STU-SOP-ADM-001 – Standard Operating Procedure on Standard Operating Procedures

1. Purpose

This Standard Operating Procedure (SOP) describes the process of developing, approving, reviewing, distributing and deactivating any SOP developed by Swansea Trials Unit (STU).

2. Background

SOPs are succinct formal documents designed to achieve consistency in project functions through specifying standard practice. They are written instructions and records of procedures agreed and adopted as standard practice. SOPs should be clear, concise, of common format and style specifying when, how and by whom tasks should be completed. Each SOP will be written with sufficient information so that any person who reads it can successfully follow the procedure.

STU SOPs accord with all relevant regulations, including the European Union Clinical Trial Directive, UK Clinical Trials Regulations, the principles of Good Clinical Practice (GCP), the MHRA Good Clinical Practice Guide and the current UK policy framework for health and social care research. SOPs will distinguish between regulations for Clinical Trials of Investigational Medicinal Products (CTIMPs), while reflecting best practice for research conducted by STU.

3. Roles and Responsibilities

The **STU Director** has overall responsibility for developing, approving, improving and disseminating the SOP portfolio, including training.

The **STU Manager** has responsibility for managing, documenting, and implementing the SOP portfolio, including the oversight of training and monitoring of adherence. The STU Unit Manager will assign an SOP Author (where appropriate) to lead the writing of a new SOP and to allocate reviewers.

The **Trial Manager (TM)** has responsibility for indicating to STU manager when new site staff require training and access to SOPs.

The **SOP Author** is responsible for writing and updating the SOP.

The **SOP Reviewers** are responsible for independently reviewing the SOP and making any recommendations for change to the STU Document Review Group (DRG).

The **Document Review Group (DRG)** is responsible for ensuring STU have an appropriate set of SOPs in place for conducting research projects.

The **DRG Secretary** is responsible for collating signatures, managing dissemination of approved and released SOPs, and ensuring that the latest version is available on Q-Pulse.
Superseded versions of electronic SOPs will be archived by Q-Pulse following release of an updated SOP version.

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 Developing, reviewing and approving an SOP

4.1.1 When any STU staff member identifies a need for a new SOP the identifier should complete the New SOP Creation Request wizard in Q-Pulse, including a suggested SOP title. This will be automatically sent to the STU Manager for consideration.

4.1.2 The STU Manager, in conjunction with the DRG, will assess whether the SOP has already been covered or is required. If a new SOP is required, the STU Manager will assign responsibilities for authorship (in discussion with identifier) and review. Details of this process should be added to the new SOP creation request in the Quality Management System (QMS) for audit purposes. Where appropriate, the SOP author can select development group members, usually to comprise 2 – 4 members with skills appropriate to the area of interest for the SOP.

In consultation with development group members, the SOP author should draft a new or revised SOP using the new SOP wizard or the Revise a Document function in Q-Pulse, utilising the SOP template (STU-AD-TMP-002) and assign it to the reviewer at least two weeks before a DRG meeting.

4.1.3 The DRG Secretary will collect and circulate comments usually one week before the meeting.

4.1.4 The DRG will review the draft SOP along with the reviewer's comments and agree action:

- Request major revision - author redrafts SOP and reviewer reviews revised SOP before resubmission to next available DRG meeting;
- Approve with minor revisions - author revises SOP to be signed off by DRG Chair without need for further review by DRG;
- Approve without change;
- Agree the review date if different from section 4.4.

4.1.5 The DRG Chair, or a delegate of the Chair, will electronically sign the final SOP on Q-Pulse. Q-Pulse will maintain an audit trail of amendments and approvals.

4.1.6 The STU Manager will implement a staff training plan via the STU SOP training matrix form available on Q-Pulse. All STU staff and members of research teams of adopted research projects must undertake appropriate training to ensure they meet the training requirements mandated by their employers, GCP and the needs of the specific project. The STU manager will ensure that training plans are implemented for all STU SOPs, according to STU-SOP-ADM-003 Training.

4.1.7 STU staff will be expected to log in to Q-pulse to complete self directed learning as required. Research site staff will document learning via training logs held in the project Trial Master File. Further training session will be mandated as necessary.

4.1.8 Final SOPs will be available for use following an implementation period where appropriate staff will have undertaken training in the SOP as required. The DRG Secretary will ensure the availability of a 'pdf' version of the approved SOPs through Q-Pulse and the STU website. Superseded versions of SOPs will be removed from the website and archived in Q-Pulse. All approved SOPs will be accessible by STU staff and staff engaged in projects that have been adopted by STU. Access to Q-Pulse is controlled by STU, who will provide log in and password details as required. The website will be publicly accessible.

4.1.9 Where an amendment to an existing SOP has been identified, a change request should be raised against the SOP within Q-Pulse, which will inform the SOP owner who will consider the need for and urgency of the change in consultation with the STU manager/DRG where necessary.

4.2 Process for reviewing, updating and deactivating a live SOP

4.2.1 All SOPS are due for periodic review every 3 years, or earlier if there are significant changes in legislation or circumstances. The DRG Secretary should manage the review process on Q-Pulse and the DRG. The author will decide whether a document requires "Revision", "No Revision" or "Deactivation", which will be recorded on Q-Pulse.

4.2.2 Users are encouraged to feedback on SOPs. Feedback should be recorded using the change request function within Q-Pulse. Feedback will be acknowledged and, when appropriate, comments will be disseminated to the assigned author.

4.2.3 A SOP may be deactivated due to a major change in current practice or incorporation into another SOP or other reasons as detailed by STU. SOP deactivation must be approved by the DRG and archived.

4.3 SOP document control

4.3.1 Whole version numbers are used to identify new versions of a SOP e.g. version 1 becomes version 2. The SOP author is responsible for altering the version number when amendments have been made. Any minor amendments to the SOP should be retained until the next major amendment is highlighted and made.

4.3.2 SOPs stored electronically in Q-Pulse will be identified by SOP labels, comprise the characters "STU", and an appropriate 2-3 letter document abbreviation (e.g. Administration (ADM), Trial Management (TM) or Associated Document (AD)), a three-digit SOP number, SOP abbreviated name and version number in the appropriate fields. For example:

STU-SOP-ADM-001 SOP on SOPs V2

Further details and descriptions of the abbreviations used for the document control process can be found in the SOP on Document Control, STU-SOP-ADM-002.

4.4 Circulation and dissemination

4.4.1 In addition to the responsibilities of the DRG Secretary defined in section 3, the Trial Manager (TM) of a project should indicate to STU manager/DRG secretary when new site staff require training and access to the SOPs. The STU Manager should indicate when new STU staff require training and access to the SOPs.

4.4.2 An SOP will be issued prior to the effective date to allow dissemination and allow staff to become familiar with changes. SOPs will be issued directly to staff via Q-Pulse. If a major change has been made, or a new procedure implemented, face-2-face SOP training may be required and will be facilitated by the STU Manager and the SOP author as appropriate.

Effective dates for the SOP will usually be 2 weeks after the approval date in order to provide time for circulation and dissemination. All staff will be enabled access to the SOPs on Q-Pulse.

4.5 Situations where STU SOPs may not be used

STU SOPs should always be used in preference to other procedures except when the use of Sponsor SOPs is mandatory. This should be noted in the contractual agreement between the Sponsor and STU.

In exceptional circumstances, the development of project Specific Operating Procedures may be required for an individual project. These should be developed and used alongside STU SOPs but should not override the procedures outlined in STU SOPs. They should only be developed when STU SOPs do not adequately cover the details of a project process.

5. References

- 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

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-TMP-002	SOP Template	Q-Pulse

7. Abbreviations

List of Abbreviations	
AD	Associated Document
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DRG	Document Review Group
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare products Regulatory Agency
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	25-Mar-2024
Description of changes:	Moved onto SOP template v5 Minor text and format adjustments Amendment of external use statement		

Appendix 2: Flowchart for developing, reviewing and approving an SOP.