# STU-SOP-TS-008 – Standard Operating Procedure on Writing a Research Protocol to Good Clinical Practice

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| **Version No:** | 4 | **Effective Date:** | 20-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** | |
|---|---|
| **CI** | Chief Investigator |
| **CTIMP** | Clinical Trial of an Investigational Medicinal Product |
| **GCP** | Good Clinical Practice |
| **ISF** | Investigator Site File |
| **MHRA** | Medicines and Healthcare products Regulatory Agency |
| **REC** | Research Ethics Committee |
| **SOP** | Standard Operating Procedure |
| **STU** | Swansea Trials Unit |
| **SU** | Swansea University |
| **TM** | Trial Manager |
| **TMF** | Trial/Project Master File |
| **TMG** | Trial Management Group |

## 1. Purpose

This Standard Operating Procedure (SOP) describes the process for writing a research project protocol. Both interventional and non-interventional research protocols should be compliant with the principles of Good Clinical Practice (GCP).

Clinical Trials of Investigational Medicinal Products (CTIMPs) must also adhere to the Medicines for Human Use (Clinical Trial) regulations and the standard protocol items recommendations for interventional trials (SPIRIT) guidelines.

## 2. Background

The research protocol forms the basis for an agreement between the Sponsor and Chief Investigator and is distinct from any funding application.

The protocol is a full description of the research project and should be adhered to by the research team. It is a version-controlled document which is amended as the project evolves.

## 3. Roles and Responsibilities

The **Sponsor** is responsible for reviewing and agreeing the research protocol. For interventional research projects a sponsor representative will usually sign the final protocol and ensure subsequent amendments are managed appropriately.

The **Chief Investigator (CI)** with the research team is responsible for developing a high quality in line with relevant legislation. Parts of the protocol draft may be delegated to the wider research team.

The **Trial Statistician (TS)** is responsible for ensuring robust trial design by defining appropriate statistical methods to analyse the required project data.

The **Trial Manager (TM)** is responsible for coordination of the draft protocol, obtaining the required authorisation signatures and approvals.

**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 Protocol Template

All CTIMP project protocols must be based on the templates and guidance available from the Health Research Authority (HRA), unless there is agreement in advance with STU to use an alternative sponsor template.

For non-interventional research the Non-CTIMP Protocol Template (STU-AD-TMP-039) may be used. The HRA also provide non-interventional and qualitative protocol templates.

Current regulations advise that protocols should:

a) include instructions to avoid loss of already collected data when participants withdraw, thereby preventing bias.
b) Implement proactive risk management
c) Minimise unnecessary burden on participants and investigators

All draft and approved protocols must be version controlled, as per SOP-ADM-002 Document Control, and dated and saved in the TMF.

## 4.2 Research Team input

The CI with input from specialist team members from the Trial Management Group e.g. statistician, pharmacist, laboratory manager will populate and distribute the draft protocol for review. The CI must agree a near final draft protocol prior to it being sent for Sponsor review.

## 4.3 Sponsor review

The Sponsor will review the draft protocol and may request revisions. If significant revisions are required, the modified draft must again be reviewed by the research team and/or CI and resubmitted to Sponsor.

## 4.4 Protocol approved

When a protocol has completed review it must be signed and dated by the Sponsor, CI, and relevant specialists as appropriate. If wet ink signatures are used, the original must be saved in a paper TMF and it should be scanned into an electronic TMF.

The protocol is then submitted for appropriate regulatory authorisations from a relevant Research Ethics Committee (REC), and MHRA for CTIMPs or device trials in accordance with the SOP on Applying for ethics approval (STU-SOP-TS-009).

### 4.4 Protocol modifications

If a protocol is modified for a research project, the drafts and final approved version should be managed in accordance with the SOP on Document Control (STU-SOP-ADM-002) and submitted for approval in accordance with the SOP on Managing sub and non-substantial modifications (STU-SOP-TM-015).

## 5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- HRA protocol templates: Protocol - Health Research Authority (hra.nhs.uk)
- Standard Protocol Items: Recommendations for Interventional Trials – The SPIRIT Statement – GUIDANCE FOR CLINICAL TRIAL PROTOCOLS (spirit-statement.org)
- 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

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-039 | Non-CTIMP Protocol Template | QMS |
| STU-SOP-ADM-002 | Document Control | QMS |
| STU-SOP-TS-009 | Applying for Ethics Approval | QMS |
| STU-SOP-TM-015 | Managing Submission of Non-Substantial and Substantial Amendments | QMS |