Archiving Essential Study Documentation

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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 documentation from only the Lothian site for archiving, if this service is required by the study Sponsor.

1.4 Arrangements for archiving will be verified at the Site Initiation Visit (SIV).

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 documentation, and ACCORD internal documents and records.

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, Admin Assistants, ACCORD Clinical Trials Monitors, Quality Assurance (QA) personnel, and study Investigators.

4 Responsibilities

4.1 The Sponsor is responsible for providing a service to facilitate archiving of essential study documentation.

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

4.3 The 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.

4.4 The Investigator, or designee, is responsible for;

- Ensuring that all costs associated with archiving are factored into research funding applications.
- 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.
- 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 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.

4.5 The R&D Administration Manager, or designee, is responsible for archiving and tracking study documentation according to this procedure, in conjunction with the external contractor (Crown Records Management).

4.6 The Assistant Management Accountant, or designee, is responsible for confirming appropriate funding is in place for the proposed archiving retention period.

4.7 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.

4.8 The Deputy R&D Director is responsible for authorising destruction of documents for studies sponsored by NHSL or co-sponsored by NHSL and UoE, where the archive period is complete.

4.9 The QA Manager, or designee (e.g. QA Coordinator), is responsible for archiving ACCORD internal documents and records, and verifying archiving facilities for use for regulated studies Sponsored by NHSL and/or UoE.

4.10 The ACCORD Admin Assistants are responsible for archiving R&D internal documents and records.

5 Procedure

5.1 Study Archiving Period

5.1.1 The archive period should be discussed and agreed at the start of the study, and funding identified for archiving. The archiving period should be documented in the study protocol.

5.1.2 Non-regulated study essential documents 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 documents on a per study basis.

5.1.3 Essential documents from Clinical Trials of Investigational Medicinal Products (CTIMPs) or Clinical Investigations of Medical Device (CIMDs) that will not be used in support of a marketing authorisation, will be archived for a minimum of 5 years. If the study supports a marketing authorisation this period will extend to a minimum of 15 years.

5.1.4 Commercial studies will be archived for a minimum of 15 years.

5.1.5 Advanced Therapy Investigation Medicinal Product (ATIMP) studies will be archived for a minimum of 30 years.

5.1.6 The required archiving period for paediatric (including neonatal), obstetric, oncology, genetic, mental health and implanted device studies will be confirmed

with the study Sponsor and defined in the study protocol in line with NHSL Health Record Policy.

5.1.7 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 an Investigator wish to archive study material (including source data) electronically at the conclusion of the study, this must be agreed with the Sponsor prior to commencement of the study, with terms and conditions documented.

5.2.2 Data held on electronic systems, for example the study database, must be retained and held on a secure server or transposable media. Access to archived data 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).

5.2.3 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.

5.3 Initiating Archiving of Study Essential Documentation

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, the Clinical Trials Monitors 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 or an approved vendor, they will inform the R&D Administration Manager, or designee, and the QA Coordinator of the facility or on-site secure location where TMFs/ISFs will be archived and the contact person.

5.3.4 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 files are stored in a secure fireproof and lockable cabinet. 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 archive material appropriately in the supplied boxes and record 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 Admin Assistant. 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, material from the Lothian site 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 Admin Assistant, 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) or by internal post and kept on

file 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, 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, either 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

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.

5.6 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 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 If a response is not received 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, 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.

5.6.4 The R&D Administration Manager, or designee, will provide a copy of this certificate to the Investigator.

5.6.5 Alternatively, the boxes 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 boxes 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. 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 boxes.

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 documents and 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.

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 Admin 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.

5.8 Tracking Archiving Requirements

5.8.1 The R&D Administration Manager and the Admin Assistant(s) will update the Scottish Research Management Database Application (SReDA) system with the location and date of archive. The R&D Administration Manager and the Admin Assistant(s) will update the project information tab with information relating to the archiving of the TMF, ISF and the electronic archiving of R&D files.

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

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, inline 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.

8 Approvals

Sign	Date
Heather Charles Heather Charles (Dec 17, 2024 10:33 GMT) AUTHOR: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	Dec 17, 2024
Lesley Saeed Lesley Saeed (Dec 17, 2024 10:44 GMT) APPROVED: Lesley Saeed, R&D Admin Manager, NHS Lothian, ACCORD	Dec 17, 2024
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD	Dec 17, 2024

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