Royal Papworth Hospital NHS Foundation Trust

Document Title: Trial Closure and End of Trial Reporting

Document Number: PTUC SOP021

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	July 2025

Summary of Amendments

Version No:	Modification:
5.0	Updated in line with combined review process. Section added to confirm position regarding premature closing of a site

Key Points of this Document

- This document sets out the procedures to be followed by all Staff who are involved in the close-down, termination, suspension or final reporting of research studies and clinical trials.

- It provides guidance on how patients, staff and trial related documentation is managed during close-out so as to ensure compliance with the Trust's Information Governance Policies, the Data Protection Act (2000), and the UK Policy Framework for Health and Social Care Research (2018).

1 Purpose and Content

a. This document defines the Trust's research procedures for trial closure and end of trial reporting of Research Studies and Clinical Trials managed by Royal Papworth Trials Unit Collaboration (PTUC) and sponsored / hosted by Royal Papworth NHS Foundation Trust.

b. The definition of the end of trial is outside the scope of this SOP and is described in PTUC SOP019: Research Protocol Design.

c. Trial closure should be completed following TPL026 Study close out checklist

d. The document describes the responsibilities and actions of the Investigator and Sponsor in the event of premature termination or suspension of a trial. The archiving of study data is outside the scope of this SOP and is described in PTUC SOP011: Archiving SOP.

2 Roles & Responsibilities

a. This Policy applies to all personnel who are conducting research at the Trust.

b. Staff involved in running or managing research studies must comply with the requirements set out in section 4.

c. It is the responsibility of the Principal Investigator based at Royal Papworth, or the Trial Manager, to inform the Sponsor, PTUC and Royal Papworth's R&D Department (if different) of trial closure or suspension at Royal Papworth Hospital.

d. The Chief Investigator, or their designee, is responsible for informing the applicable regulatory authorities of the end of trial and submitting the necessary end of trial reports.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Procedure for studies managed by PTUC or sponsored by Royal Papworth

4.1 Early termination or temporary suspension of a trial

a. For temporary suspension of studies the main REC (and MHRA if the study is a CTIMP or new device study) should be notified within 15 days

   1. The notification should be made as a substantial amendment using the amendment tool accessible via IRAS. For non-CTIMP studies, the amendment must be submitted to REC using the standard IRAS platform. For CTIMP or device trials the amendment must be submitted via the combined review IRAS platform.

   2. To restart a trial that has been temporarily suspended, you should make the request as a substantial amendment using the notification of amendment form, providing evidence that it is safe to restart the trial.

b. For early termination (closure) of studies the main REC (and MHRA if the study is a CTIMP) should be notified within 15 days using the Declaration of End of Trial form via the same routes as outlined above.

c. The Sponsor and R&D Unit must be notified immediately. This can be by telephone but must be followed up by a written report.

d. All investigators must be informed of the trial termination/suspension using expedited means of communication and receipt of notification acknowledged. The reasons for early termination (or temporary suspension) must be made clear.

e. The Chief Investigator and Sponsor must decide if participants need to be contacted to tell them of the termination or suspension of the study and any actions that need to be carried out. This decision must be documented.

f. Documentation and all records should be archived according to PTUC SOP011: Archiving SOP.

4.2 End of trial

4.2.1 Regulatory Reporting

a. The Chief Investigator (or their delegated individual) is responsible for informing the following that the trial is closed, by using the appropriate Declaration of End of Clinical Trial

Forms which are available from http://www.hra.nhs.uk/research-community/end-ofstudy-and-beyond/ . This should be submitted within 90 days of the end of the study.

1. Ethics Committee which approved the research
2. HRA (where a study has HRA approval but did not require REC approval)
3. Regulatory bodies (e.g. MHRA)
4. Royal Papworth CTU
5. Royal Papworth R&D Unit
6. Sponsor
7. CPMS and the CRN

b. The Chief Investigator, or their designee, should submit the End of Study report (there is no defined format for this report) to the REC and MHRA within 12 months of the end of the study.

4.2.2 Closure of sites:

a. The Chief Investigator, or their designee, should inform the Principal Investigators at other sites, in writing, that the trial has closed. This should include:

1. summarise patient status (recruitment, withdrawals, SUSARS, SAEs etc)
2. remind the investigator of any continuing trial obligations (e.g. archiving)
3. advise of the dates of site closure, audit or inspections visits
4. solicit any queries in procedure
5. arrange for the return of trial supplies and/or drug supplies, if applicable
6. outline the results of the trial or provide a copy of the report (if available) 7. inform the investigators, if possible, of the timing of publication

b. Site closure - a study visit may be necessary to verify or complete the closure process at a participating site and will be conducted by either the Chief Investigator, or their designee. A site can be deemed to be closed once the following are reconciled or complete:

1. Investigator/institution and sponsor files are reviewed and all essential documentation for a particular site are present in the relevant files to ensure a clear audit trail of study conduct at the site
2. All site data are collected, entered, validated and all data queries resolved where feasible. This includes queries resulting from reconciliation of the clinical and safety database
3. For studies using electronic data capture, the sponsor or their delegate has provided copies of final study data relating only to participants at that site for local study files

4. All issues from previous study monitoring procedures are resolved or documented
5. All financial matters are resolved and all site payments are complete as agreed and documented in study contracts/agreements/approvals. Finance to be notified that all financial matters are resolved and that the study site has closed.
6. All unused trial supplies are returned or destroyed according to study and/or sponsor requirements
7. All samples collected during the trial have been sent to the agreed location for analysis/storage (usually the sponsor), along with a fully completed sample log.
8. For a CTIMP final drug accountability is complete and destruction of unused study drug is documented in the site file (if destroyed locally at site)
9. Investigators are aware of the study publication policy, as documented in the study protocol and/or study contracts/agreements
10. Investigator(s) are aware of and have implemented relevant ongoing requirements such as site archiving, subsequent audit/inspection procedures and any ongoing reporting requirements

c. Details of site closure must be documented, normally in the form of a written report, and any issues raised must be followed up promptly. It should be clear who reviews closure reports to ensure that feedback is provided to the site and sponsor (where applicable). An on-site closure visit may be carried if it is deemed necessary, and this should be documented in the Sponsor File.

d. There is no regulatory requirement for the sponsor or delegate to notify routine closure of active sites at the conclusion of a study.

e. Upon closure of the trial, all study documentation is retained by the sponsor until such time as all data queries are resolved and the database is closed. Final analysis of the data (following 'lock' of the study database see SOP 077 Data Management Overview) and report writing may occur after formal declaration of the end of the project. At this time all trial documentation should be archived according to SOP011.

f. It may be necessary for a site to prematurely close; for example a site withdraws from a trial because it can no longer recruit participants as the protocol stipulates because of changes to its treatment pathway. If this occurs then the procedures for closing the site should be followed as in 4.1.1

4.3 Planned closure of hosted studies at Royal Papworth

a. Upon closure of the trial, all study documentation is retained by the study team until such time as all data queries are resolved and the trial sponsor's database is closed. At this time all trial documentation is archived according to the sponsor requirements.

4.4 Trial closure and study samples

a. Upon closure of the trial all remaining study samples must be stored/destroyed in accordance with the conditions of the research ethics approval, trial protocol and individual signed consent forms.

b. A fully completed sample log must be saved in the study TMF (see SOP 013 and FRM021 Sponsor File Index) prior to archiving.

c. If consent was given for the remaining samples to be stored for future use the samples should be transferred to the appropriate freezer, the freezer sample log must be updated and proof of consent electronically stored.

d. If samples are to be transferred to a Biobank (e.g. Royal Papworth Hospital Research Tissue Bank), this should be completed prior to archiving of trial

e. The member of study team delegated to take responsibility for the samples at the end of the trial must complete the Sample Declaration (FRM 069) and this must be counter signed by the Investigator

4.5 End of Trial Reporting

Royal Papworth Sponsored Studies

a. It is the responsibility of the Chief Investigator to ensure the results of the study are analysed and reported within a reasonable timeframe.

b. A summary of the final report on the research should be sent to the MHRA ,as required, REC and R&D Unit within 12 months of the end of the trial.

c. The Chief Investigator should make all necessary efforts to get the results reported in a peer reviewed journal.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved date]
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	July 2025

I certify the contents of this SOP has been reviewed and ratified

DocuSigned by:
Dr Patrick Calvert
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13-Jul-2022

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Signed by Dr Patrick Calvert, Clinical Director of R&D — Date