

Study Closure and Archiving

Document No.:	CR009 v7.0
Author:	Elizabeth Craig
Issue Date:	14 APR 2026
Effective Date:	28 APR 2026

1 Introduction

- 1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).
- 1.2 The definition of the end of study should be clearly documented in the protocol. A change in this definition will require a protocol amendment.
- 1.3 Archiving requirements should be documented in the protocol.
- 1.4 Archived documentation needs to be stored in a way which preserves the integrity and readability of the source records (paper and electronic). Storage conditions within each archive facility must contain functional measures to prevent damage from fire, water and natural disasters and any other physical/electronic damage. Storage conditions must provide for adequate and suitable space and ensure that records are maintained in a legible condition. Archived records must be labelled and stored to allow timely and accurate retrieval when required. Access should also be restricted to appropriate individuals only. Source records must also be protected from unauthorised alterations during archiving. Archived records should consist of all the essential records defined under GCP and contain all the information necessary to independently verify the study conduct and to recreate the study and its findings if necessary.

2 Purpose

- 2.1 To define the procedure for closing a study that is sponsored by NHSL and/or the UoE. It also outlines who is responsible and the requirements for archiving essential records (paper and electronic).

3 Scope

- 3.1 The SOP is applicable to clinical researchers at NHSL and the UoE working on a study that is sponsored by NHSL and/or the UoE (this includes Clinical Trials of Investigational Products (CTIMPs) and non-CTIMPs).
- 3.2 References to archiving SOP GS005 (Archiving Research Essential Records) only apply to studies sponsored by NHSL and/or UoE.

4 Responsibilities

- 4.1 It is the responsibility of the Chief Investigator (CI), or designee (e.g. Trial Manager) to;
- Notify the sponsor(s), R&D, Research Ethics Committee (REC) and Medicines and Healthcare products Regulatory Agency (MHRA, where applicable) once the defined study end point is reached, or if the study end date is changed / extended.
 - Ensure that end of study reports are finalised and submitted to the appropriate bodies on time e.g. to the funder, REC
 - Publish summary results on the publicly accessible database that the trial was registered with, on behalf of the Co-Sponsors
 - Ensure that all essential study records are complete and filed in the Trial Master File (TMF) prior to archiving.
 - Arranging archiving of the TMF with the Sponsor, including archiving of electronic records.
- 4.2 It is the responsibility of the Principal Investigator (PI), or designee, to; Notify local R&D offices of the defined end point and when this is reached
- Arrange a close out visit with the ACCORD Clinical Trials Monitor (where applicable).
 - Ensure that all essential study records are complete and filed in the Investigator Site File (ISF) prior to archiving.
 - Archive the ISF, including archiving of electronic records.
- 4.3 The Clinical Trials Monitor is responsible for performing close out visits in accordance with SOP CM003 (Close Out Visits).

5 Procedure

5.1 Defining the End of the Study

- 5.1.1 If there is a proposal to change the definition of the end of the study as detailed in the protocol, for example, the CI plans to extend/curtail the research beyond/before the stated end date or recruitment target, this should be discussed with the Sponsor Representative. A modification may need to be submitted to the MHRA (where applicable), REC and R&D.
- 5.1.2 In addition, if there is an early termination proposal/request, this should be discussed with the Sponsor Representative. This may require amending contracts and will require notification to the MHRA (where applicable), REC and R&D including end of trial documentation. Any decision to modify the study timelines should be documented in writing and filed in the TMF.
- 5.1.3 For studies subject to combined risk assessment (SOP GS002), the events described in sections 5.1.1 and 5.1.2 will trigger a review of the risk assessment by the Sponsor Representative. The following items (not an exhaustive list) should be considered: end of trial notification timelines, Trial Steering Committee (TSC) oversight (as applicable), funder oversight, continuing trials unit roles and possible effect on study documents. Decisions should be documented in writing and filed in the TMF.
- 5.1.4 Before the end of study declaration form is submitted, study teams should review the plans that were approved (e.g. by REC) for use of tissue and data collected in the course of the study, providing information to participants, and dissemination of results. If any changes to these arrangements are required, then study teams should consider whether a modification is required before submitting the end of study notification.
- 5.1.5 Once a study is declared closed by submission of the Declaration of the End of a Trial/Study form then the study cannot be reopened or amended.

5.2 Notification of End of Study to ACCORD Monitors

- 5.2.1 Where a study is subject to ACCORD clinical trial monitoring, the PI, or designee (e.g. Trial Manager), must contact the ACCORD Clinical Trial Monitor **before the end of the study** to arrange a monitoring close out visit to any study location(s), in accordance with SOP CM003 (Close Out Visits).

5.3 End of Trial Notification for CTIMP Studies

- 5.3.1 For a Clinical Trial of Investigational Medicinal Products (CTIMP) the CI must complete a Declaration of the End of a Trial Form when the trial ends. The method for this will depend on the method of trial submission. For combined review trials the end of trial notification will be submitted through the Integrated Research Application System (IRAS). For trials which were not submitted for combined review the forms are available on the MHRA website; <https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#end-of-trial>.
- 5.3.2 For multi-centre CTIMPs, the Declaration of the End of a Trial Form must be completed by the CI when the trial has ended at all locations (including international locations).
- 5.3.3 The CI, or delegate, must send the Declaration of the End of a Trial Form to the MHRA, REC and the sponsor within 90 days of the trial ending.
- 5.3.4 A Declaration of the End of a Trial Form must also be completed by the CI for CTIMPs that are terminated early. The CI must clearly explain the reasons for terminating the trial and submit the report to the MHRA, REC and the sponsor within 15 days of the trial ending.
- 5.3.5 If the study was submitted via the Combined Review process, the end of trial declaration should be submitted via IRAS. This automatically submits the notification to the REC and MHRA. For trials that were not submitted via the Combined Review process, the form must be completed and submitted via MHRA submissions to the MHRA and via email to the REC.
- 5.3.6 Under regulation 26 of the Clinical Trials Regulations, a clinical trials approval (CTA) from the MHRA will lapse after 24 months if no participants have been recruited to the trial (i.e. signed a consent form) in the UK. If a CTIMP did not start following receipt of a CTA or the approval lapses and the CI does not apply for an extension, the CI must notify the MHRA, REC and the sponsor in writing. The CI must explain the reasons for not starting the trial and submit an end of trial notification.
- 5.3.7 The local PI will ensure that the local R&D department have been informed of the end of the study and have completed any other local obligations.

5.4 End of Study Notification for Non-CTIMP Studies

- 5.4.1 The local PI will ensure that the local R&D department have been informed of the end of the study and have completed any other local obligations.

- 5.4.2 The CI must complete a National Research Ethics Service (NRES) Declaration of the End of a Study Form when the trial ends. The forms are available on the HRA website; <http://www.hra.nhs.uk/resources/during-and-after-your-study/end-of-study-notification-studies-other-than-clinical-trials-of-investigational-medicinal-products/>. This should be submitted to the REC (which gave favourable opinion) via email within 90 days of the conclusion of the study or within 15 days of early termination. The CI should also notify the Sponsor Representative via email (resgov@accord.scot).
- 5.4.3 For studies approved by a University REC, the CI or designee will contact the applicable ethics committee to ascertain what documents are required to notify them of the end of study and submit these as required.

5.5 Additional Reporting Requirements

- 5.5.1 The CI will write and finalise any required end of study reports and submit these on time e.g. to the funder. Reporting will be completed within 12 months of the end of trial.
- 5.5.2 Requirements for study reporting and publication of results are detailed in SOP CR011 (Research Study Reports & Publication of Results).

5.6 Study Location Closure

- 5.6.1 The Sponsor/CI/PI, or designee, will ensure that all essential study records are complete (paper and electronic) and filed in the TMF/ISF where applicable.
- 5.6.2 Where a location closes early during the course of a study, for example due to resource issues or lack of recruitment, closure will be initiated when the final participant completes the study at that location/the decision for closure is made if no recruits.
- 5.6.3 Studies subject to monitoring by ACCORD clinical trials monitors will be closed down according to SOP CM003 (Close Out Visits) and local study teams must ensure that all monitoring issues have been resolved prior to archiving. Where applicable, each location will have a close out visit conducted prior to final analysis of the trial dataset

in order to ensure that any location specific data related issues identified during close out are addressed prior to statistical analysis.

- 5.6.4 For studies that are not subject to monitoring by ACCORD clinical trial monitors, the CI/PI, or designee, will complete form CR009-F01 (Study Closure Checklist) prior to archiving the ISF and any electronic records.
- 5.6.5 The Sponsor/CI/PI will ensure that all necessary declarations of the end of study forms, letters and e-mails, and final reports are filed in the TMF/ISF.

5.7 Archiving

- 5.7.1 The CI should discuss and agree arrangements for archiving paper and electronic records with the Sponsor Representative during study-set up if not detailed in the protocol.
- 5.7.2 The Sponsor and/or CI, or designees, will make arrangements to archive the TMF at the end of the study, referring to SOP GS005 (Archiving Research Essential Records).
- 5.7.3 The PI will ensure the ISF, including the pharmacy file (where applicable), source records and any other records required to recreate the study are archived. This includes documentation held at external study locations and electronic records.
- 5.7.4 Archived documents, including source data and any associated metadata, must be made available upon request by representatives of the Sponsor(s), CI, REC or MHRA.
- 5.7.5 Any transfer of ownership of the archived data must be documented and agreed with the Sponsor(s).
- 5.7.6 Where records are archived on electronic, magnetic, optical or other media, controls should be implemented to ensure that these records cannot be altered without appropriate authorisation and the creation of an audit trail For studies co-sponsored by NHSL & UoE and subject to a combined risk assessment (GS002 Combined Risk Assessment), the QA Manager or QA Coordinator will perform a computer system validation check (QA010) of the electronic archiving platform prior to the initiation of the archive period (see GS005 Archiving Research Essential Records).
- 5.7.7 If original documents are transferred to other media for archiving, the processes for transfer should be validated and tested to ensure that information will not be lost or altered. The accuracy and completeness of the transfer must also be verified by the local PI or the CI. Where a copy is used to permanently replace an original record this

must fulfil the requirements for a certified copy (i.e. a copy that has been verified (i.e. by a dated signature or by generation through a validated process) to have the same information as the original, including relevant metadata where applicable). If unsure of requirements, please contact QA@accord.scot.

5.7.8 Consideration will be given to the threat of material becoming obsolete, with respect to electronic storage media. Archived records held on electronic media will be transferred to a more suitable alternative media if the current electronic media is at risk of becoming obsolete. If unsure of requirements, please contact QA@accord.scot.

5.7.9 When the minimum retention period has been reached, material will not be destroyed without authorisation from the CI and the Sponsor(s) (GS005 Archiving Research Essential Records).

6 References and Related Documents

- [National Research Ethics Service \(NRES\) Declaration of the End of a Study Form](#)
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031), as amended
- CR009-F01 Study Closure Checklist
- CM003 Close Out Visits
- GS005 Archiving Research Essential Records
- CR011 Research Study Reports & Publication of Results

7 Document History

Version Number	Effective Date	Reason for Change
1.0	22 MAR 2011	New procedure
1.1	20 FEB 2014	Update to archiving procedure
2.0	29 AUG 2016	New SOP template. Introduction shortened. Reference to CR009-W01 and Archiving Policy removed (now obsolete). Reference to new Study Closure Checklist form (CR009-F01) added and also reference to new SOP GS005. Additional information added to introduction and main text regarding archiving conditions/requirements. Links to MHRA and NRES websites, and SOP GS005 added. Minor changes to text throughout.
3.0	02 OCT 2018	Update to references

4.0	10 NOV 2020	Minor administrative changes throughout
5.0	24 FEB 2022	Clarification on timing of site closure added to section 5.6 (5.6.2, 5.6.3).
6.0	13 JUN 2024	Responsibilities section clarified with requirement to publish on publically accessible database included (4.1). Addition of items to be considered when a study is terminated early (5.1). Addition of end of trial notification process for studies submitted via Combined Review (5.3). Requirement to notify local R&D of end of study added to non-CTIMP section alongside clarification of notification timelines (5.4). Removal of text regarding additional reporting requirements - CR011 referenced (5.5).
7.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). Addition of specific requirements for archiving of electronic records to section 5.7.6 and requirements for notification of end of trial to University RECs to section 5.4.2. Updates to CR009-F01 to ensure relevance for non-CTIMP trials and add requirements for archiving of electronic records.

8 Approvals

Sign	Date
<p><i>Elizabeth Craig</i> <small>Elizabeth Craig (13-Apr-2026 11:20:19 GMT+1)</small></p> <p>AUTHOR: Elizabeth Craig, Senior Clinical Trials Monitor, NHSL, ACCORD</p>	13-Apr-2026
<p><i>Alice Graves</i> <small>Alice Graves (13-Apr-2026 11:03:35 GMT+1)</small></p> <p>APPROVED: Alice Graves, Senior Clinical Trials Monitor, NHSL, ACCORD</p>	13-Apr-2026
<p><i>L. Mackenzie</i></p> <p>AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD</p>	14-Apr-2026







CR009 Study Closure and Archiving v7.0


Final Audit Report

2026-04-14

Created:	2026-04-13 (British Summer Time)
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAszMt8lvxbTESqpuL5c2vOFmF8nDvUZ1Y

"CR009 Study Closure and Archiving v7.0" History

-  Document created by Roisin Ellis (v1relli8@exseed.ed.ac.uk)
2026-04-13 - 10:53:47 AM GMT+1- IP address: 62.253.82.243
-  Document emailed to elizabeth.a.craig@nhslothian.scot.nhs.uk for signature
2026-04-13 - 10:55:23 AM GMT+1
-  Document emailed to alice.graves@nhslothian.scot.nhs.uk for signature
2026-04-13 - 10:55:23 AM GMT+1
-  Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2026-04-13 - 10:55:24 AM GMT+1
-  Email viewed by alice.graves@nhslothian.scot.nhs.uk
2026-04-13 - 11:02:56 AM GMT+1- IP address: 52.102.17.85
-  Signer alice.graves@nhslothian.scot.nhs.uk entered name at signing as Alice Graves
2026-04-13 - 11:03:33 AM GMT+1- IP address: 62.253.82.243
-  Document e-signed by Alice Graves (alice.graves@nhslothian.scot.nhs.uk)
Signature Date: 2026-04-13 - 11:03:35 AM GMT+1 - Time Source: server- IP address: 62.253.82.243
-  Email viewed by elizabeth.a.craig@nhslothian.scot.nhs.uk
2026-04-13 - 11:20:01 AM GMT+1- IP address: 52.102.17.117
-  Signer elizabeth.a.craig@nhslothian.scot.nhs.uk entered name at signing as Elizabeth Craig
2026-04-13 - 11:20:17 AM GMT+1- IP address: 62.253.82.242
-  Document e-signed by Elizabeth Craig (elizabeth.a.craig@nhslothian.scot.nhs.uk)
Signature Date: 2026-04-13 - 11:20:19 AM GMT+1 - Time Source: server- IP address: 62.253.82.242
-  Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2026-04-14 - 8:28:17 AM GMT+1- IP address: 52.102.16.181

 Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)

Signature Date: 2026-04-14 - 8:28:48 AM GMT+1 - Time Source: server- IP address: 77.97.224.249

 Agreement completed.

2026-04-14 - 8:28:48 AM GMT+1