

STU-SOP-TC-003 – Standard Operating Procedure on End of Project Reporting and Publications

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List of Abbreviations	
CAG	Confidentiality Advisory Group
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
MHRA	Medicines & Healthcare products Regulatory Agency
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TMF	Trial Master File

1. Purpose and Definitions

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures and responsibilities for the reporting requirements at the end of a research project for studies involving Swansea Trials Unit (STU).

It will also provide advice on publication plan development.

2. Background

For any research project there is a requirement to correctly close down the project. This involves informing the relevant organisations involved in giving approval and the funder (and the MHRA if relevant).

At the point of applying for approvals, the definition of the end of the study should have been stated in the ethics application and the protocol. Once this has been reached, a series of actions must be carried out before the project can be submitted for archiving (see STU-SOP-TC-001). These are detailed in Section 4.

3. Roles and Responsibilities

The **Sponsor** is responsible for the oversight of end of research project activities and the delivery of planned actions in line with ethical, legal and funding requirements.

The **Chief Investigator (CI)** is responsible ensuring that the relevant end of study activities are completed in a timely manner in accordance with the relevant requirements. They will also approve the contents of any Publication Plan.

The **Trial Manager (TM)** may be delegated responsibility for completing tasks required at the end of a study and overseeing the publication strategy, ensuring that any funder requirements for publications are followed.

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.

For non-NHS projects with University REC approval, local committee procedures for study closure should be followed.

4. Procedure

4.1 End of study timepoint

The definition of the end of the study should be documented in the protocol.

For most research projects this will be the date of the last visit of the last participant. It may also be defined instead as the completion of any follow-up monitoring and data collection. For international studies, this is the end of study in all participating countries, not just in the UK.

Any change to the end of study definition after approval has been given for the research should be notified as a modification to the appropriate review bodies.

4.2 Extending the end of study definition for tissue analysis

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, you can store samples 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 you want to keep and use tissue for future research purposes, you should obtain consent for this from the donors. You must store it at an establishment with a HTA licence or submit a new proposal for REC review.

4.3 Notifications required for research projects

You must declare the end of a study to the Research Ethics Committee (REC) that gave a favourable opinion within 90 days of the study ending using the end of study declaration form.

Final analysis of the data (following 'lock' of the study database) and report usually happens after formal declaration of the end of the study. This must be defined in the protocol and any analysis plans.

For studies that have HRA and HCRW approval, but did not require REC review, you should notify the HRA at approvals@hra.nhs.uk including your IRAS ID and your contact information (phone and email).

If you have an application with the Confidentiality Advisory Group (CAG) you should notify the confidentiality advice team once it has ended.

4.4 Additional notifications for CTIMPs

For clinical trials of investigational medicinal products (CTIMPs), the same end of trial form is used to notify both the REC and the Medicines & Healthcare products Regulatory Agency (MHRA). The declaration must be sent to MHRA within 90 days of the end of trial date and within 15 days of the premature end of trial.

For trials submitted through the combined review process (C-WOW), you should complete and submit the end of trial form in the new part of Integrated Research Application System (IRAS). This automatically submits the notification to the REC and MHRA.

For CTIMPs that were not submitted through combined review, you will need to complete the form available on the MHRA website and email this to the MHRA and REC.

4.5 Final reports

All REC-approved projects need to submit a final report to the REC (and the MHRA if it is a CTIMP) within 12 months of the end of the study (unless the study is listed as an exception).

The report should be uploaded to <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/> unless it is a CTIMP submitted on CWOW. These reports can be submitted via the CWOW system.

A lay summary of the results will need to be submitted for publication as a funder requirement and should follow their guidelines. The HRA may also publish aggregate data collected from the final reports on their website, as part of our annual research transparency reporting. This must not contain any personally identifiable information.

4.6 Post-research care of participants

The CI and Sponsor are responsible for explaining and justifying what will happen to participants once they have finished taking part. RECs are responsible for considering the arrangements.

Where research includes a therapeutic intervention, the sponsor should include information about what happens at the end of the study in the participant information sheet. It must be clear whether participants will have continued access to any benefits or intervention that they may have obtained during their participation in the research, once the research study stops.

Unless specific arrangements have been put in place for the supply of a treatment after research, the clinical decision about what happens after the study will come under the normal limitations of the NHS commissioning arrangements.

If your study involved human tissue at the 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 <https://gdpr-info.eu/> and the Data Protection Act <https://www.legislation.gov.uk/ukpga/2018/12/contents> (see also STU-SOP-TC-001).

4.7 Dissemination of findings to the public

Where applicable, participants should be thanked for their contribution and told about how it helped the researchers. The HRA have guidance on writing plain English summaries of research findings <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/writing-plain-language-lay-summary-your-research-findings/>

4.8 Publishing results

Research findings, whether positive, negative, neutral, or inconclusive should be made accessible when the study ends. Ideally publications would be submitted within 12 months of the end of the study and in line with funder requirements/agreed publication plans. Every effort should be made to public as open access, funding permitted.

Additional consideration should be given to dissemination to non-academic audience via pre-specified dissemination plan in the protocol.

For trials registered on a clinical trial registry e.g. ISRCTN, Clinicaltrials.gov, the report should be published at the relevant registry.

Information relating to data sharing should be available so that external teams can request data for meta-analysis (see STU-SOP-DMS-012).

The study may opt to have a Publication Plan (see STU-AD-TMP-058) which would be developed early in the study to help focus on findings, potential journals and authorship.

5. References

- HRA end of trial reporting portal <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/>
- HRA writing end of trial summaries <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/writing-plain-language-lay-summary-your-research-findings/>

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-058	Publication Plan template	QMS