STU-SOP-ADM-008 – Standard Operating Procedure on the Swansea Trials Unit Quality Management System

Version No:	5	**Effective Date:**	27-Mar-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system.		

List of Abbreviations	
CAPA	Corrective And Preventative Action
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare products Regulatory Agency
QA	Quality Assurance
QC	Quality Control
QAM/O	Quality Assurance Manager/Officer
QMS	Quality Management System
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TMG	Trial Management Group
TMF	Trial Master File

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the Quality Management System (QMS) to oversee the delivery of research projects adopted, managed or supported by Swansea Trials Unit (STU).

This SOP covers all research including, but not limited to, Clinical Trials of Investigational Medicinal Products (CTIMPs).

Definitions	
Quality Control (QC)	Regular ongoing review of research sites' data collection and work activities to ensure the approved research protocol and procedures are being followed. Involves monitoring by a member of the research team with good knowledge of the protocol e.g. Trial Manager, Data Manager.
Quality Assurance (QA)	Periodic, planned, objective review of research related activities to ensure compliance with Good Clinical Practice (GCP), SOPs and regulatory requirements. Usually involves independent audit by a representative of the Sponsor organisation or delegate to assure the reliability of the QC procedures for the research project.
Quality Management System (QMS)	Formal way of facilitating an oversight system which involves maintaining a set of procedures, policies and processes, while documenting responsibilities required to help assure a consistent approach to working and compliance with required processes or regulations. The QMS

	encompasses QC and QA processes in addition to institutional policies, procedures and guidance.

2. Background

A QMS includes tools that enable efficient design and conduct of research project protocols, procedures for data collection and processing, and the collection of information that is essential to record decision making. This involves the development of written instructions in the form of SOPs, associated documents, guidelines and policies to oversee all research projects.

For CTIMPs, the Clinical Trial Regulations state that Sponsor organisation(s) are responsible for implementing and maintaining procedures to ensure CTIMPs are conducted according to GCP, the protocol and other applicable regulations. All other research projects involving human participants should also follow the principles of GCP to help ensure that data and reported results are credible while the rights, safety, well-being and confidentiality of participants are protected.

The methods used to confirm the quality of a research project should be proportionate to the inherent risks of the project, the importance of the information to be collected, and focus on project activities essential to ensuring participant protection and the reliability of results. All aspects of a research project should be feasible, avoid unnecessarily complex procedures and data collection whilst ensuring that protocols, case report forms (CRFs) and other project documents are clear, concise and consistent. A risk assessment may be conducted to detail associated risks and mitigations.

3. Roles and Responsibilities

The **Sponsor** is responsible for ensuring a system to manage quality throughout all stages of the research project is available. Although aspects of quality may be delegated, the sponsor retains responsibility for QMS oversight.

Swansea Trials Unit (STU) is responsible for developing and implementing a QMS to fulfil the requirements of all projects adopted, managed or supported by STU. This will involve implementing procedures for QC and QA of research projects and internal oversight of the QMS assuring compliance with applicable regulations, guidelines, contractual and project requirements where applicable.

The **Quality Assurance Manager/Officer** (QAM/O) is responsible for the management of the STU QMS system, including the management of new and existing users, STU SOPs and STU equipment for projects.

The **Chief Investigator** (CI) is responsible for the scientific quality and delivery of a research project. The CI is usually the first named applicant on the project funding application and delegates tasks for QC within the Trial Management Group (TMG).

The **Trial Manager** (TM) or delegate is responsible for the day-to-day conduct of a research project and liaises with the CI, research sites and aspects of QC for that project.

4. Procedure

The STU QMS will be used for the following purposes:

4.1 Standard Operating Procedures (SOPs)

Procedures are documented in SOPs or policies have previously been approved by the STU Document Review Group before implementation. Current procedures require the SOPs to be reviewed by the QAM/O and STU Director prior to approval. All revisions or updates are performed under strict document control rules as per STU-SOP-ADM-001 SOP on SOPs.

4.2 Training

All STU personnel and research site staff, where required, should read relevant SOPs or policies according to their roles within STU or the project. Where required, role specific training will be providing and documented in a personal training file, and a TMF as required. The personal training file will be held within the QMS. A paper copy may also be kept by the individual. A central record will be kept by STU of training requiring periodic updates as per STU-SOP-ADM-003 (Training).

4.3 Equipment

Records are maintained of essential equipment maintenance, repair and disposal e.g. computers, lab equipment for STU and individual research projects as per STU-SOP-TS-004 (Selection & Oversight of Vendors).

4.4 Incident/Deviation Reporting

All incidents/deviations from SOPs within STU or a research project are documented and will follow a corrective and preventative action (CAPA) plan detailing the management and investigation of the event as per STU-SOP-ADM-009 (Audit).

4.5 Quality Control

Monitoring is an integral function in the QC of a research project and is designed to verify the quality of the data collected. The level of QC undertaken will be determined per research project.

The purpose of monitoring is to verify:

- The rights and well-being of research participants are protected.
- Reported trial data are accurate, complete and verifiable from source documents.
- The conduct of the trial complies with the current approved protocol, with GCP and with any applicable regulatory requirements.

Monitors should be familiar with the research project protocol and other project or sponsor documentation relevant to the monitoring being undertaken.

4.6 Quality Assurance

QA uses audit as a tool to assess a trial's QC systems by measuring performance against required SOPs, GCP, the approved protocol or any applicable sponsor or regulatory requirements. The level of audit undertaken will be determined by a project risk assessment.

The purpose of audit is to:

- Ensure research participant and staff safety
- Assist researchers with compliance to regulatory requirements, SOPs and policies
- Improve research systems and data quality
- Prepare researchers for external audit processes
- Demonstrate robust research processes to external funders and industry.

Auditors should preferably be independent to the research team at STU and have knowledge of the QMS and any regulations applicable to the research project.

4.7 Oversight / Inspection

To oversee compliance with the QMS, sponsor and applicable regulatory requirements, STU will conduct project specific and internal audits of the QMS to assess compliance. There may be instances where audits are contracted to a third-party service provider.

Sponsors of a research project may review or request evidence of the STU QMS. Additionally, the STU QMS, Sponsor oversight of STU and individual research projects may be subject to audit and inspection by external parties such as the funder or the regulatory authorities, such as the Medicines and Healthcare products Regulatory Agency (MHRA). The STU Executive Group will review all audits and oversee corrective actions as required.

5. Security

STU is in a secure building on a floor with controlled access during usual working and non-working hours. Access to research project files (paper and electronic) is restricted to STU and site staff. STU hosts a document archive facility remote from the STU building.

All STU computers are networked and data are stored and backed up on servers remote from the STU building. This process is managed by policies and SOPs central to Swansea University.

6. 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 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents
- ICH Harmonised guideline - Good Clinical Practice E6 (R3) https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

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

7. Associated Documents

Number	Title	Location
N/A	N/A	N/A