STANDARD OPERATING PROCEDURE FOR CLOSURE OF HEALTH AND SOCIAL CARE RESEARCH STUDIES

SOP NUMBER:	TASC SOP016 v10
AUTHOR:	Patricia Burns
EFFECTIVE DATE:	21 Jan 2024
REVIEW DATE:	21 Jan 2026

1. PURPOSE

This document describes the processes that must be followed at the closure/end of health and social care research studies.

2. SCOPE

This SOP applies to all health and social care research studies sponsored or co-sponsored by the University of Dundee or NHS Tayside including Clinical Trials of Investigational Medicinal Products (CTIMPs).

Final analysis of the data (following 'lock' of the study database) and report writing is normally considered to occur after formal declaration of the end of the study.

3. RESPONSIBILITIES

Chief Investigator:

- To ensure completion of any study activities (i.e. follow-up visits) before declaring end of study.
- To ensure permissions to retain data (e.g. from record linkage) are appropriate for study and comply with all regulations.
- To ensure compliance with all conditions of Approvals prior to declaring the end of the study i.e. the use, destruction and/or storage of tissue.
- To ensure Principal Investigators (PI) at sites have received their participant data from central database and shall archive on site.
- To declare the end of the study using the appropriate form.
- To provide a final report to the Sponsor and appropriate body(ies) within required timeframe.
- To upload results to Public Register (or Registers) within correct timeframe.
- To ensure the details of the study on any Public Register are up to date and all conditions of the Register have been met.
- To disseminate the results of the study.
- To notify the Sponsor (tascgovernance@dundee.ac.uk) of any issues or concerns regarding close out procedures.

Research Governance Manager:

- to ensure Monitoring team, Good Clinical Practice (GCP) archivist and Legal department are aware the End of Trial (EOT) Declaration has been received.

4. PROCEDURE

4.1 Timelines

Notification of the end of the study (as defined in the Protocol) must occur within:

- 90 days of the end of the study.
- 15 days if the study terminates early. (*Early termination does not include completion of recruitment earlier than expected.)*
- 15 days if a CTIMP does not recommence after a formal halt.
- A Final Summary Report must be provided within 12 months of the end of the study.
- Summary Results must be uploaded onto each and every Public Register the study is registered with, within the timelines required by the Registry.

4.2 Notification of the end of a clinical trial (CTIMP)

4.2.1 For CTIMPs submitted through the Combined Review Service, the EOT form is to be completed and submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) in the new part of Integrated Research Application System (IRAS). This automatically submits the notification to the Research Ethics Committee and MHRA. A separate email must be submitted to the lead R&D.
For CTIMPs that were not submitted through Combined Review, the form available on the MHRA website must be downloaded and emailed to the Sponsor, MHRA, REC and lead R&D.

4.2.2 Once the declaration form is submitted, no further documentation will be accepted by the REC or MHRA **except** the EOT report.

4.3 CTIMPs that do not start or do not recommence after a formal halt:

4.3.1 The EOT form must be downloaded from the MHRA website.

On completion, the form must be forwarded to the:

1. MHRA (following current guidance on their website)
2. Sponsor (tascgovernance@dundee.ac.uk
3. Relevant NHS REC
4. Lead NHS R&D Office.

4.3.2 A covering letter must identify the protocol and Public Register identifiers, with a brief explanation of the reasons for not starting the study or not starting it again.

4.4 Declaration of end of study (all other research) to the Sponsor, NHS REC and NHS R&D

For studies that do **not** fall under the remit of the MHRA, the appropriate form ("*all other research"*) must be downloaded from the Health Research Authority (HRA) website.

Once complete, the form must be emailed to:

1. the Sponsor (tascgovernance@dundee.ac.uk)
2. the relevant NHS REC
3. the lead R&D office
4. other approvers as required.

4.5 End of study with HRA Approval

Where a study has HRA Approval and has been reviewed by an NHS REC, the HRA do NOT require separate notification.
Where a study has HRA Approval and was NOT reviewed by an NHS REC, the HRA MUST be notified by an email to hra.approval@nhs.net.
The email must include the IRAS ID and email and telephone number of Chief Investigator.
The Sponsor, tascgovernance@dundee.ac.uk, must be copied into the email.

4.6 Final report

For CTIMPs submitted via the Combined Review Service, the Final Report Form must be completed and submitted in the new part of IRAS.

For all other project-based research reviewed by an NHS REC, the Final Report Form should be completed and submitted on the webform on the HRA website.

For clinical investigations of devices, the MHRA (devices) asks to be informed of when the trial has been completed and requests a copy of the final report when available.

4.7 Clinical trial summary results

Research summary results must be published in the Public Register (or Registers) where the trial is registered within one year of the EOT (within 6 months for paediatric trials).

For CTIMPS only:

Email CT.Submission@mhra.gov.uk and tascgovernance@dundee.ac.uk.
The subject line of the email notification must state 'End of Trial: result-related information: EudraCT XXXX-XXXXXX-XX'.

If the trial is registered on EudraCT, those taking place within the European Union (EU), the steps to follow are described in the European Medicines Agency (EMA) webpage 'Tutorials on posting results'.

A letter from the Sponsor confirming permission to carry out this task is provided by tascgovernance@dundee.ac.uk.

4.8 Additional End of Study Processes

- Ensure all conditions of Approvals have been met.
- Follow up all Adverse Events as per TASC SOP on Reporting Adverse Events.
- Ensure all tissue samples consented to be stored for future research have been registered with Tayside Biorepository.
- Ensure destruction of tissue samples following analysis if not consented for
- storage for future research.
- Ensure all Investigational Medicinal Product (IMP) managed as per Protocol i.e. destroyed and certificate stored in Trial Master File.
- Resolve all data queries prior to data lock.
- Ensure all Logs (Drug Accountability, Subject, Delegation etc) are completed and in Trial Master File.
- Check to confirm all essential documents are stored in Trial Master File, including a record of file paths to electronic data.
- Ensure Trial Master File and Case Report Forms are stored in a secure location.
- Notify Sites when they can archive (as per agreement) and request information on location.
- Meet any reporting requirements to Funder.
- Fulfil commitments with participants/patient and public collaborators.

5. ABBREVIATIONS & DEFINITIONS

CTIMP	Clinical Trial of an Investigational Medicinal Product
EMA	European Medicines Agency
EOT	End of Trial
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

6. ASSOCIATED DOCUMENTS & REFERENCES

None

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
9	Patricia Burns (Senior Research Governance Manager)	21/01/2022	Text amended to take into account new process following departure from EU. Minor changes to text throughout.
10	Patricia Burns (Senior Research Governance Manager)	21/01/2024	Minor updates regarding Combined Review Service and EudraCT.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	18 Jan 2024