

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

<b>Version No:</b>	4	<b>Effective Date:</b>	10-Apr-2026
<b>Description of changes:</b>	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	
<b>CI</b>	Chief Investigator
<b>CTIMP</b>	Clinical Trial of an Investigational Medicinal Product
<b>DM</b>	Data Manager
<b>ISF</b>	Investigator Site File
<b>MHRA</b>	Medicines and Healthcare products Regulatory Agency
<b>PI</b>	Principal Investigator
<b>REC</b>	Research Ethics Committee
<b>SOP</b>	Standard Operating Procedure
<b>STU</b>	Swansea Trials Unit
<b>TM</b>	Trial Manager
<b>TMF</b>	Trial Master File
<b>TMG</b>	Trial Management Group
<b>TSC</b>	Trial Steering Committee

### 1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for the closure, suspension and reactivation of a research project or an individual research location (i.e. recruiting hospital, GP practice, etc).

### 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 modification submitted to the ethics committee (and regulatory bodies for CTIMPs) 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 project and/or 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 Officer** (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 outlined below.

Any site withdrawing from a research project prematurely should notify the CI (or TM) in writing and will be asked to undergo the same checks.

##### 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.

The DM will ensure that any outstanding data queries are resolved prior to agreement to commence closure of the site on the database.

##### 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 meeting 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. The TM should confirm the archivist at the site.

## 4.2 Research Project closure

### 4.2.1 Defining the end of a project

For most clinical trials this will be the date of the last visit of the last participant recruited. It may also be the completion of any follow-up monitoring and data collection, as described in the protocol.

For studies involving human tissue, the analysis of the samples should be undertaken as part of the data collection before the end of study is declared. However, samples may be stored for a maximum of 12 months after this date to verify or check the quality of the research data, without needing a Human Tissue Authority (HTA) research licence, where this is detailed in the protocol.

If the use of tissue for future research purposes is needed, you should obtain consent for this from the donors. It must be stored at an establishment with a HTA licence or submit a new proposal for REC review.

### 4.2.2 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
- the Confidentiality Advisory Group (where applicable)

### 4.2.3 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. For CTIMPs using the combined review process the End of Trial Notification form is sent to both REC and MHRA automatically. For earlier CTIMPs that pre-date the joint review process there is a form on the MHRA website to be completed and emailed to REC and MHRA.

### 4.2.4 Data release

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

### 4.2.5 Samples and data

If your study involved human tissue at the end of the study (in line with the protocol and terms of the consent from the donors) you may have agreed to dispose of the human tissue or transfer the tissue to a licensed establishment. You should also ensure any research data and personal data is stored or destroyed appropriately, as detailed in your protocol and in line with GDPR and the Data Protection Act.

### 4.2.6 End of research project reporting

Final analysis of the data (following 'lock' of the study database) and report usually happens after formal declaration of the end of the study.

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).

### 4.2.7 Informing participants

Where applicable, people who have taken part in a research project should be thanked for their contribution and told about what it helped the researchers find out. A summary of the

research findings should be made available e.g. on the project / STU website, and in accordance with the project protocol and/or dissemination plan.

#### 4.3 Suspension and reactivation 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) - <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/>
- 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/ukxi/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-033	Site Closure Checklist	QMS