

Archiving Research Essential Records

Document No.:	GS005 v7.0
Author:	Heather Charles
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 For studies sponsored by NHSL or co-sponsored by NHSL and UoE, and with appropriate funding in place, ACCORD will provide an archiving service for study documentation.
- 1.3 For studies hosted by NHSL, ACCORD may accept study essential records from only study locations in Lothian for archiving, if this service is required by the study Sponsor.
- 1.4 Arrangements for archiving (paper and electronic records) will be verified at the Site Initiation Visit (SIV) or directly with the Sponsor prior to initiation for all studies and confirmed a study close out.
- 1.5 Archiving arrangements for studies single sponsored by the UoE is out with the scope of this SOP and will be defined in the study protocol.

2 Purpose

- 2.1 To describe the ACCORD procedure for archiving research essential records (paper and electronic), and ACCORD internal records (paper and electronic).

3 Scope

- 3.1 This SOP applies to studies sponsored by NHSL, co--sponsored by NHSL & UoE, and research studies hosted by NHSL.

3.2 This SOP applies to the R&D Administration Manager, R&D Administration Assistants, ACCORD Clinical Trials Monitors, Quality Assurance (QA) personnel, the R&D Finance team, study Investigators and research teams.

4 Responsibilities

4.1 The Sponsor is responsible for providing a service to facilitate archiving of essential study records (paper and electronic).

4.2 If a study has an assigned ACCORD Clinical Trials Monitor, they are responsible for verification of archiving arrangements at the SIV and close out visit.

4.3 The ACCORD QA team is responsible for oversight of platforms used to archive electronic records for studies that have undergone combined risk assessment (SOP GS002).

4.4 The ACCORD Senior Clinical Trials Monitor, or designee, is responsible for reviewing the contents of the Sponsor File and/or Trial Master File (TMF) and arranging archiving of these files with the R&D Administration Manager, or designee e.g. R&D Administration Assistant.

4.5 The Investigator, or designee, is responsible for;

- Ensuring that all costs associated with archiving are factored into research funding applications, where applicable.
- Consideration of any special archiving conditions in advance of the study, to ensure archived data does not degrade e.g. electronic records, x-rays, video clips.
- Agreeing archiving arrangements (paper and electronic) with the Sponsor prior to study initiation.
- Reviewing the contents of the TMF and/or Investigator Site File (ISF) prior to arranging archiving requirements.
- Contacting the R&D Administration Manager to arrange archiving of paper records at the end of the study.
- Packing archive material appropriately in the boxes provided and recording the contents on the relevant form.
- Informing the R&D Administration Manager, if the contact details of the person responsible for the boxes changes during the archiving period.
- Contacting the relevant Information Governance/IT department in the UoE or in NHSL regarding archiving of electronic records.
- Informing R&D of any updates to archiving arrangements e.g. arrangements for archiving electronic records, CI leaving the organisation.

- 4.6 The R&D Administration Manager, or designee, is responsible for archiving and tracking study records (paper) according to this procedure, in conjunction with the external contractor (Crown Records Management). They are also responsible for tracking the location of any electronic records archived by the Investigator.
- 4.7 The Assistant Management Accountant, or designee, is responsible for confirming appropriate funding is in place for the proposed archiving retention period.
- 4.8 The Deputy R&D Director, the Principal R&D Manager or the Head of Research Governance (NHSL) is responsible for approving uplift of boxes by Crown Records Management.
- 4.9 The Deputy R&D Director is responsible for authorising destruction of records for studies sponsored by NHSL or co-sponsored by NHSL and UoE, where the archive period is complete.
- 4.10 The QA Manager, or designee (e.g. QA Coordinator), is responsible for archiving ACCORD internal records (paper and electronic), and verifying archiving facilities for use for regulated studies Sponsored by NHSL and/or UoE.

5 Procedure

5.1 Study Archiving Period

- 5.1.1 The archive period for paper and electronic records should be discussed and agreed at the start of the study (e.g. at SIV), and funding identified for archiving. The archiving period should be documented in the study protocol.
- 5.1.2 Non-regulated study essential records will be archived for a minimum of 3 years, or as required by the funding body or Sponsor. On request, the Sponsor can advise on what are considered essential records on a per study basis.
- 5.1.3 Essential records from Clinical Trials of Investigational Medicinal Products (CTIMPs), and combined CTIMP/Clinical Investigations of a Medical Device (CIMD) trials will be archived for a minimum of 25 years. This requirement applies whether or not the trial is intended to support a marketing authorisation or conformity assessment.
- 5.1.4 If, at the point the standard 25-year retention period expires, the data generated by the trial are being used to support an application for a UK marketing authorisation,

the Sponsor shall ensure the essential records are retained for a minimum of two years from the day following the grant of that UK marketing authorisation.

- 5.1.5 For trials that use an authorised product (e.g. has a UK/EU manufacturing authorisation) that supports a manufacturing authorisation, essential records should be retained for as long as the product is authorised with the final clinical study report being retained for 5 years after the product is no longer authorised. This applies whether used within MA or off-label.
- 5.1.6 Advanced Therapy Investigation Medicinal Product (ATIMP) studies will be archived for a minimum of 30 years after product expiry or longer if required by the clinical trial authorisation.
- 5.1.7 CIMD trials will be archived for a minimum of 5 years and will be defined in the investigation plan (protocol).
- 5.1.8 The R&D Administration Manager, or designee, will seek clarification from the Investigator, or designee, if there is any perceived discrepancy in the specified retention period.

5.2 Electronic Archiving

- 5.2.1 Should a Sponsor or Investigator wish to archive essential records (including source data) electronically at the end of the study, this must be agreed prior to commencement of the study, with terms and conditions and any associated costs discussed and documented e.g. at SIV.
- 5.2.2 The Investigator, or designee, will agree arrangements and costs associated with archiving essential records electronically with the appropriate Information Governance/IT department within UoE or NHSL.
- 5.2.3 Essential records held on electronic systems, for example the study database, must be retained and held on a secure server / validated archiving platform or transposable media. Access to archived records must be restricted and protected from unauthorised changes to maintain data integrity. Consideration should be given to retaining more than one copy (e.g. back-up server or back-up media).
- 5.2.4 The Investigator will consider the most appropriate media for archiving electronic data, in consultation with the Sponsor, and provisions should be made if the selected

medium becomes obsolete during the archive period and require transfer to a more appropriate media format.

- 5.2.5 The Investigator, or designee, will document the details and location of essential records archived electronically on the Archive Information Form (GS005-F01) (GS005-W01 Archiving Guidance for Researchers) (see Section 5.4).

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.

- 5.2.6 For studies sponsored by NHSL or co-sponsored by UoE/NHSL, electronic archiving services are available to local investigators (e.g. DataVault UoE). Where electronic records need archived on NHSL systems, the Investigator should contact the NHSL Information Governance team in the first instance.

- 5.2.7 When migrating essential records from the original storage location (e.g. shared drive) to a long-term archiving platform such as DataVault, a documented process is required to ensure the secure, compliant, and long-term preservation of clinical trial data. Prior to migrations, the following needs to be considered:

- Create an inventory to classify files by type (e.g. TMF index)
- Standardise file formats (PDF / CSV / EML)
- Remove duplicates
- Create secure back-ups

- 5.2.8 Migration to DataVault will be performed using encrypted transfer methods, with all files uploaded to the designated collection accompanied by complete metadata, appropriate access controls and retention periods set.

- 5.2.9 Once the migration is complete, the Investigator must perform quality control activities including confirming file completeness and readability, review metadata accuracy, and test user access. All steps of the migration, including QC outcomes and any issues encountered, will be fully documented and filed in the Trial Master File

5.3 Initiating Archiving of Study Essential Records

- 5.3.1 All Investigator or Clinical Trials Monitor requests for archiving should come through the R&D Administration Manager, or designee.
- 5.3.2 Where a close out visit is being performed for a UoE/NHSL co-sponsored study that has undergone risk assessment (SOP GS002 Combined Risk Assessment), the Clinical Trials Monitor will inform the R&D Administration Manager, or designee, of the requirement for archiving as part of the close out visit process (CM003 Close Out Visits).
- 5.3.3 Where the Clinical Trials Monitor identifies that archiving is not being facilitated by the ACCORD office, local R&D office or an approved vendor, or if records are being archived electronically, they will inform the R&D Administration Manager, or designee, and the QA Coordinator of the facility / electronic archiving platform or on-site secure location where TMFs/ISFs (i.e. paper records) will be archived and the contact person.
- 5.3.4 For studies that have undergone combined risk assessment (GS002), the QA Manager, or designee, will consider assessing the archiving facility based on risk as per ACCORD SOP QA009 (Vendor Assessment). The QA Manager, or designee, will verify paper essential records are stored in a secure fireproof and lockable cabinet. Where records are archived electronically, the QA Manager or designee will consider applying a CSV check following QA010 (Use of Computerised Systems in Research). A list of facilities / on-site secure archive locations will be documented in the ACCORD QA files on SharePoint.
- 5.3.5 For studies that are not monitored by ACCORD Clinical Trials Monitors, including hosted studies, archiving will be initiated via a request from the Investigator, or designee, to the R&D Administration Manager, or designee.
- 5.3.6 When a request for archiving is received, the R&D Administration Manager, or designee, will send the Investigator, or designee, Archiving Guidance for Researchers (GS005-W01), the Archive Information Form (GS005-F01), the Box Label Template (GS005-T01) and a box price list (which includes box sizes).
- 5.3.7 The R&D Administration Manager, or designee, will provide archive boxes to the Investigator once the terms of archiving are agreed by e-mail.

5.4 Study Archiving Process

- 5.4.1 The Investigator, or designee, will pack paper essential records to be archived appropriately in the supplied boxes and document the contents of archive boxes on the Archive Information Form (GS005-F01) (GS005-W01 Archiving Guidance for Researchers).
- 5.4.2 The Investigator must then ensure that the archive boxes and Archive Information Form (GS005-F01) are checked by a second person. This check can be performed by the R&D Administration Manager or designee. With permission from the R&D Administration Manager, the Investigator may ask another member of the research team to verify that the content of the archive boxes match the details on the Archive Information Form (GS005F01). The member of the research team who packs the boxes and completes the form cannot be the person who verifies box content and form completion.
- 5.4.3 For hosted studies, essential records (e.g. ISF) from NHSL locations only will be checked and accepted.
- 5.4.4 Any issues identified will be resolved before archiving is completed and the R&D Administration Manager, or designee, will complete the internal use only sections of the Archive Information Form (GS005-F01).
- 5.4.5 A copy of the completed Archive Information Form (GS005-001) will be sent to ACCORD by e-mail (LOTH.ArchivingRDO@nhs.scot) and kept on file in the R&D shared drive administration teams 'ARCHIVING' folder by the R&D Administration Manager, or designee. A copy must also be retained in the appropriate archive box.

5.5 Uplift/Retrieval of Archiving

- 5.5.1 Once the completed Archive Information Form (GS005-F01) has been checked by the R&D Administration Manager, or designee, and the archiving period has been confirmed and authorisation from R&D Finance and either the Deputy R&D Director, the Principal R&D Manager or the Head of Research Governance (NHSL) has been obtained, the R&D Administration Manager, or designee, will arrange uplift of boxes by Crown Records Management. Uplift will be from the ACCORD R&D offices or directly from the research teams department.
- 5.5.2 Crown Records Management will provide a receipt to the contact person for uplift and a copy must be forwarded to the R&D Administration Manager, or designee (see GS005-W01 Archiving Guidance for Researchers).

- 5.5.3 Access to archived boxes is restricted to the Sponsor, Investigator, or designee, or the R&D Administration Manager or designee.
- 5.5.4 Any requested retrievals will be delivered by Crown Records Management to the ACCORD R&D Office, where boxes may be accessed by the Investigator, or designee.
- 5.5.5 The R&D Administration Manager, or designee, will request uplift of the retrieved boxes after required access is concluded. Prior to uplift, the contents of the box(es) will be checked by the R&D Administration Manager, or designee. Crown Records Management will provide a 'pick-up' receipt to the R&D Administration Manager, or designee.
- 5.5.6 Access to archived electronic records must be approved by the Sponsor and Investigator

5.6 Destruction of Boxes/Minimum Retention Period of Archiving

- 5.6.1 When the destruction/minimum retention date is imminent, the R&D Administration Manager, or designee, will contact the Investigator and Sponsor to let them know the period of archiving (paper and/or electronic) has almost ended and request approval for the boxes to be destroyed. For studies sponsored by NHSL or co-sponsored by NHSL & UoE, this authorisation will be given by the Deputy R&D Director.
- 5.6.2 For studies that are hosted, if a response is not received from the Sponsor/Investigator after three attempts of contact via email, telephone, or in person, the R&D Administration Manager, or designee, will escalate this to the Deputy R&D Director. With the agreement of the Deputy R&D Director, the R&D Administration Manager, or designee will send the Investigator or Sponsor a final reminder with a definitive date to reply. If a response is not received, the boxes will be sent for destruction.
- 5.6.3 Once approval from the Investigator and Sponsor has been secured (paper), the R&D Administration Manager, or designee, will submit a request for destruction of boxes to Crown, detailing barcode(s), giving approval for destruction and requesting a Certificate of Destruction. For electronic records, the Investigator, or designee, will arrange destruction/deletion with the relevant organisation and confirm with the R&D Administration Manager when complete.
- 5.6.4 The R&D Administration Manager, or designee, will provide a copy of the confirmation of destruction certificate to the Investigator.
- 5.6.5 Alternatively, the boxes (e.g. paper records) may be retrieved for destruction by the

Investigator, or designee. Boxes will be retrieved from Crown Records Management as per section 5.5, and they will be informed that the boxes are being withdrawn for destruction.

- 5.6.6 The R&D Administration Manager, or designee, will oversee destruction of the boxes by the Investigator, or designee.
- 5.6.7 If approval to destroy the records is not granted, the R&D Administration Manager, or designee, will confirm with the Sponsor the period of additional retention required, and the additional costs associated with extending the archive period. At the end of this period, the R&D Administration Manager, or designee, will contact the Investigator and Sponsor and request approval for destruction of the records.
- 5.6.8 For any studies, sponsored by NHSL or co-sponsored by UoE/NHSL, that have not arranged archiving services through ACCORD, Sponsor and Investigator approval for destruction must be sought. ACCORD should be informed of this decision and the date of destruction.

5.7 Archiving ACCORD Internal Documents and Records

- 5.7.1 The QA Manager, or designee, will archive obsolete ACCORD internal records indefinitely (for an initial period of 6 years) e.g. training records, either securely in the ACCORD offices or using Crown Records Management in consultation with the R&D Administration Manager. All other records (e.g. obsolete SOPs) will be kept electronically indefinitely on the ACCORD SharePoint site.
- 5.7.2 Once the initial archive period of 6 years has surpassed, the R&D Administration Manager will inform the Deputy R&D Director and QA Manager and a decision will be made on whether the internal documents and records can be destroyed.
- 5.7.3 The R&D Administration Assistant(s) will archive R&D documents and records (e.g. contracts with wet ink signatures) as per the study archive period detailed in the protocol, either securely in the ACCORD offices or using Crown Records Management in consultation with the R&D Administration Manager. Electronic R&D records will be retained indefinitely in the appropriate folder in the R&D shared drive.

5.8 Tracking Archiving Requirements

- 5.8.1 The R&D Administration Manager, or designee will update the Scottish Research Management Database Application (SReDA) system with the location and date of

archive. The R&D Administration Manager, or designee, will update the project information tab with information relating to the archiving of the TMF, ISF.

5.8.2 The R&D Administration Manager, or designee, will maintain an ACCORD archiving tracker, which is located on the NHS R&D Shared Drive.

6 References and Related Documents

- Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (E2) Guidelines
- GS005-F01 Archive Information Form
- GS005-T01 Box Labels
- GS005-W01 Archiving Guidance for Researchers
- CM003 Close Out Visits
- GS002 Combined Risk Assessment
- QA010 Use of Computerised Systems in Research

7 Document History

Version Number	Effective Date	Reason for Change
1.0	29 MAR 2016	New SOP.
2.0	31 MAY 2017	Updated to new SOP template. Minor edits to SOP throughout. SOP now includes the responsibilities of the Senior Clinical Trials Monitor and the ACCORD Admin team, and the tracking of archiving requirements.
3.0	05 JUN 2019	Responsibility added Investigator to securely archive electronic records and for ACCORD QA to assess archive locations when archiving is not facilitated by ACCORD. Section 5.2 added to further detail requirements for electronic archiving. Escalation process added to section 5.7. The Business Research Manager title has been changed to R&D Administration Manager.
4.0	26 MAY 2021	Process updated at section 5.4.2: investigators have been delegated responsibility of checking archive box contents against the archive information form (GS001-F01). Minor edits to SOP throughout.

		Associated forms updated to align to change here (GS005-F01 & GS005-W01).
5.0	27 APR 2023	Minor typographical changes throughout. Section 4.7 & 5.6 updated to document Deputy R&D Director responsibility for authorisation of document destruction. Section 5.5 updated to clarify the need to check box contents prior to uplift. Section 5.7 updated to remove need to archive wet ink signed R&D management approval letter (now signed electronically).
6.0	06 JAN 2025	Finance responsibilities added to 4.6. ACCORD archiving email address updated in section 5.4.5. ACCORD internal documents and record retention updated to 6 years in sections 5.7.1 & 5.7.2, in line with NHSL policy. SOP and associated documents (GS005-F01 v7.0, GS005-W01 v6.0) moved to new template, with minor administrative changes to both.
7.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). Timelines for retention of essential records updated in line with new regulations. Additional instructions added throughout regarding archiving of electronic essential records, highlighting the need to agree archiving arrangements and potential costs (paper and electronic) during study set-up. Additional responsibility and instruction added for the ACCORD QA team is for oversight of platforms used to archive electronic records for studies that have undergone combined risk assessment (SOP GS002). GS005-F01 (v8.0), GS005-T01 (v2.0) and GS005-W01 (v8.0) also updated.

8 Approvals

Sign	Date
<p><i>Heather Charles</i> Heather Charles (14-Apr-2026 11:52:47 GMT+1)</p> <p>AUTHOR: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD</p>	14-Apr-2026
<p><i>Lesley Saeed</i> Lesley Saeed (13-Apr-2026 11:05:41 GMT+1)</p> <p>APPROVED: Lesley Saeed, R&D Admin Manager, NHS Lothian, ACCORD</p>	13-Apr-2026
<p><i>L. Mackenzie</i></p> <p>AUTHORISED: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD</p>	14-Apr-2026











GS005 Archiving Research Essential Records 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:	CBJCHBCAABAAtkQbIWyyOtzVa4fi2Z7soHeSLm__fUT6

"GS005 Archiving Research Essential Records v7.0" History

-  Document created by Roisin Ellis (v1relli8@exseed.ed.ac.uk)
2026-04-13 - 10:59:17 AM GMT+1- IP address: 62.253.82.243
-  Document emailed to heather.charles@nhslothian.scot.nhs.uk for signature
2026-04-13 - 11:01:06 AM GMT+1
-  Document emailed to lesley.saeed@nhslothian.scot.nhs.uk for signature
2026-04-13 - 11:01:07 AM GMT+1
-  Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2026-04-13 - 11:01:07 AM GMT+1
-  Email viewed by lesley.saeed@nhslothian.scot.nhs.uk
2026-04-13 - 11:05:15 AM GMT+1- IP address: 62.253.82.242
-  Signer lesley.saeed@nhslothian.scot.nhs.uk entered name at signing as Lesley Saeed
2026-04-13 - 11:05:39 AM GMT+1- IP address: 62.253.82.243
-  Document e-signed by Lesley Saeed (lesley.saeed@nhslothian.scot.nhs.uk)
Signature Date: 2026-04-13 - 11:05:41 AM GMT+1 - Time Source: server- IP address: 62.253.82.243
-  Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2026-04-14 - 8:29:17 AM GMT+1- IP address: 52.102.18.53
-  Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2026-04-14 - 8:29:28 AM GMT+1 - Time Source: server- IP address: 77.97.224.249
-  Email viewed by heather.charles@nhslothian.scot.nhs.uk
2026-04-14 - 11:52:28 AM GMT+1- IP address: 52.102.17.101

 Signer heather.charles@nhslothian.scot.nhs.uk entered name at signing as Heather Charles

2026-04-14 - 11:52:45 AM GMT+1 - IP address: 62.253.82.244

 Document e-signed by Heather Charles (heather.charles@nhslothian.scot.nhs.uk)

Signature Date: 2026-04-14 - 11:52:47 AM GMT+1 - Time Source: server- IP address: 62.253.82.244

 Agreement completed.

2026-04-14 - 11:52:47 AM GMT+1