Archiving of Essential Research Records

Research & Innovation SOP J-5014

University Hospitals of Leicester NHS
NHS Trust

Trust Ref: B25/2025

1. Introduction and Who Policy Applies To

This Standard Operating Procedure (SOP) describes the procedures and requirements for the archiving of essential records for clinical research undertaken at University Hospitals of Leicester NHS Trust (UHL).

The conduct of clinical research generates many records. ICH Good Clinical Practice (GCP) guidelines define and list all records that are considered 'essential'. Essential records permit and contribute to the evaluation of the conduct of a research project and the reliability of the results produced. They also serve to support oversight, by demonstrating compliance with the standards of GCP, UHL policies and applicable regulatory requirements.

Essential records can take any form that describes or documents the research methods, conduct, results, factors affecting it and any actions taken. Certain essential records may not be specific to the research itself but may be related to facilities, processes or systems (e.g. standard operating procedures, equipment maintenance records, computer databases etc.)

For the purposes of this SOP, archiving refers to the long-term retention of essential research records. To ensure compliance with relevant legislation and GCP, the Sponsor and Investigator / Institution must archive essential research records in a way that ensures they remain complete, readable and readily available. Any alteration to the essential records should be traceable, and they must remain directly accessible upon request by regulatory authorities, monitors and auditors for the duration of the required retention period.

This SOP should be applied in conjunction with the UHL Health Records Management Policy (B31/2005) and the NHS Records Management Code of Practice (2021), particularly where healthcare records form part of the essential research record and vice versa.

This SOP applies to all UHL staff and others with responsibility for archiving essential clinical research records.

2. Policy Standards and Procedures

2.1. Responsibility for Archiving

At UHL, the Research and Innovation (R&I) Deputy Director of Operations has overall organisational responsibility for the governance and retention of essential research records and for ensuring that access to retained records is controlled and limited to authorised individuals, including themselves, formally nominated delegates, auditors and inspectors.

The Chief Investigator (CI) is responsible for the completeness and quality of the records that make up the Trial Master File (TMF).

The local Principal Investigator (PI) is responsible for the completeness and the quality of the records that make up the Investigator Site File (ISF).

For each research project, a designated contact from the research delivery team should be assigned to take ownership of the archiving process, and act as the point of contact for all archiving arrangements.

Archiving can be delegated to a Clinical Trials Unit (CTU) via appropriate contractual arrangements if a CTU is managing the research project. For multicentre research, each participating location will be responsible for archiving their ISF.

Where UHL is a research location, the ISF must remain under the control of the local PI and must not be transferred to the Sponsor, except where the Sponsor and Investigator are the same organisation or where explicit participant consent and appropriate documented agreements are in place.

Transfer of records to an independent third-party organisation nominated by the Sponsor is acceptable, provided suitable contractual, confidentiality, and access controls are in place, as follows:

- Archive arrangements are formally agreed and documented between the Sponsor and the Investigator or Host Institution.
- A formal procedure is in place such that archived materials can only be accessed, or released from the external archive, with the approval of the Investigator or Host Institution. It is recommended that this is tested for robustness.
- Records are transferred directly between the Investigator location and an archive facility independent of the Sponsor, thereby ensuring that the Sponsor does not have uncontrolled access to the Investigator files.

Control of source records must remain with the local PI unless specific consent has been obtained from research participants for their personal information to be released from the research location.

2.2. Archiving Costs

Costs for archiving must be agreed between the Sponsor and/or CI and participating locations before research activity starts. Archiving costs are the responsibility of the CI and, wherever possible, must be included in any funding applications and applicable contracts.

For commercial research, archiving costs should be stipulated in the Clinical Trial Agreement (mCTA), or Chief Investigator Agreement (CIA) for CI led studies. Where archiving costs are not explicitly itemised, these must be confirmed during research setup and contract negotiation.

Any archiving-related costs must be paid by the Sponsor, CI or PI as appropriate. Invoices will be sent to the agreed billing addresses and must be paid promptly.

2.3. Archiving Location

The CI or PI, as appropriate, must ensure essential records remain secure, readable, and readily accessible. The storage location must have appropriate environmental controls to protect records against fire, flood, rodents and pests. Archiving arrangements must also comply with applicable data protection legislation. Appropriate technical and organisational measures must be in place to ensure records are protected from unauthorised access and alteration throughout the retention period.

Electronic records must be stored using secure, validated and access-controlled systems with scheduled backups. The preferred option for long-term electronic archiving of UHL research records is the Florence Healthcare eBinders document management system (Florence). Use of removable media (e.g. compact discs, USB drives) should be avoided for long-term archiving.

Physical records may be archived locally or off-site. For off-site storage, UHL has a contract with an external archiving facility managed by Stor-a-File Ltd. This is the preferred option for archiving of physical UHL research records. Their address is:

Unit 5 Wanlip Road Industrial Estate, Syston, Leicestershire LE7 1PD

The use of alternative off-site archiving facilities must be risk-assessed and approved by the Sponsor, and appropriate contracts put in place.

The Sponsor and Investigator / Institution must maintain an accurate record of the location of all essential records, including source records, for the duration of the retention period.

2.4. Archiving Duration

The Investigator or sponsor institution must retain essential research records in accordance with applicable regulatory requirements and guidelines, or until informed by the Sponsor that these records are no longer required, whichever is the longest.

Minimum retention periods for essential research records are defined in R&I Template T1076 - Retention Periods for Essential Research Records. Although every effort will be made to ensure this template is maintained and updated to reflect current regulatory and governance requirements, it remains the responsibility of the CI and research Sponsor to ensure that essential records are retained for the required period.

For research Sponsored by UHL, the Quality Assurance Manager will be responsible for contacting the CI, Investigator(s) and Institution(s) to confirm requirements for record retention once the end-of-study declaration has been submitted.

For research hosted by UHL, or where UHL is a research location, the research team must liaise with the Sponsor to confirm archiving retention periods and associated arrangements.

2.5. Preparation of Essential Records for Archiving

Prior to archiving, essential research records must be appropriately prepared, and the pre-archiving checklist completed (see R&I Template T-1038). This is the responsibility of the research delivery team, co-ordinated by the designated contact person.

Before archiving, research records should be assessed for:

- material that could be disposed of, where permitted (for example, duplicates, working records, items on shared drives, promotional material, irrelevant correspondence, copies of source records)
- records that may be subject to rapid deterioration and will therefore require transfer to a more robust medium prior to archiving (for example, thermal printer paper)

When a copy is used to permanently replace the original essential record, the copy must meet the requirements for certified copies.

Where centralised records have been held (for example, staff training logs or CVs), these must be considered as part of the archiving arrangements, as they may be required to demonstrate compliance. Records from supporting services, such as laboratories or clinical trials pharmacy, should also be included where appropriate.

2.5.1. Preparation of Physical Records

Before storing paper records, documents must be removed from lever arch / ring binders, folders and plastic wallets. Any dividers, paper/bulldog clips, staples and metal treasury tags must also be removed.

Redaction is not permitted in the ISF as this would hinder any essential reconstruction of the research. The ISF is therefore expected to contain personal identifiers. However, participant identifiers or personal

information must not be held in the TMF or by the Sponsor. Where practical, documents containing personal identifiers should be placed in sealed envelopes and labelled as 'Confidential'.

Only one research project must be filed per box. Boxes must be clearly labelled with the research title and box number, if more than one box is being stored.

Where Stor-a-File facilities are used for off-site storage, each box must be labelled with a unique Stor-a-File barcode, as provided.

2.5.2. Preparation of Electronic Records

The use of removable media (e.g. compact discs or USB drives) is not recommended for long-term electronic archiving of essential records. Where possible, electronic records should be transferred to a suitable managed system or platform. At UHL, the Florence document management system is the preferred option for long-term electronic archiving of electronic research records.

Systems and storage media may change or become obsolete over time. The migration of archived data to newer formats or platforms may therefore need to be considered during the retention period to ensure continued accessibility, usability and data integrity.

To maintain authenticity and data integrity, electronic records must be protected from unauthorised alteration. Access to electronic data must therefore be appropriately restricted and controlled.

It is recommended that more than one copy of the electronic archive is retained, for example on a secure backup server located separately from the primary system.

2.5.3. Preparation of Patient Health Records

Patient health records are subject to the arrangements of the NHS organisation that owns them, but clear identification that a patient has been involved in clinical research must be evident in the health record.

Where health records also form part of the essential research record, any source data (such as research documentation, test results, scans etc.) should remain with the health record. A file note must be included in the research record detailing the location of source data.

Duplicate copies of source data must not be archived with the research record.

To ensure health records are retained for the required archiving period, they must be flagged on Nervecentre as 'Not for Destruction'.

For paper clinical case notes, a 'Do Not Destroy' label should be attached to the front cover, with the following details clearly documented as a minimum:

- Short research title
- EDGE ID
- Retention period (years)
- Destruction date
- Research team / PI contact details

See the UHL Health Records Management policy (B31/2005) for latest guidance.

2.6. Transfer of Records to a Storage Location

Once records have been prepared, they must be checked and approved for storage by the local research manager (or delegate) prior to removal from Trust premises, or transfer to an electronic archive.

2.6.1. Off-site Archiving using Stor-a-File

To arrange off-site archiving with Stor-a-File, follow the process outlined in R&I Template T-1074: UHL R&I Archiving Process Map. The template outlines the process for:

- ordering archive boxes and barcode labels
- requesting collection of boxes

For archiving costs, contact the R&I office: uhl-tr.researchandinnovationadminmailbox@nhs.net

The R&I Office will contact Stor-a-File to arrange delivery of boxes and barcode labels to the location specified on the request form. A minimum of 10 boxes and 10 barcode labels will be provided at each request.

Once records have been prepared (as per section 2.5) they can be placed in boxes together with an index and a copy of the completed archiving checklist. All archiving must be checked and authorised by a delegated manager within the relevant specialty area prior to storage.

Collection of packaged boxes for transfer to Stor-a-File can be requested using the R&I Archiving Request form: https://forms.office.com/e/cCdBKqwYmU. The research delivery team must retain a copy of the request form for their records, together with a record of the box barcode numbers and contents. The R&I office will notify Stor-a-File that boxes are ready for collection. Stor-a-File will arrange the date and time of collection directly with the person nominated on the archive request form.

2.6.2. Off-site Archiving Using an Alternative Storage Location

Where a research team wishes to use an off-site location other than Stor-a-File, they are fully responsible for organising and coordinating storage arrangements, including sourcing storage boxes and arranging transfer of records.

Details of the storage provider, location, box identifiers, and contents must be retained by the research team and kept up to date throughout the retention period. A copy must be sent to the R&I office for upload to EDGE: uhl-tr.researchandinnovationadminmailbox@nhs.net

2.6.3. On-site Archiving

Where records are archived on-site, research teams are responsible for transferring prepared records to the designated archiving location, as agreed with the Sponsor. No additional arrangements are required, provided records have been prepared, packaged and labelled in accordance with this policy.

Where research records are archived within a secure office or locked storage area controlled by the research team or Investigator (CI/PI), responsibility for managing access to those records remains with the CI/PI.

Details of the storage location, box identifiers, and contents must be retained by the research team and kept up to date throughout the retention period. A copy must be sent to the R&I office for upload to EDGE: uhl-tr.researchandinnovationadminmailbox@nhs.net

2.6.4. Electronic Archiving

At UHL, the preferred option for long-term archiving of electronic research records is via the Florence document management system. To comply with data protection legislation and UHL governance requirements, access to Florence is strictly controlled and limited to authorised staff. To arrange electronic archiving in Florence, follow the process outlined in R&I Template T-1074 Research & Innovation Archiving Process Map.

Once a request is received, the Florence archive manager, or delegate, will create a new archive folder and send a secure link to the designated contact. The link will remain active for a limited period, during which electronic records should be uploaded. Where additional time is required, an extension should be requested via the Florence mailbox (uhl-tr.florence@nhs.net).

Once upload is complete, the archive will be locked.

Where a research team wishes to use a location other than Florence for electronic archiving, they are fully responsible for organising and coordinating storage, and for ensuring the system used is validated and access controlled.

Details of the storage location and contents must be retained by the research team and kept up to date throughout the retention period. A copy must be sent to the R&I office for upload to EDGE.

2.7. Retrieval of Archived Records

The following applies only to records stored at Stor-a-File or in Florence. For all other records, responsibility for arranging retrieval and return rests with the relevant research team.

The R&I Office will facilitate all requests for retrieval of research records stored by Stor-a-File and Florence. Only authorised personnel are permitted to request retrieval. Requests must be submitted using the Archiving Process Request Form (https://forms.office.com/e/cCdBKqwYmu).

***For Stor-a-File records**:* the retrieval request should be submitted via the R&I Office to Stor-a-File, including details of delivery location and the responsible person. The receiver must notify the R&I Office once the records have arrived.

To request the collection of retrieved boxes by Stor-a-File, a further Archiving Process Request Form must be completed. It is essential that all physical records retrieved are returned in full, and that the R&I Office is notified once return to storage has been completed.

For Florence records: retrieval requests should be submitted via the R&I Office to the electronic archive manager. The requestor will be notified once the records are available for access, and a secure link will be provided. Access to archived records will be provided on a read-only basis to prevent unauthorised alteration of essential records.

Access to records will be restricted to authorised personnel and regulatory authorities only, to prevent any alteration to the essential record. Access to archived records is limited to a maximum of one month, unless prior agreement has been obtained from the R&I Director of Operations for extended access.

2.8. Change of Ownership of Essential Research Records

There may be occasions where a change of ownership or custodianship of essential research records may be required, for example where Investigators retire, leave the organisation or where a CTU or external location closes.

In such circumstances, the Sponsor must be notified in advance of any proposed transfer of ownership or custodianship so that appropriate arrangements can be agreed and documented. Responsibility for record retention, access, and regulatory compliance must be clearly defined and documented to ensure the essential records remain secure, complete and accessible for inspection for the remainder of the retention period.

2.9. Destruction of Archived Records

It is the responsibility of the Sponsor to notify Investigators when the archiving period for their research project has expired. Essential records must not be destroyed until written authorisation from the Sponsor has been received. Where a notification has not been received, research locations may request Sponsor authorisation to destroy archived records once the minimum retention period has been reached. Where Sponsor authorisation cannot be obtained, the R&I Director of Operations may be approached to authorise destruction, provided the research location is able to demonstrate that all reasonable efforts have been made to acquire Sponsor authorisation. Documented evidence of attempted contact with the Sponsor (for example, searches, correspondence, phone calls) should be retained with the destruction records.

Essential records must not be destroyed if a research project is subject to an ongoing audit, inspection, investigation, or unresolved regulatory query, regardless of whether the minimum retention period has been reached.

Once approved, it is the responsibility of the Investigator or a delegated member of the research team to carry out the destruction of all remaining essential records (both physical and electronic) in accordance with UHL or local policies and procedures, as applicable. Destruction must be documented using the Essential Records Destruction Checklist (R&I Template T-1075).

For multi-centre research, it is the responsibility of the CI, or delegated individual, to notify all participating locations that essential records may be destroyed and to ensure that each research location confirms destruction using the R&I Destruction Confirmation form:

https://forms.office.com/e/w5SwUhKJ2R

Records relating to destruction of essential records must be retained for a minimum of five years from the date the essential records were destroyed. These records should include a copy of the Sponsor authorisation to destroy, a completed Destruction Checklist and the Destruction Confirmation form. A copy of all destruction records should be sent to the Florence mailbox (uhl-tr.florence@nhs.net) for upload to Florence.

Note: if essential research records include, or are held within, UHL healthcare records, destruction must be carried out in accordance with the UHL Health Records Management Policy (B31/2005). Core healthcare records must only be destroyed by Medical Records Services or their authorised contractors.

2. Education and Training

Staff involved in the preparation, transfer, storage, retrieval, or destruction of essential research records must be made aware of this SOP and any associated templates relevant to their role. This may be achieved through local induction, role specific training, or documented communication.

3. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Adherence to preparation requirements and completion of pre-archiving checklist	Audit of completed checklists (T-1038)	R&I Director of Operations	As part of routine audit schedule	Report to R&I Governance Meeting
Compliance with storage requirements (physical and electronic)	Audit of storage environments and systems	R&I Director of Operations	As part of routine audit schedule	Report to R&I Governance Meeting

Compliance with retention period	Audit of actual retention period against planned	R&I Director of Operations	As part of routine audit schedule	Report to R&I Governance Meeting
Compliance with retrieval and destruction process	Audit of stored contact information and destruction checklists	R&I Director of Operations	As part of routine audit schedule	Report to R&I Governance Meeting

4. Equality Analysis Assessment

The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

As part of its development, an Equality Analysis on this policy has been undertaken and its impact on equality has been reviewed and no detriment was identified.

5. EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

6. Supporting References

- UHL Health Records Management policy (B31/2005)
- SOP J-5019 Use of Florence eBinders for UHL Research
- T-1038 Pre-Archiving Checklist
- T-1074 R&I Archiving Process Map
- T-1075 Essential Records Destruction Checklist
- T-1076 - Retention Periods for Essential Research Records
- R&I Archiving Process Request Form
- MHRA 'GxP' Data Integrity Guidance and Definitions

7. Key Words

Archiving, Records, Clinical, Research, Trials, Volunteers, Participants, Destruction, Stor-a-file, TMF, ISF, CTU, Storage, Retrieval, Retention, CTIMP, Non-CTIMP

This line signifies the end of the document

CONTACT AND REVIEW DETAILS	
Policy Lead: Adam Lewszuk R&I Head of Quality	**Executive Lead:** Professor Nigel Brunskill Director of Research & Innovation
Details of changes made during review: • Updated guidance and terminology to reflect GCP and UK regulations • Provision made for electronic records • Added new Process Map and Destruction Checklist • Moved detailed processes to templates • Added new UHL policy statements and matched to new template	