STU-SOP-ADM-003 – Standard Operating Procedure on Training

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of ensuring that Swansea Trials Unit (STU) staff are appropriately trained and qualified to perform their role.

The purpose of this SOP is also to ensure that all individuals completing research related tasks maintain a personal training record appropriate to the tasks and research projects they undertake.

2. Background

The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines and the UK policy framework for health and social care research (RGF) state that all personnel involved in conducting research should be qualified by education, training and experience to perform their respective task(s). Such training should be proportionate to the needs of the research project.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) adherence to the principles of GCP is incorporated into UK legislation. The UK Clinical Trials Regulations (SI2004:1031, as amended) states that no person shall conduct a CTIMP other than in accordance with the conditions and principles of GCP listed above. The legislation does not define the frequency or level of GCP training required.

3. Roles and Responsibilities

All STU staff involved in establishing or undertaking research projects within STU shall document evidence of education, training and experience by establishing and maintaining a training file. This will be maintained in Q-Pulse for STU staff.

All research site staff shall document training as required by their employing organisation. Relevant details will also be held in the Trial Master File (TMF) as appropriate for the research project they are involved with.

STU require that staff and researchers involved in research projects undertake GCP at least once every three years, unless there are major updates to the clinical trial legislation, or research sponsor's dictate an earlier GCP refresher course should be completed.

It is the responsibility of an individual to create and update their own training record. They are also responsible for identifying any areas of training required.

The STU employee's line manager is responsible for agreeing and identifying any additional areas of training required and ensuring that this training is undertaken in a timely manner.

It is the responsibility of the individual to make their full training record available for review during internal or external audits, monitoring visits or inspections as appropriate.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS

organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 New Staff Members

New STU staff members involved with research projects will have met the essential criteria for their role as described in the applicable job description. Relevant previous training should be documented in the Q-Pulse training record and any certificates from this training uploaded to the record.

Site research staff will be directed to relevant SOPs and receive training during site initiation which is appropriate for the research project and their project involvement.

4.2 Induction

Each new STU staff member will undertake a general induction in SU procedures. This will involve training in health and safety and basic fire training.

Site research staff will follow the appropriate process for their employing organisation. They will also receive appropriate training during site initiation.

4.3 Essential Training

STU and research site staff training requirements will include reading of applicable SOPs, as identified in the STU SOP Matrix (SOP-AD-GDN-006) and GCP training. Some SOP training will be mandatory for all staff, and some for staff involved in particular projects e.g. CTIMPs. Line Managers will advise where additional training is required for the individual's role.

All SOP training will be documented within the staff member's training file on Q-Pulse.

SOPs can be discussed with the staff members' line manager or the STU manager if required. Further training or assessment will be provided as described in section 5.6.

SOPs should be referred to regularly on Q-pulse. When a SOP is reissued or updated, acknowledgement of reading will be documented on the individual's SOP log within Q-Pulse.

4.4 GCP Training

Each STU staff member undertaking or involved with research projects must complete GCP training at least once every three years, unless there are major changes to legislation which require an update to be completed earlier.

STU staff will direct researchers to relevant GCP training either for local attended or online courses. This is usually via the local NHS organisation.

STU staff GCP training certificates should be kept in the individuals training records electronically on Q-Pulse. STU staff and site researchers will document or maintain GCP certificates in the TMF of research projects for which they are named on the delegation log.

4.5 Training File

An electronic training file should be set up and maintained within in the Q-Pulse training module. Each STU staff member will maintain their own training file, which will contain as a minimum the following documents:

- Current job description – signed and dated;

- Current CV – updated annually, signed and dated;
- Training Log – details of all relevant training, including equipment training;
- Certificates or evidence for all training attended (including GCP).
- Training from previous posts if relevant

The training file is an ongoing cumulative list of internal and external training. Formal training courses, attendances at conferences, seminars, relevant meetings and job shadowing should all be documented within the electronic training file.

Where the certificate does not detail content of the course/conference, it is advisable to keep copies of handouts and agendas within the training file to enable the verification of topics during audit or inspection. These can be uploaded as attachments to the training record.

An individual should take a copy of their training file on leaving their role. The electronic copy of the file within the Q-Pulse training module will be retained as an electronic archive for inclusion in TMFs or inspection purposes as appropriate.

4.6 Other training

Additional training might comprise:

- Formal in-house training sessions, which may include the delivery of a presentation.
- Shadowing or accompanied visits – this may be particularly relevant to Trial or Data Managers. In such instances, this will be recorded and there may also be an assessment of competency by their line manager/trainer before the staff member is considered competent to work unsupervised.
- Training sessions provided by external organisations either in person or remotely via electronic training or webinars.
- Attendance at relevant conference or symposia
- Sponsor-specific training where required e.g. on sponsors SOPs
- Therapeutic area training by investigators.

All such training will be documented and filed within the training file.

STU staff need permission from their line manager and the STU Executive Group to attend external training or a conference. To request this, the individual should complete the Training Request Form (STU-AD-FRM-035). If the request requires funding from STU, the individual should list three objectives they hope to achieve from the training/conference and state how the training/conference will support the job role and benefit STU. Staff will be expected to present a short summary of their learning at the next operational group meeting.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2004 -

http://www.legislation.gov.uk/uksi/2004/1031/contents/made

- International Conference of Harmonisation (ICH) Good Clinical Practice (GCP) E6 Guideline – http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-FRM-035	Training Request Form	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
MHRA	Medicines and Healthcare products Regulatory Agency
R&D	Research and Development
REC	Research Ethics Committee
RGF	UK policy framework for health and social care research
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University

8. Appendices

Appendix 1: Document History

Version No:	4	**Effective Date:**	22-Apr-2024
Description of changes:	Updated to SOP Template v5		