STU-SOP-ADM-009 – Standard Operating Procedure on Audit

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of internal and external audits of the Swansea Trials Unit (STU) Quality Management System (QMS) or adopted research projects which use the STU QMS.

2. Background

Under the UK policy framework for health and social care (2017), any project that involves human participation, is required to promote and follow good research practice. This includes ensuring that research projects are designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency of the research project.

Audit is the systematic and independent examination of project related activities in accordance with the QMS, GCP, applicable regulatory requirements and the approved protocol.

The purpose of audit in the context of this SOP is to ensure that the QMS is fit for purpose, complies with relevant legislation and the principles of GCP.

Audits may be conducted internally by STU or by third parties appointed by STU or a sponsor organisation.

3. Roles and Responsibilities

The **Sponsor** is responsible for agreeing an audit schedule for research projects (usually based on an assessment of risk), to ensure that projects are managed safely and effectively in compliance with relevant SOPs, approved project protocols and applicable regulations.

Swansea Trials Unit (STU) is responsible for maintaining Quality Assurance (QA) staff to oversee a QMS, ensuring audits of facilities and activities are completed as appropriate.

STU Executive Group (STU Exec) is responsible for overseeing the STU QMS and ensuring it remains applicable to the functions of STU.

Document Review Group (DRG) are responsible for overseeing the development and management of SOPs.

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 Audit Schedule

STU QA shall maintain an annual Audit Schedule within Q-Pulse, documenting the frequency and type of internal audit to be completed to include:

- System audits – several projects are selected to look at whether processes are being followed across projects.
- Project audits – a single project will be selected to check for conformance with the STU QMS and any required standards.

The type and frequency of internal audits to be conducted will vary, depending on the risk of the process or projects to be considered.

Additional audits may be undertaken if potential or actual quality and/or safety issues arise, or they are requested by Sponsor and agreed by the STU Exec.

The audit schedule may be amended where:

- Concerns are raised regarding research practice
- Monitoring/other audits has highlighted concerns
- Information provided to STU is inconsistent or causing concern
- The Medicines and Healthcare Products Regulatory Agency (MHRA), or other regulatory/inspection body, have indicated they are to conduct an inspection.
- It is requested by the STU Exec.

When an external company has been appointed to conduct an audit on behalf of STU or a Sponsor, this must be agreed in writing.

4.2 Audit Process

Each system or project audit is conducted according to an audit plan, input to Q-Pulse in advance by STU QA, detailing the specifics to be audited. Previous project or systemic findings may be included in the scope of the audit. Checklists will be prepared by STU QA to prompt an audit as appropriate.

Before planned/scheduled audits are undertaken, STU QA shall contact the individuals concerned (auditees) to agree a convenient date and time for the audit. Any relevant documents required for the audit may be requested at this time.

STU QA will create an audit number when the audit is scheduled in Q-Pulse.

The scope of the audit will be discussed at an opening meeting. Any findings identified during the audit will be discussed with the auditee(s) as part of the audit process. Retrospective corrections and Corrective Actions and Preventative Actions (CAPA) will be discussed and agreed at a closing meeting and documented within Q-Pulse. A signature sheet for CAPA sign off (STU-AD-FRM-034) will be provided when the auditees are not Q-Pulse users.

Audit reports and CAPA reports will be generated from Q-Pulse and issued to the auditee, sponsor, local R&D departments, and other relevant parties within 21 calendar days as required. The report will clearly highlight findings and required/recommended. Any retrospective correction and CAPA detailed in the audit report will be as agreed and discussed at the closing sessions. Auditees have a maximum of 28 days from receipt of the audit report to close out findings and inform STU QA. A shorter timescale may be imposed for serious findings.

Findings will be classed as deviations if they do not comply with the Principles of GCP, the approved trial protocol, STU or trial specific SOPs.

Where the potential for a deviation is identified and there is an opportunity for improvement it should be documented as an observation.

A deviation that affects, or has the potential to affect the rights, wellbeing or safety of participants, or the scientific integrity of the project will be treated as serious requiring immediate attention. Such findings will be referred to the STU Exec and, where appropriate, the local NHS R&D office for information and action. A finding may also be reported as a breach (see STU-SOP-TM-011). Less serious deviations will be reviewed by STU QA.

STU QA will review the status of findings, corrections and CAPA before closing a report, or referring back to the auditee for further action if necessary.

Failure to complete CAPA within agreed timescales may be considered a serious deviation and be referred to the STU Exec, the local NHS R&D department and Sponsor for action where appropriate.

STU reserve the right to perform unannounced system and project audits.

4.3 Reporting an Audit

The audit and CAPA reports will be issued electronically by STU QA to the auditee, sponsor, local R&D departments and other relevant parties as required, using Q-Pulse where possible.

The audit report will include an overview of the audit visit detailing the scope of the audit and any findings noted. A CAPA report will detail deviations and observation, and their status (i.e. open, closed or N/A (for observations only)). If there are no findings this shall be recorded on the audit report.

If necessary, a follow up visit may be conducted to review progress in ensuring retrospective corrections and CAPA have been completed. STU QA shall notify the auditee by email when all findings and the audit are closed.

Audit reports should be reviewed and escalated as necessary by a project Trial Management Committee or Data Monitoring Committee.

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

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-034	CAPA Signature Sheet	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CAPA	Corrective and Preventative Actions
CTIMP	Clinical Trial of an Investigational Medicinal Product
DRG	Document Review Group
GCP	Good Clinical Practice
IT	Information Technology
ISF	Investigator Site File
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance
QMS	Quality Management System
R&D	Research and Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TMF	Trial Master File

8. Appendices

Appendix 1: Document History

Version No:	4	**Effective Date:**	08 Aug 2024
Description of changes:	Update to procedure		