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

SOP NUMBER:	TASC SOP016 v12
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1. PURPOSE

This document describes the processes that must be followed at the closure/end of health and social care research studies, including Clinical Trials of Investigational Medicinal Products (CTIMPs) in compliance with all UK regulatory requirements, including UK Clinical Trial Regulations effective from 28 April 2026.

Formal declaration of the end of the study marks the end of collection of data. Final analysis, data lock and report writing may occur after the formal declaration of end of study, in accordance with Regulatory requirements.

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:

- CTIMPs
- Other Medicines and Healthcare products Regulatory Agency (MHRA) regulated research
- Non-CTIMP research reviewed by an NHS Research Ethics Committees (REC)
- Studies Sponsored before 28 April 2026 that end on or after 28 April 2026
- Studies Sponsored on or after 29th April 2026.

3. RESPONSIBILITIES

Chief Investigator:
The Chief Investigator is responsible for ensuring that study closure is conducted in accordance with Protocol, Approvals and applicable regulations.

Responsibilities include:

- Ensuring completion of any study activities (i.e. follow-up visits) before declaring end of study.
- Ensuring permissions to retain data (e.g. from record linkage) are appropriate for study and comply with all regulations.
- Ensuring compliance with all conditions of Approvals prior to declaring the end of the study, i.e. the use, destruction and/or storage of tissue.

- Ensuring Principal Investigators (PI) at all locations have received their participant data from central database and shall archive on site.
- Declaring the end of the study using the appropriate regulatory route and digital submission system.
- Providing a final report to the Sponsor and appropriate body(ies) within required timeframe.
- Uploading summary of results to all applicable public trial registries within required timelines.
- Disseminating the results of the study.
- Notifying the Sponsor (tascgovernance@dundee.ac.uk) of any issues or concerns regarding close out procedures.

Research Governance Manager:

- For CTIMPs, to ensure Monitoring team, Good Clinical Practice (GCP) archivist and Legal department are informed the End of Trial (EoT) Declaration has been received.
- To confirm regulatory notifications and reporting obligations have been completed.
- To support oversight of compliance with transparency and reporting requirements.

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.

For CTIMPs sponsored before 28 April 2026, but ending on or after that date, the new transparency and reporting requirements apply.

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

4.2.1 For CTIMPs submitted through the Combined Review Service:
The EoT notification must be submitted using the MHRA digital service through IRAS Submission automatically notifies:

- MHRA
- NHS REC.

A separate notification must be submitted to the lead R&D.

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

- Final report
- Results-related submissions
- Safety follow-up notifications if required.

4.2 CTIMPs that do not recruit within two years of approvals:

- Approvals shall lapse
- End of trial must be declared.

4.3 Declaration of end of study (all other research)

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.

Notification must include:

- Integrated Research Application System (IRAS) ID
- Chief Investigator (CI) contact details.

Once complete, the form must be emailed to:

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

4.4 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.

4.5 Final reports

CTIMPs

- Final reports must be submitted within 12 months of EoT, via the MHRA digital service within IRAS.

Other REC approved research

- Final reports must be submitted via the HRA platform.

Medical Device Investigations

- MHRA Devices, must be informed of trial completion and provided with the final report when available.

4.6 Clinical trial summary results - Transparency Requirements

Summary results must be made publicly available on the relevant public register(s) in which the trial is registered, and a lay summary of the results must be offered to all relevant persons:

- Within one year of the EoT
- Within 6 months of the EoT for paediatric trials.

CTIMPs

- Results submissions and notifications must comply with MHRA transparency requirements.
- Sponsor authorisation is required prior to Registry submission.

Failure to publish results within required timelines may constitute a regulatory Breach.

4.7 Additional End of Study Processes

The CI must ensure:

- All conditions of Approvals have been met.
- All Adverse Events are followed up in accordance with Sponsor SOPs.
- Tissue samples are managed in line with consent and Tayside Biorepository requirements.
- Investigational Medicinal Products are reconciled, destroyed, and documented.
- Data queries are resolved prior to database lock.
- Trial Master File and essential records are complete, secure and archived.
- All locations are notified when archiving may commence and archive locations are recorded.
- All funder reporting obligations are fulfilled.
- Commitments to participants/patients and public collaborators are met.

5. ABBREVIATIONS & DEFINITIONS

CTIMP	Clinical Trial of an Investigational Medicinal Product
EoT	End of Trial
GCP	Good Clinical Practice
HRA	Health Research Authority
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 European Union. Minor changes to text throughout.
10	Patricia Burns (Senior Research Governance Manager)	21/01/2024	Minor updates regarding Combined Review Service and EudraCT.
11	Patricia Burns (Senior Research Governance Manager)	21/01/2026	Biennial review. Vocabulary changed in line with ICH-GCP R3 updated terms
12	Patricia Burns (Senior Research Governance Manager)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

8. APPROVALS

Approved by:	Date:
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	30 Mar 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	27 Mar 2026