# STU-SOP-ADM-001 – Standard Operating Procedure on Standard Operating Procedures (SOPs)

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| **Version No:** | 4 | **Effective Date:** | 20-Mar-2026 |
| **Description of changes:** | Review of SOP to reflect changes to GCP (R3) and the Clinical Trials Regulations 2025.<br>SOP updated to reflect the change of staff roles at STU.<br>The Document Review Group has been disbanded.<br>Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system. | | |

| List of Abbreviations | |
|---|---|
| **AD** | Associated Document |
| **DM** | Data Manager |
| **GCP** | Good Clinical Practice |
| **MHRA** | Medicines and Healthcare products Regulatory Agency |
| **QAM/O** | Quality Assurance Manager/Officer |
| **QMS** | Quality Management System |
| **SOP** | Standard Operating Procedure |
| **SM** | Study Manager |
| **STU** | Swansea Trials Unit |
| **SU** | Swansea University |
| **TM** | Trial Manager |

## 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.



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# 3. Roles and Responsibilities

The **STU Director** has overall responsibility for developing, approving, improving and disseminating the SOP portfolio, including training. Specific responsibilities are delegated to the following roles with STU as follows:

The **STU Quality Assurance Manager/Officer (QAM/O)** has responsibility for managing, documenting, and implementing the SOP portfolio, including the oversight of training and monitoring of adherence. The QAM/O is the SOP coordinator and may assign a SOP author/reviewer (as appropriate) to lead the writing of a new SOP or the review of existing SOPs.

**The STU Trial / Study Managers (TMs/SMs)** have responsibility to the QAM/O when new STU staff require SOP training and access to SOPs on STU's Quality Management System (QMS). Where there is only a **STU Data Manager (DM) or statistician** and no TM/SM, those roles will be responsible for requesting SOP access and training where required.

The **SOP Author** is responsible for writing a new SOP.

The **SOP Reviewer(s)** are responsible for reviewing and amending the SOP for the SOP author.

**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

When any STU staff member identifies a need for a new SOP e.g. UKCRC requirements for a new SOP or internal additional training and guidance is needed, the identifier should request this in the QMS system, including a suggested SOP title. This will be automatically sent to the QAM/O for consideration.

The QAM/O, in conjunction with the STU Director, will assess whether the topic of the SOP has already been covered or is required. If a new SOP is required, the QAM/O will assign responsibilities for authorship (in discussion with identifier). Details of this process should be added to the new SOP creation request in the 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 SOP utilising the SOP template (STU-AD-TMP-002) and assign it to a nominated reviewer(s) at least two weeks before the deadline issued.

The QAM/O will review the submitted SOP, collate comments and will either:

- Request major revision - author redrafts SOP and reviewer reviews revised SOP before resubmission to the QAM/O.
- Approve with minor revisions - author revises SOP to be signed off by the QAM/O without need for further review.



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- Approve without change.

The QAM/O will also agree the future review date (see Section 4.4). The QAM/O will electronically sign the final SOP on the QMS which will maintain an audit trail of amendments and approvals.

The QAM/O will implement a staff training plan in line with the STU SOP training matrix form (STU-AD-GDN-006). 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 QAM/O will ensure that training plans are implemented for all STU SOPs, according to STU-SOP-ADM-003 Training.

STU staff will be expected to log into the QMS to complete self-directed learning as required. SOPs assigned must be acknowledged on the QMS once read as evidence of training being completed.

Final SOPs will be available for use following an implementation period where appropriate staff will have undertaken training in the SOP as required. The QAM/O will ensure the availability of a 'pdf' version of the approved SOPs through the QMS and the STU website. Superseded versions of SOPs will be removed from the website and archived in the QMS. All approved SOPs will be accessible by STU staff and staff engaged in projects that have been adopted by STU. Access to the QMS is controlled by the QAM/O and will be supported by the STU IT Manager who will provide login and password details as required. The website SOPs will be publicly accessible.

Where an amendment to an existing SOP has been identified, a change request should be raised against the SOP within the QMS, which will inform the SOP owner who will consider the need for and urgency of the change in consultation with the QAM/O where necessary.

### 4.2 Process for periodic and ad hoc reviewing, updating and deactivating a live SOP

All SOPS are due for periodic review every 3 years, or earlier if there are significant changes in legislation or circumstances. The QAM/O should manage the review process on the QMS. The QAM/O and assigned SOP author will decide whether a document requires "Revision", "No Revision" or "Deactivation", which will be recorded on the QMS.

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

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 in writing by the STU Director and archived.

### 4.3 SOP document control

Whole version numbers are used to identify new versions of a SOP e.g. version 1 becomes version 2. The QAM/O 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 made.

SOPs stored electronically in the QMS will be identified by SOP labels, comprise the characters "STU", and an appropriate 2-3 letter document abbreviation (e.g. Administration (ADM), Trial



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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

In addition to the responsibilities of the QAM/O defined above, the Trial / Study Manager (TM/SM) of a project should indicate to the QAM/O when new trial staff require training and access to the SOPs.

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 the QMS to allow electronic acknowledgement. If a major change has been made, or a new procedure implemented, face-to-face SOP training may be required and will be facilitated by the QAM/O and the SOP author as appropriate.

Changes to staff roles may require additional SOPs to be assigned for acknowledgement. It is the responsibility of the staff member to request access to the relevant SOPs by the QAM/O. The QAM/O will keep a tracker of SOP allocations for all STU staff.

### 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 (2025) - https://www.legislation.gov.uk/uksi/2025/538/contents

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 | QMS |
| STU-AD-GDN-006 | SOP matrix | QMS |



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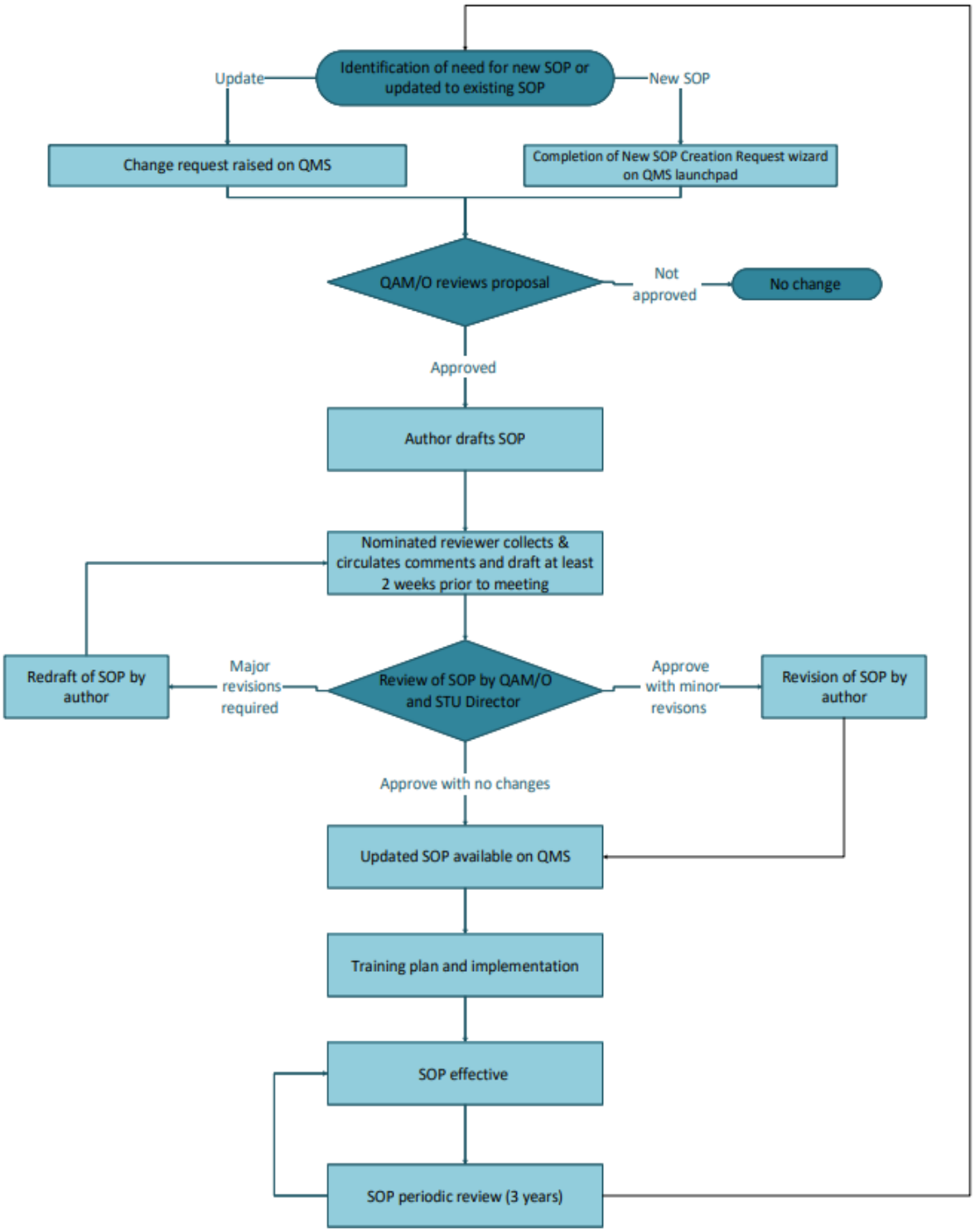
# 7. Appendices

Appendix 1: Flowchart for developing, reviewing and approving an SOP.



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