Standard Operating Procedure	Lancaster University

Title: End of Study Procedures for Lancaster University Sponsored Studies (non-CTIMP)

SOP Reference: HSCR-SOP007	**Date Effective From: 19/08/2025**
Version and Date: V1.0 16th June 2025	**Review Cycle: 2 Years**
Superseded SOP (version and date): NA	**Date of Next Review: 19/08/2027**

Author: Rebecca Anderson, Clinical Research Governance Officer

Approved by: Health and Social Care Research Sponsorship Committee (HSCRSC)

Date:19/08/2025

Document History

Version	Date	Reasons for Change
V1.0	16/06/2025	New Document

1. Background, Purpose and Scope

1.1 All health and social care research must be formally closed once study activities are complete. This includes declaring the end of study and reporting to the relevant regulatory and ethical bodies such as the NHS Research Ethics Committee (NHS REC) and/or Health Research Authority (HRA).

1.2 The end of study timepoint must be defined in the study protocol, but must always occur after the final participant visit, and once all follow-up and monitoring activities are complete.

1.3 As the Sponsor, Lancaster University holds overall responsibility for ensuring timely and compliant study closure. Responsibilities include:

- Maintaining documented ethical and compliant procedures for researchers to adhere to.
- Completing final monitoring and audits of data and documentation where required.
- Retaining documentation of the study conduct, including closure information.
- Ensuring retained data is stored securely as per the protocol and IRAS application.

1.4 Chief Investigators (CIs), under delegation from the Sponsor, are responsible for:

- Performing closure and reporting in line with sponsor and regulatory requirements.
- Maintaining the Trial Master File (TMF) and all study records in accordance with Good Clinical Practice (GCP) and institutional policies.
- Verifying that all data is complete, queries resolved, and data lock is achieved.
- Notifying all study sites of closure and halting all site activity.
- Informing participants of early termination or study outcomes, in line with protocol dissemination plans.
- Publishing results transparently and storing electronic data securely (password-protected, per IRAS and protocol conditions).

All CIs must receive and sign a delegation of responsibilities declaration (HSCR-FORM004) outlining these duties.

1.5 A structured closure procedure, as documented in this SOP ensures transparency, accountability, and respect for participants, while upholding research integrity.

1.6 This SOP applies to the closure of all Lancaster University–sponsored non-CTIMP studies.

2. End of Study Reporting Procedure

2.1 The end of study reporting is triggered when the end-of-study definition (as per the approved protocol) is reached; or the study is terminated early.

2.2 One month before the IRAS-listed end date (or latest approved amended end date), the CI will receive a notification from the Sponsor with guidance on the closure process.

2.3 If the protocol-defined endpoint has not been met, the definition is no longer an appropriate point to close, or the study is being terminated earlier than planned, an amendment to the original study proposal must be requested (see HSCR-SOP006).

2.4 When the study is ready to be closed, the CI or a delegate must first submit the Internal Declaration of End of Study form.

2.5 The CI or delegate must then complete the required external reporting as follows:

2.5.1 **For studies with HRA approval only (no NHS REC)** reporting the end of study is by email to the Health Research Authority (HRA) at approvals@hra.nhs.uk. Emails must include IRAS ID; contact details; and the study end date.

2.5.2 **For studies with NHS REC approval (with or without HRA)** must instead complete the NHS REC End of Study Declaration form for 'all other studies' found on the HRA webpage. The form must be submitted via email direct to the NHS REC that gave the original favourable opinion, within 90 days of the study ending.

2.6 A final study report is required for all Lancaster University sponsored studies within 12 months of closure, regardless of which ethical and regulatory approvals are held. All final reports should comply with the HRA guidance on lay summaries. The Clinical Research governance team also provide a template and guidance to support the writing of the lay summary.

2.7 All final reports are to be submitted to the sponsor via email to sponsorship@lancaster.ac.uk; and if the study was given favourable opinion from an NHS REC, also submitted via the NHS REC's final report webform*.

***F**or studies with HRA approval only (without NHS REC favourable opinion), the report is submitted to the sponsor only; the HRA webform does not need to be completed.

3.0 Research Site Closure

3.1 CI's or a delegate must formally notify research sites of study closure, and all research activities must cease following notification.

3.2 In the event of early termination, the CI or delegate must provide the site with the reason for closure; number of participants still receiving treatment; and management plan for those participants.

3.3 Research sites maintaining an ISF must be sent an ISF Close Down Checklist (HSCR-TEMP010) to complete.

3.4 A template checklist can be obtained from the Sponsor (HSCR-TEMP010), and study details must be inputted by the research team before sharing with the research site. Details should include titles, dates and version numbers of all current and superseded documents.

3.5 Upon being notified of the end of study and receiving the checklist, research site staff must review their ISF, request any missing documents from the Sponsor and document the contents of the file on the checklist.

3.6 Completed ISF Close Down Checklists must be:

- Signed by site staff, the CI, and Sponsor;
- Submitted to **sponsorship@lancaster.ac.uk; and**
- Stored in the ISF and TMF prior to archiving.

4. Archiving Essential Documents

4.1 All study documents, data, ISF's and TMF must be archived in accordance with Good Clinical Practice (GCP) guidelines; the research Data Management Plan; and the archiving provisions stated in the IRAS application.

4.2 Lancaster University does **not** fund TMF or ISF archiving costs, unless agreed in advance during sponsorship review or covered by the study funding.

4.3 Research sites required to maintain an ISF must be informed by the CI or delegate of the archiving arrangements during site setup.

5.Informing Participants

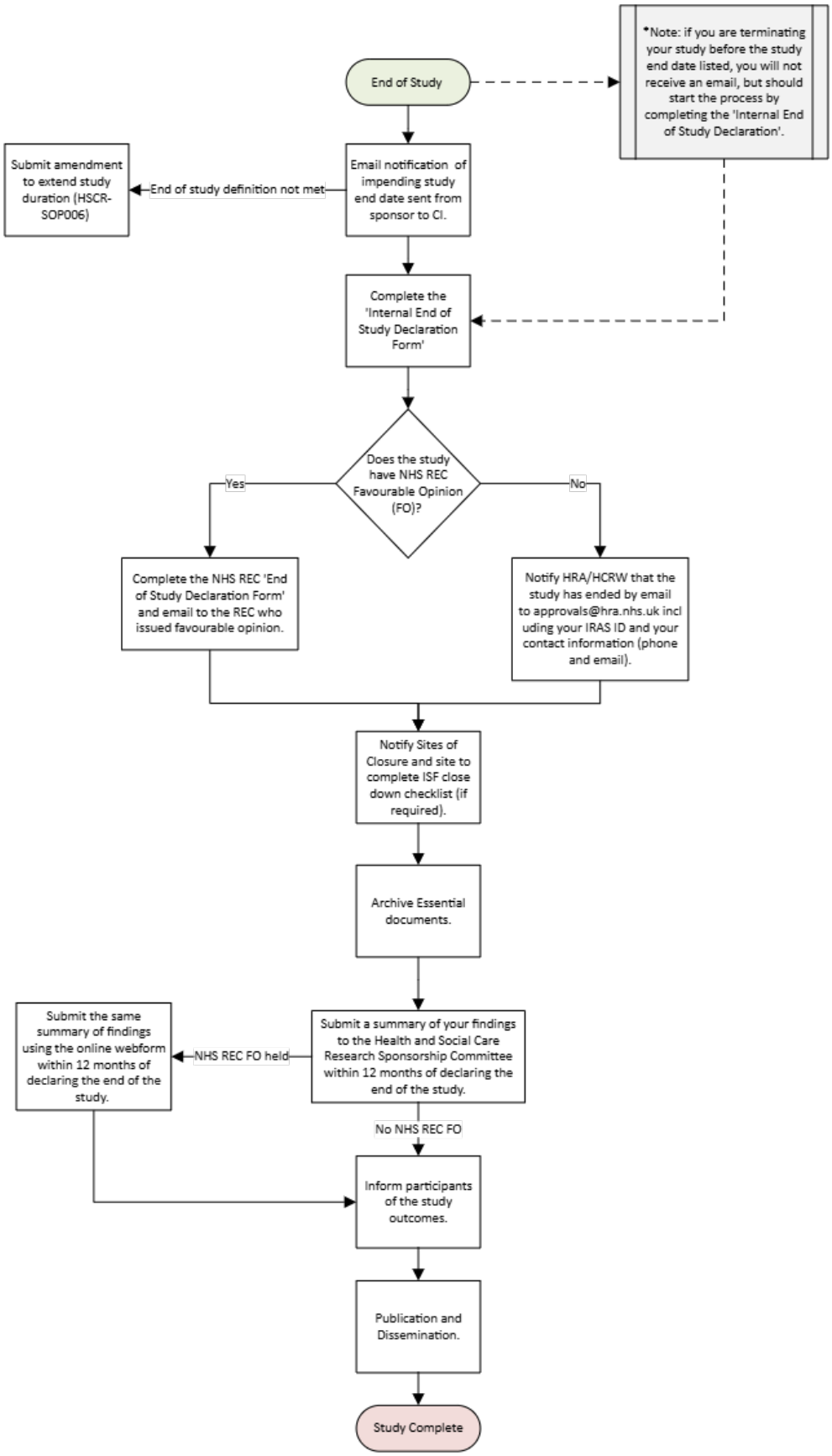
5.1 Researchers must fulfil all commitments to inform participants of the study outcomes as outlined in the IRAS application, study protocol, and Participant Information Sheet (PIS) in accordance with HRA guidance on providing clear and accessible study results to participants.

6. Publication and Dissemination

6.1 All publications and final reports must include the **IRAS ID** to support transparency and accountability; reflect the transparency commitments made to the **funder, REC, and HRA; and c**omply with **Lancaster University** and **HRA** publication standards HRA website – transparency in Research.

7. Flow Chart

The below flow chart outlines the end of study procedures for Lancaster University sponsored studies.


End of Study
*Note: if you are terminating your study before the study end date listed, you will not receive an email, but should start the process by completing the 'Internal End of Study Declaration'.
Email notification of impending study end date sent from sponsor to CI.
End of study definition not met
Submit amendment to extend study duration (HSCR-SOP006)
Complete the 'Internal End of Study Declaration Form'
Does the study have NHS REC Favourable Opinion (FO)?
Yes
No
Complete the NHS REC 'End of Study Declaration Form' and email to the REC who issued favourable opinion.
Notify HRA/HCRW that the study has ended by email to approvals@hra.nhs.uk including your IRAS ID and your contact information (phone and email).
Notify Sites of Closure and site to complete ISF close down checklist (if required).
Archive Essential documents.
Submit a summary of your findings to the Health and Social Care Research Sponsorship Committee within 12 months of declaring the end of the study.
NHS REC FO held
Submit the same summary of findings using the online webform within 12 months of declaring the end of the study.
No NHS REC FO
Inform participants of the study outcomes.
Publication and Dissemination.
Study Complete