STU-SOP-TC-002 – Standard Operating Procedure on Trial Closure Including Early Termination or Suspension

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of closing a site or research project, suspension and reactivation.

2. Background

A well-defined process for closing research projects is an important part of robust quality control processes and helps ensure requirements of the Medicines for Human Use (Clinical Trials) Regulations (2004) are met. These requirements include informing the appropriate bodies of research project closure, reconciling research project activities, ensuring accurate reporting through good quality data, and archiving key documentation.

Research project closure must be defined in the research project protocol. This can only be changed by means of an approved substantial protocol amendment or as the result of an urgent safety measure. Research project closure is not determined in relation to final analysis or reporting.

Possible reasons for site closure or suspension could include:

- Change/loss of key staff members
- Protocol changes that affect the site's suitability (including substantial amendments)
- Lack of recruitment at the site over a long period of time
- Consistent/significant protocol violations (may require an audit and/or plan to prevent reoccurrence before the research project may resume)
- Urgent safety measures that require the site to suspend recruitment.

3. Roles and Responsibilities

The Sponsor is responsible for notifying the MHRA (for CTIMPs), the authorising Research Ethics Committee (REC) and other regulatory bodies that a site/research project has closed or been suspended. These responsibilities may be delegated to the Chief Investigator.

The Trial Steering Committee (TSC) is responsible for implementing urgent safety measures, which may include closure or suspension of a site/research project.

The Trial Management Group (TMG) makes the decision to close individual sites.

The Chief Investigator (CI) is responsible for ensuring all activities relating to research project or site closure as appropriate. Many of these tasks can be delegated to the Trial Manager.

The Trial Manager (TM) assists the CI with research project closure procedures.

The Data Manager (DM) is responsible for verifying the completeness of data prior to site/research project closure.

The STU IT Manager (or delegate) is responsible for revoking access to any research project-specific IT infrastructure/resources controlled by STU.

Site Principal Investigators (PIs) are responsible for closing a research project at their site.

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 Site closure

Sites should be closed as per the protocol. The CI (or TM) will write to the site to inform them, triggering the site closure process.

Any site withdrawing from a research project must notify the CI (or TM) in writing.

4.1.1 Site closure checks

The TM will send the PI or delegate a Site Closure Checklist (STU-AD-TMP-033) which must be completed by an agreed date.

4.1.2 Site closure meeting(s)

A site closure meeting(s) will be held to discuss the completed Site Closure Checklist and to agree on-going responsibilities of site staff (e.g.in the event of an audit). This can be face-to-face or via teleconference.

4.1.3 Confirmation of site closure

When all parties are satisfied that the site can be closed, the CI (or TM) writes to confirm closure. Once this is received, the site may complete its archiving process.

4.2 Research Project closure

4.2.1 Notification of end of research project

At research project closure, the following should be informed at minimum:

- the Sponsor
- the funding body
- all research project sites
- site R&D departments
- research project committees

4.2.2 Notify regulatory bodies

The Sponsor is required to notify the appropriate regulatory bodies within 90 days of a planned closure, or 15 days of an early closure. This includes the MHRA (for CTIMPs), authorising REC and the funding body.

4.2.3 Data release

Research project sites may be provided with a copy of their own data (for archiving with their ISF).

4.2.4 End of research project reporting

All end of research project reports must be completed within stipulated timescales and according to the specific reporting requirements (e.g. REC and MHRA reports must be submitted within 12 months of closure).

4.3 Suspension and reopening of a site/research project

Following discussions with sponsor, where a site/research project has been suspended, the MHRA (for CTIMPs) and REC must be informed within 15 days.

No participants may be enrolled onto a suspended research project, and no follow-up activities may take place unless directly related to participant safety or administrative tasks (e.g. data verification). An audit may be carried out to identify the root cause of the suspension and to recommend a resolution.

The site(s)/research project may only be reactivated when it is safe to resume and all parties agree. Where this is not possible, the site(s)/research project must be closed and the MHRA (for CTIMPs) and REC informed.

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-TMP-033	Site Closure Checklist	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
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
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	25-Mar-2024
Description of changes:	Clarification of Research project closure procedure Clarification of Site/research project suspension & reopening procedure Moved to SOP template v5		