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

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 available Health Research Authority (HRA) templates and guidance, 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. HRA CTIMP Protocol Development Tool (see references).

All draft and approved protocols must be version controlled.

4.2 Research Team input

The CI with input from specialist team members 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 amended 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.

The protocol is then submitted for appropriate regulatory authorisations e.g. Research Ethics Committee (REC) and MHRA for CTIMPs or device projects.

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 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-TMP-039	Non-CTIMP Protocol Template	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DSUR	Development Safety Update Report
DRG	Document Review Group
GCP	Good Clinical Practice
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
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

8. Appendices

Appendix 1: Document History

Version No:	3	Effective Date:	20-Jun-24
Description of changes:			