STU-SOP-TS-005 – Standard Operating Procedure on Risk Assessment

Version No:	4	**Effective Date:**	17-Apr-2026
Description of changes:	Review of SOP to reflect changes to GCP and the Clinical Trials Regulations 2025. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system. Removal of site risk assessment.		

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CtQ	Critical to Quality
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare products Regulatory Agency
IMP	Investigational Medicinal Product
PI	Principal Investigator
RA	Risk Assessment
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
TM	Trial Manager
TMF	Trial Master File

Definitions	
Critical to Quality (CtQ)	The attributes of a clinical study that are fundamental to ensuring: 1. Participant protection and safety. 2. The reliability and interpretability of study results. 3. The ability of the study to meet its objectives (decision-making).

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of evaluating the potential risks and hazards in Swansea Trials Unit (STU) adopted interventional research projects and to document how identified risks will be mitigated and managed to reduce their potential impact.

STU adopted projects which require a comprehensive risk assessment are Clinical Trials of Investigational Medicinal Products (CTIMPs), regulated device projects and any other interventional research project which has been assessed by the sponsor as requiring a risk assessment and where this has been delegated to STU.

2. Background

The UK Policy Framework for Health and Social Care Research indicates the responsibility to manage risk and comply with proportionate Good Clinical Practice (GCP) for all research

undertaken within its remit and covers both clinical and non-clinical research. A risk assessment should be conducted at an early stage of project development so that any required modifications to mitigate risks are incorporated into the project.

All interventional research projects contain a level of risk. Identified risks should be continually assessed and managed at each stage of the research project to ensure the safety, rights and wellbeing of participants and research staff and the integrity and successful completion of the project.

GCP states that clinical trial processes, measures and approaches should be implemented in a way that is proportionate to the risks to participants and to the importance of the data collected. This will avoid placing an unnecessary burden on participants and investigators. Clinical trials Units must also adopt risk-based working practices aligned with GCP and sponsor expectations.

3. Roles and Responsibilities

The **Sponsor** has responsibility to facilitate and confirm acceptance of an appropriate risk assessment, and for overseeing the project and ensuring ongoing review the risk assessment. Some tasks may be delegated to the CI.

Swansea Trials Unit (STU) when assigned by CI or Sponsor, are responsible for ensuring that Sponsor's responsibilities are met by coordinating the risk assessment process for adopted interventional research projects.

The **Chief Investigator** (CI) is responsible for undertaking the analysis of the risks required and to assess the mitigations and management of these required to reduce their potential impact.

The **Trial Manager** (TM) or delegate is responsible for ensuring that the risk assessment is completed and revisited during the life cycle of the project and for keeping a log of the revisions made.

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 Initiation of the risk assessment

The Risk Assessment Decision Flowchart (Appendix 1) should be used by STU in conjunction with the CI and Sponsor to assess if a formal risk assessment using the Risk Assessment Proforma (STU-AD-TMP-049) should be completed.

All interventional projects identified as low risk will complete an adapted process. Any adaptations will be considered and documented as part of the risk assessment.

4.2 Completing the risk assessment documentation

Following delegation, STU with the CI and TM (if appointed) will complete the Risk Assessment Proforma (STU-AD-TMP-049) or an equivalent Sponsor template during project development. Expertise will be sought from other parties as appropriate to their role in the research project e.g. Sponsor, R&D, pharmacy.

Project specific questions will be added to the Risk Assessment proforma when appropriate. Consideration will be given to: Participant Risk; Project Risk; Organisational Risk; resources and finances. Interventional projects not considered to adequately address all of these considerations are unlikely to be adopted by STU.

Data items deemed Critical to Quality (CtQ) should be considered when assessing the risk of a study, for example:

- Is participant consent collected correctly?
- Is the collection of primary outcome data appropriate?
- Can the relevant safety data be collected in a timely manner to ensure patient safety?
- Are data related to the intervention and compliance being collected? Is there a process for managing protocol and GCP deviations?

The concerns associated with each risk should be assessed and compared to standard care or equivalent practices and categorised based on the likelihood of occurrence and the severity of the impact on participants and/or data collection. Decisions and mitigations to be implemented will be captured on the Risk Assessment Proforma (STU-AD-TMP-049).

It is the CI's responsibility to ensure that the risk assessment is finalised and signed prior to confirmation of project initiation by the sponsors.

The completed risk assessment should guide the development of a monitoring plan (STU-SOP-TM-009), alongside oversight by the Trial Management Group, Trial Steering Committee and Data Monitoring Committee as applicable for the research project.

At each substantial project and/or protocol amendment, the risk assessment should be revisited by the TM to mitigate any change to project risk. The revised risk assessment requires approval from the CI, STU and sponsor.

Signed final versions of the risk assessment (initial and superseded) will be filed in the Trial Master File (TMF).

4.3 Clinical Trials of Investigational Medicinal Products (CTIMPs)

STU will review whether risk adaptions can be made to a CTIMP following guidance from the MHRA risk adapted approaches document.

Risk adaption, categorises studies and the monitoring required based on the risk to participant safety in relation to the Investigational Medicinal Product (IMP) as below:

- Type A – no higher than the risk of standard medical care (low intensity monitoring)
- Type B – somewhat higher than the risk of standard care (moderate intensity)
- Type C – markedly higher risk than the risk of standard medical care (high intensity).

The dual strategy adopted by the MHRA also includes defining the risks associated with trial conduct by examining the trial design, population and procedures to identify specific areas of vulnerability and to determine how any risks can be mitigated.

Justification for the category assigned should be provided on the Risk Assessment Proforma (STU-AD-TMP-049) which can be sent with the application to the regulatory body for a clinical trial authorisation.

Risk adaptions implemented in a CTIMP must be described in the final clinical trial report.

4.4 Continued Risk Assessment Review

The risk assessment form should be reviewed at least annually from the date of sign off.

The risk assessment should also be reviewed following:

- Substantial amendments made to the research project that change protocol procedures, benefits/risks to participants or update reference safety information.
- Deviations or violations of the protocol.
- Serious breaches of GCP.
- Significant changes to the monitoring plan or case report forms.

Where an amendment to the risk assessment is required, this should follow the procedures stated above. Should no update be required to the risk assessment following review, the decision should be noted at the next TMG.

The revised risk assessment will supersede the previous version and will be filed in the TMF.

4.5 Sponsor overview of the risk assessment

Sponsor procedures will be followed for the review of all completed Risk Assessment proformas (STU-AD-TMP-049). This will be coordinated by the TM.

All projects which retain medium or high likelihood risk scores following mitigations, will have a moderate or high intensity monitoring. A monitoring plan which is project specific and based on the risk assessment will be completed (STU-SOP-TM-009).

There may be some instances, where no acceptable mitigations can be found. In such cases, the Sponsor must decide whether to continue as Sponsor or refuse sponsorship until such time as appropriate mitigations are put forward.

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 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents
- Good Clinical Practice (R3) https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- MRC/DH/MHRA Joint Project Risk-adapted approaches to the management of Clinical Trials of Investigational Medicinal Products (CTIMPs) - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/343677/Risk-adapted_approaches_to_the_management_of_clinical_trials_of_investigational_medicinal_products.pdf

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-049	Risk Assessment Proforma	QMS

Appendix 1: Risk Assessment Decision Flowchart