

SOP-QA-32 V6	
Title: Archiving	
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Author: Richard Cowie, Named Archivist	
QA Approval: Richard Cowie, Ethics and QA Manager	
Approver: Prof Seshadri Vasani, R&D Director	
Approver: Prof David Blackburn, Head of School	



Document History

Version	Description of update	Date Effective
5	Updated GDPR reference at 3.4. Clarification of archive period at 3.6 Updated contact details and reference to hosted/commercial studies in appendix 1.	1-12-22
6	Removal of requirement to complete destruction forms at 3.16 Update to medical records archive at Appendix 2	26-11-25

1. Scope

- 1.1 This SOP applies to all researchers, archive, R&D and Sponsor staff participating in research projects sponsored/co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG), and any hosted studies. It may be used for archiving of **any** data, including e-data.
- 1.2 Archiving of samples that afford re-evaluation or support reconstruction of a trial may need to be retained. Retained samples shall be archived in conditions that minimise deterioration, eg freezing (see SOP-QA-38 – Equipment). Routine safety assessment samples need not be retained.
- 1.3 Where a third party archive facility is used, a contractual agreement shall be in place. Any changes to arrangements shall be agreed by the Named Archivist. Regular audits of any third party archive shall be undertaken by the QA Manager, or delegate, to ensure that the third party archive continues to meet the Sponsor requirements.
- 1.4 It is a legal requirement that a Sponsor appoints a Named Archivist who is responsible for archiving essential records which have been part of the TMF, and who controls access to archived material. The Named Archivist must have a clearly documented role (including a legal link to the Sponsor) and be appropriately trained and supported to carry out their role.

2. Responsibilities

Named Archivist	Ensure data is stored securely, retrieved, destroyed and recorded appropriately.
Chief Investigator (CI)	Ensure research data is archived in a way that permits accurate reconstruction of the research and is not destroyed before the agreed date, nor retained longer than stated in the REC application, funder's obligation or sponsor's institutional policy. Ensure research data is available for audit and inspection as appropriate. Ensure archiving costs are agreed before study start-up. Inform the Sponsor in writing if there is to be a change in CI and ensure archiving arrangements are in place prior to the change.
Sponsor	Ensure sufficient archiving facilities are available and a suitable Named Archivist is identified. Archive the Sponsor file appropriately with the TMF.

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3. Procedure

Introduction

Clinical research documents

- 3.1 Clinical research documents are those which are contained within the Sponsor file, Investigator TMF (held by the CI), any site file (held by the Principal Investigator (PI)) pharmacy file (held by the Clinical Trial Pharmacist) and Laboratory file, if any laboratory analysis takes place. All parts of the TMF must be archived once the trial is completed (close-out visit completed and reported, and the end of trial report written) although individual teams may archive completed sections once an activity is complete (see SOP-QA-31 – Research project closure).
- 3.2 Research data may be generated in electronic and/or paper form and source documents may be original documents or records. Where data exists electronically provision must be made to transfer this to e-archive (see 3.12).
- 3.3 NHS R&D files shall be archived separately to those listed at 3.1 and for a period of five years from study closure.

Suitability of archiving facility


- 3.4 For Clinical Trials of Investigational Medicinal Products (CTIMPs), clinical trial regulations require that all clinical trial information shall be recorded, handled and stored in a way that allows accurate reporting, interpretation and verification, and that the confidentiality of records which could identify subjects shall be protected; in accordance with the requirements of the UK General Data Protection Regulation (UK GDPR) and Data Protection Act (2018).
- 3.5 For records to be considered to have been archived they must come under the control of a Named Archivist; responsible for ensuring the integrity of all archived data in their custody. The Named Archivist shall assess the storage facilities to consider:
- Size and location: are facilities large enough with appropriate off-floor shelving?
 - Environmental conditions/pests: is the risk of fire, flood and pests minimised?
 - Confidentiality and security: is there controlled access and are appropriate authorised records maintained of all removals, requests for review, relocation and/or return?
- 3.6 Archive retention periods shall be documented in the application to the Research Ethics Committee (REC) from which favourable opinion was sought. CTIMPs and Medical Device Clinical Investigation (MDCIs) shall be archived for **twenty-five years**, unless subject to other third party obligations eg funder's terms and conditions, or are subject to legal requirements (ie Legal Hold). All other studies shall be archived as stated in the protocol, or Sponsor's institutional guidelines.
- 3.7  It is essential that arrangements are made to ensure that patient medical records, and the source data held within, are retained throughout the archiving period. It is NHSG policy for paper medical records of adults to be scanned and destroyed six years after their last hospital attendance or three years after death. In order for paper records to be retained, it is essential that the medical records of **all** patients involved in an interventional research project are marked by activating an alert on TrakCare® and placing a sticker on the pink sheet of the patient medical record documenting the following:
- Patient name
 - CHI number (Community Health Index (a unique ten digit identifier for NHS patients))
 - Research study
 - Do not destroy until
 - Contact
 - Signature

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- 3.8 If essential records and data are required to be kept for longer than originally stated, it is the responsibility of the CI to seek agreement from the appropriate body/authority (eg REC, funder and/or Sponsor) to extend the retention period of the archived material.



Costs

- 3.9  Archiving arrangements and costs shall be agreed and documented between the Sponsor, funder and CI at set-up and included in any contractual agreement. These shall detail the format in which any e-records shall be maintained throughout their lifecycle (if appropriate), the retention period and procedures for making data available for inspection. If there is no agreement in place regarding costs please contact R&D for advice.


Archiving and retrieval process for researchers (see Appendix 1)

- 3.10 For multicentre research projects, the CI shall determine where the site file and other essential data shall be archived. This may be at site or it may be returned to the research team for archiving and shall be documented in the TMF.
- 3.11 At trial completion, the CI, or delegate, shall contact the Named Archivist, or delegate, in the first instance; the **Archive Approval form** (TMP-QA-34) must be completed. For hosted studies, the Sponsor remains responsible for archiving; the PI shall check to establish if archiving has been delegated from Sponsor.
- 3.12 Where historical data, which should have been archived, is identified the CI must be contacted to take responsibility immediately. If this is not possible, details of the data must be passed to the Named Archivist to establish if data still requires archiving or may be destroyed (see Appendix 2).

Archiving electronic data (e-archive)

- 3.13  If retained on a computerised system, electronic data files (including metadata) shall be held on a UoA or NHSG secure networked server using a validated system. Data files shall be 'locked' in a read only format, so that they cannot be altered or deleted, and access restricted only to those authorised to view them, as documented in the TMF. Assistance may be required from IT.
- 3.14  If copies of data are stored on an intermediate storage medium, these shall be transferred to the e-archive by the CI, or delegate. The intermediate storage medium shall then be destroyed and its destruction confirmed. The CI, or delegate, should contact the e-archive team for advice.

Access to archive data

- 3.15  Access to archived material shall be controlled and restricted; access by researchers is considered unusual and shall be discouraged. Retrievals shall require approval by the Sponsor, Named Archivist and R&D Director **before** they are retrieved and shall not exceed four weeks. There may be a cost implication to the researcher for retrieval from a third party archive facility. The **Archive Retrieval form** (TMP-QA-35) must be completed.

Destruction of archive data

- 3.16 Prior to the end of the allotted archiving period, the CI, Sponsor or delegate, shall be contacted by the Named Archivist, or delegate. They shall complete the **Archive Review Notice** (TMP-QA-36) and agree destruction or retention of documents with the Named Archivist; who shall co-ordinate secure destruction with an approved agent, or e-archive team.
- 3.17 If the Named Archivist, or delegate, are unable to contact or obtain a response from the CI or Sponsor they shall review the archive record. If no valid reason can be identified for retaining the data beyond the allocated archiving period it shall be securely destroyed and the **Archive Review Notice** (TMP-QA-36) completed.

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4. Abbreviations and definitions

R&D	NHS Research and Development
TMF	Trial Master File
TrakCare®	The NHSG advanced web-based unified healthcare information system

5. Related documentation and references

SOP-QA-32 Appendix 1	Archiving and retrieval process summary for researchers
SOP-QA-32 Appendix 2	Algorithms
SOP-QA-24	Managing a change in CI of a CTIMP or MDCI
SOP-QA-31	Research project closure
SOP-QA-38	Equipment and Facilities
TMP-QA-34	Archive approval form
TMP-QA-35	Archive retrieval form
TMP-QA-36	Archive review notice

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Requesting input into the archive/e-archive

- Check with Head of Department/Supervisor and Sponsor that data is complete/ready for archive.
- Contact the archive team to discuss and obtain archive boxes and identity labels, or to arrange transfer of e-data to the e-archive (the e-archive team shall provide specific instructions).
(Named Archivist: gram.randdarchiving@nhs.scot 01224 551121).
(E-archive: digitalresearch@abdn.ac.uk).
- Download/request **Archive approval form** (TMP-QA-34) from the Grampian Research Office website <https://www.abdn.ac.uk/grampian-research-office>
- Enter details in **all** required fields with as much information as possible.
- Pack contents into specified box(es) (the weight for each box must not exceed 15 Kg*).
- Place the label on the smallest side of the box (for off-site archiving only) and write the reference number on the Archive approval form (TMP-QA-34).*
- Insert one copy of the completed Archive approval form in each box*, keep one copy for your own records and send one copy of each form to the archive team.
- Seal the archive box (ideally with tamper evident security tape).*
- On receipt of completed forms, the archive team shall direct porters or external archive (as appropriate) to arrange uplift and confirm with the researcher the agreed date and time.*
*not applicable to e-archive

❗ Archives will not accept items without prior authorisation from the Named Archivist.

❗ To avoid deterioration of archived material several actions are recommended:

- Avoid the deterioration of print by removing documents from plastic wallets.
- Staple, rather than using paper-clips or rubber-bands, to avoid loss/accidental attachment.
- Create certified copies of thermal printed material, as images fade over time.
- Consider using soft paper folders, rather than lever-arch files, to save weight and space.

Archive retrieval

❗ In exceptional circumstances, a CI/Named Contact Person may request that the data is returned to them. This represents a transfer of custody back to the individual CI/Named Contact Person. This shall be recorded on the **Archive Retrieval form** (TMP-QA-35) and, if locally sponsored, Research Governance shall be informed.

❗ Retrieved boxes can be kept for up to **four weeks** before they must be returned to the archive. If required for longer a request shall be made to the Named Archivist.

❗ On return to the archive the person to whom the material has been loaned shall identify any changes or additions that have been made to the archived material using the contents list.

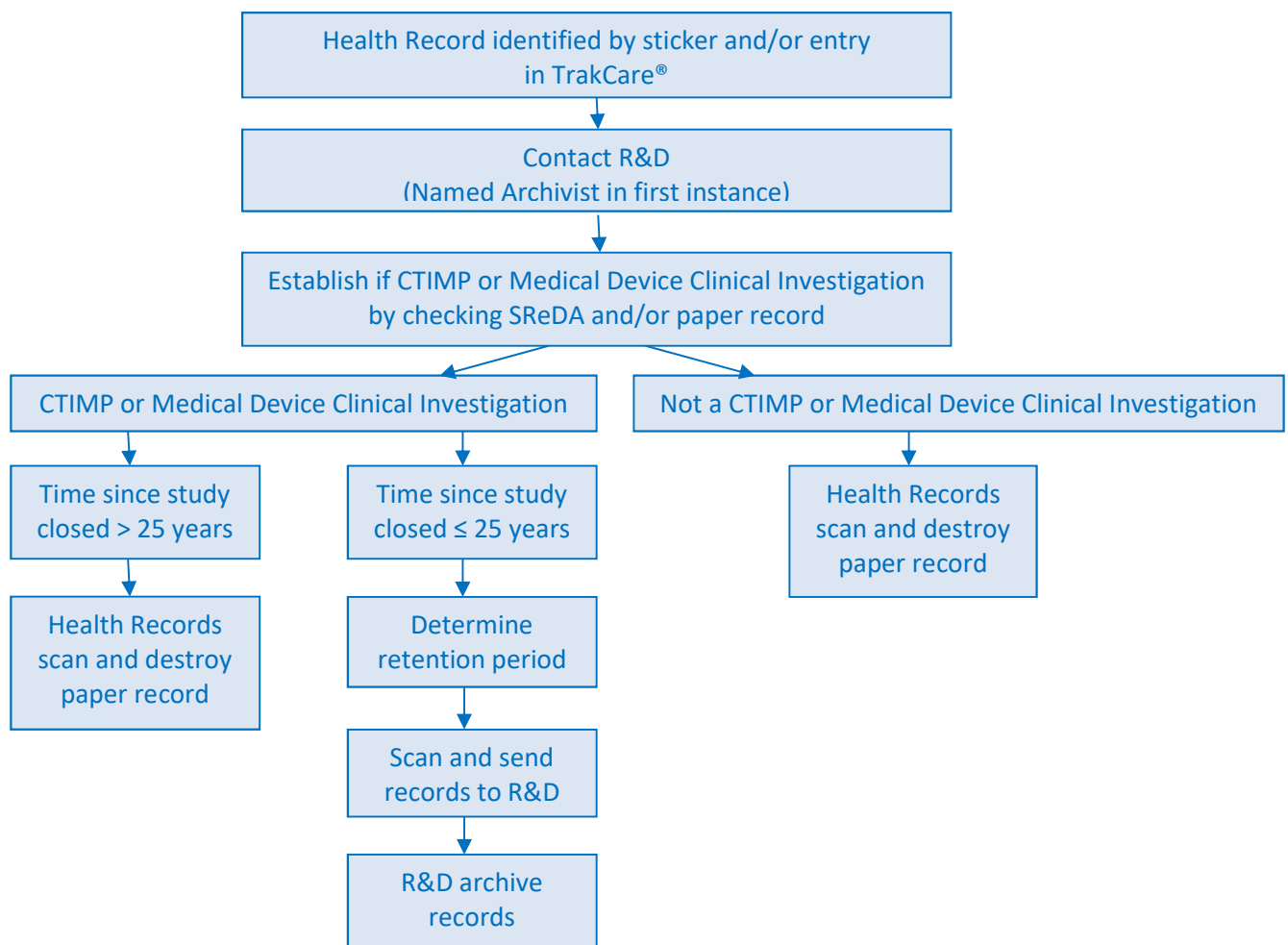
Retention date review and disposal/deletion of archive data

- When data is due for review the CI/Named Contact** shall be notified by the Named Archivist.
- The CI/Named Contact Person** shall confirm disposal or archive of the data for a further period.
- The CI/Named Contact Person** shall complete and sign the **Archive Review Notice** (TMP-QA-36).
- Disposal, using a contracted confidential waste contractor, is organised by the archive team.
- Permanent deletion of e-archive data is organised by the e-archive team.
**May be Sponsor when hosted or commercial study.

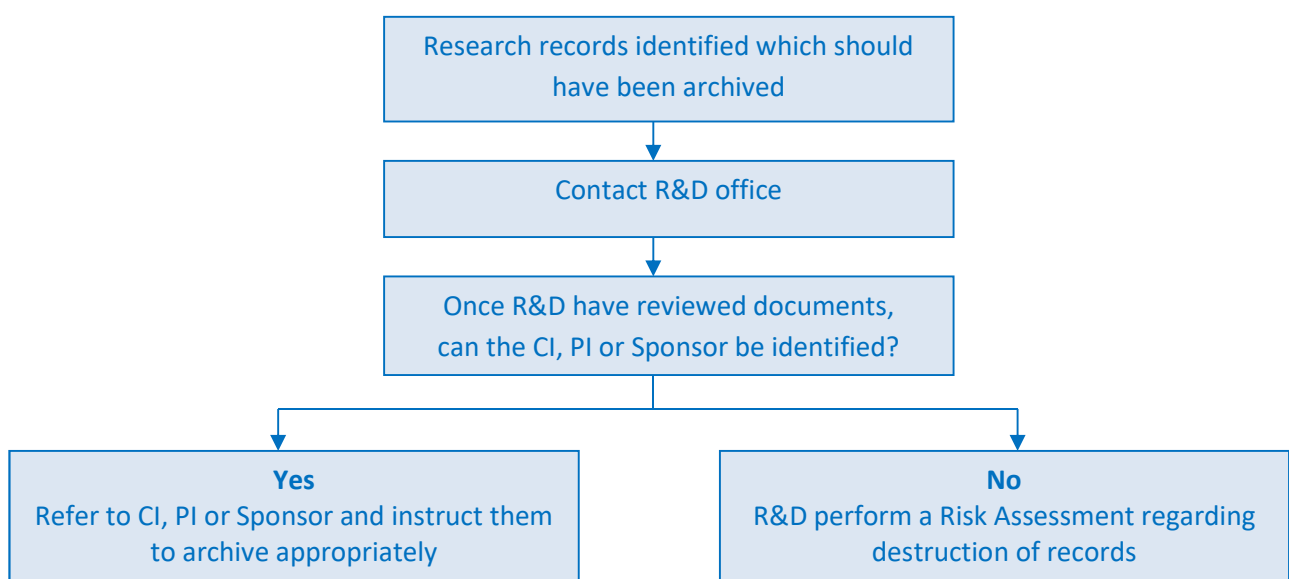
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Establishing if Paper Health Records of patients involved in clinical research can be destroyed after scanning



When historical research documentation, which should have been archived, are located:



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