal training received whilst in post. It should list all training undertaken which enables the individual to competently perform their job and the duties delegated to them as part of the trial. As a minimum, the training record log should document the following: all statutory and mandatory training and all GCP or other professional training received. The training record log may be maintained in either paper form or electronically, but, if the latter, should be printed off at the time of annual review for signing (by individual and manager) and filed in the training record file.

The training record log should be maintained on an ongoing basis and should be checked for completeness at least annually. The annual review should also identify any future training requirements.
6.2 Training flow Chart-For WWORTH staff with University Appointments

Yearly training review –Online PR form. Role profile section (1) –to be completed by WWORTH Director and Manager for new staff and updated if necessary for current staff.

Managers and staff implement agreed training plans.

Following population centrally by SU of section 2, section 3 (review of objectives) and section 4 (training needs) must be completed by the staff member, with any supporting documents added in section 5. WWORTH Director – or valid alternative – meets each member of staff to complete section 6.

Completed PR forms held electronically on personal “All about me” intranet page. Details of completion sent to Head of College.

WWORTH Director and Manager collate generic training plans (including SOP logs).

CIs and Trial Manager collate trial specific training plans (including SOP logs).

WWORTH training plan agreed.

Trial training plan agreed.
### 6.2 Annual training cycle – Swansea University

**Month 1**  
WWORTH staff complete online Professional Review (PR) Form to compare achievements with objectives set in previous cycle.

**Months 2 and 3**  
WWORTH Director or valid alternate meets each member of core staff; and CI or valid alternate meets each member of trial staff, for PR interview; & completes appropriate sections in order to summarise objectives & training plan for next year. Follow individual review, Head of College and HR are notified that the review has been completed and this PR form is saved in the “All about me” pages on the SU intranet.

**Month 4**  
CI & Trial Manager collate training plans & records including SOP logs, and agree trial training plans.

**Month 5**  
WWORTH Director and Manager collate trial training plans & records including SOP logs, and agree WWORTH training plan.

**Months 6-13**  
Managers & staff implement agreed training plans.

### 6.3 Training Cycle - for staff external to Swansea University

For staff who are employed externally to WWORTH/SU (but working with WWORTH on adopted trials), staff should follow the appropriate organisational annual review process. These may include Health Board employees and NISCHR CRC staff for example. These staff are required to attend all mandatory training for that organisation.

### 6.4 Training principles

As most WWORTH staff work for Swansea University (SU), Subsection 6.2 focuses on the WWORTH version of the SU PR policy. The basic principles of this system are:

A. Staff members compare achievements over review period with objectives set in previous review.

B. They discuss this with their team leader or line-manager and agree objectives and training plan for next review period.
C. CIs and TMs collate individual training plans & records, and agree & implement trial training plans.

D. WWORTH Director and Manager collate trial training plans & records and agree WWORTH training plan.

E. CI and TM or WWORTH Director and Manager review new staff members’ training records during induction process, and agree & implement initial training plan with particular reference to WWORTH SOPs.

F. Trial Managers & WWORTH Manager record these processes, with particular reference to SOP training logs and attendance records.

G. Through the annual cycle is important for continuity and consistency, it should not inhibit discussion of training needs at any time. Staff who wish to discuss training outside this cycle are welcome to approach their Trial Manager (or WWORTH Manager if employed by WWORTH itself) in the first instance.

6.5 Trial-specific training principles

A. It is the responsibility of the CI/PI to ensure that all staff allocated duties on the Study Delegation Log are suitably trained in the activities linked to those duties (see WWORTH SOP16 Site Setup and WWORTH SOP31 Sponsorship and Adoption).

B. Members of staff conducting trial visits or clinical participant appointments will receive appropriate training. Staff are to observe trial procedures, read the relevant SOPs, be closely supervised when carrying out procedures themselves and only be signed-off as trained when fully capable of working without supervision. How long this takes is dependent on the individual and the emphasis will be on quality of work and not speed of learning.

C. Each trial will maintain a central training log and ensure that WWORTH has access to that log, not least to integrate the logs of staff who work on more than one trial. This may be as part of the Trial Master File. As a minimum, a signed and dated staff CV and GCP certificates (if appropriate) should form part of this training log. Similarly trials will ensure that each site maintains a local training log, not least to integrate the logs of staff who work for more than one sponsor.
D. On permanently leaving the employment of WWORTH and/or SU, staff members may take their training records with them. However, a full copy must be retained along with other trial documentation until the trial's document archiving period (usually 5 years) has expired. Details regarding when the individual left employment should be added to their CV. This should be the responsibility of the CI/PI or delegated person. When a member of staff leaves before the end of the trial, there should be a hand-over process in place to ensure that training requirements for a new member of staff are appropriately addressed.

E. The costs involved in training new staff should be charged to the appropriate trial budget for trial specific staff. For WWORTH core staff, training costs should be charged to the central WWORTH budget. Where there is a limited budget for training, appropriate use of in-house or free courses (for example for trials registered with the UKCTN) should be made.

7 Training plan

All WWORTH staff involved with trials must undertake the appropriate generic and trial-specific training to ensure that they meet with the specific employers’ mandatory training requirements and the specific requirements of the trial. For example, for SU staff, all new employees must attend induction, fire and safety training (as well as role-specific training courses, e.g. laboratory safety). For new staff, additional training requirements should be identified alongside the specific role requirements and the WWORTH Unit Manager should make provision for the new staff member to attend the necessary courses as soon after appointment as is practicably possible.

It is the responsibility of the WWORTH Unit Manager (alongside the CI or TM) to identify all the SOPs that are relevant to a specific trial and in which the new member of staff should be trained. The WWORTH UM or the SOP author will provide group training for trial staff and/or one-to-one training, as required for new staff in relation to the specific SOPs identified. Training records should be filed both by the main employer and the staff member, in accordance with the specific employer requirements. Trial specific training should be filed in TMF or TSF as appropriate and every individual involved in a trial should have an individual training record (see Appendix 2).

Where the tasks specified in the individual SOPs are delegated to WWORTH staff, CIs/PIs or TMs, these delegated staff must ensure that they have attended a training course on GCP and keep up-to-date through attending refresher courses.
It is the responsibility of the CI/PI to ensure that all staff allocated duties on the study delegation log template of responsibilities are suitably trained in the activities linked to those duties (see WWORTH SOP16 Site Setup, Appendix 9 and Appendix 10).

Each trial should maintain a central training log and ensure that WWORTH has access to that log, not least to integrate the logs of staff who work on more than one trial. Similarly trials should ensure that each site maintains a local training log, not least to integrate the logs of staff who work for more than one sponsor.

8 References


9 Related SOPs

WWORTH SOP01a on SOPs
WWORTH SOP24 Randomisation
WWORTH SOP22a Data Collection Management
WWORTH SOP09 User Inclusion
WWORTH SOP01b Document Control
WWORTH SOP16 Site Setup
WWORTH SOP31 Sponsorship Adoption
WWORTH SOP13 Protocol Development
WWORTH SOP31 Sponsorship and Adoption
WWORTH SOP32 Detecting and Managing Misconduct, Serious Breaches and Deviations from GCP/protocol

10 Appendices

Appendix 1 – Training log for Training SOP
Appendix 2 – Staff training log
## Appendix 1  Training log for Training SOP

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