1. Introduction

This Standard Operating Procedure (SOP) describes the processes and requirements for archiving essential research documentation for all research conducted at University Hospitals of Leicester NHS Trust (UHL). The sponsor and investigator/institution should retain the essential research documentation in a way that ensures that this documentation remain completes, readable and readily available or directly accessible upon request by regulatory authorities, monitors and auditors. Alteration to the essential records should be traceable. This is to ensure compliance with relevant legislation and Good Clinical Practice.

Essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. Essential documents include records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

2. Scope

This SOP applies to all research conducted at UHL.

3. Procedure

3.1 Responsibility for archiving

At UHL the R&I Director of Operations is the named Archivist. This is the individual responsible for the archiving of all research documentation and for ensuring that access is restricted to themselves, nominated delegates, auditors and inspectors.

The CI is responsible for the completeness and the quality of the documentation that makes up the TMF and the local PI is responsible for the completeness and the quality of documentation that makes up the Investigator Site File (ISF). Archiving can be delegated to a Clinical Trials Unit (CTU) via appropriate contracting if a CTU is managing a trial. For multicentre studies, each participating site will be responsible for archiving their Investigator Site File (ISF).

The local Principal Investigator (PI) should retain control of the documentation contained in the ISF. The ISF should never be sent to the sponsor organisation except where the sponsor and investigator are essentially the same. This does not mean that an external sponsor cannot arrange archiving on behalf of the investigator; this is acceptable, subject to the following being implemented:

- The archive arrangements are formally agreed and documented between the sponsor and investigator or host institution.
- A formal procedure is in place such that the documents are only released from the external archive with the approval of the investigator or host institution. It is recommended that this is tested for robustness. Permission from the investigator or host organisation should also be

required to permit access to the contents of investigator site archived materials at the archive facility.

- The records go directly between the investigator site and an archive facility independent of the sponsor, thereby ensuring that the sponsor does not have uncontrolled access to the investigator files.

3.2 Notification of archiving period

For research sponsored by UHL, the Quality Assurance Manager will notify the CI, investigator(s) and institution(s) the need for record retention once the end of study declaration is submitted, specifying how long this retention is for.

For research where UHL is not the sponsor, the research team must liaise with the sponsor to determine archiving retention periods and arrangements.

3.3 Costs for archiving

Costs for archiving will be agreed between the sponsor/CI and participating site prior to a study starting. Costs for archiving are the responsibility of the CI, and where possible must be included in any applications for funding and applicable contracts.

3.4 Archiving location

Research documentation may be archived locally or may be off-site through a sponsor-approved external archiving facility.

For research teams archiving in their local areas, the CI or PI as appropriate must ensure that the facilities are secure, with appropriate environmental controls and adequate protection from fire, flood, rodent, pest and unauthorised access.

3.5 Archiving duration

The length of time required for archiving essential research documentation following the end of trial depends on the type of research study;

- For all research, the retention period is a minimum of 5 years (or longer if detailed in the approved study documentation.
- For Clinical Trials of Investigational Medicinal Products (CTIMPs) the retention period is a minimum of 25 years after the end of trial. If the trial data is being used to support an application for a UK marketing authorisation, the sponsor shall ensure the essential research documentation is retained for at least the period of 2 years after the last approval of a marketing application in an ICH region, and until there are no pending or contemplated marketing applications in an ICH region, or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product
- For clinical trials with Advanced Therapy Medicinal Products (ATIMPs) a minimum retention period of 30 years is required.

- For medical device trials, a minimum retention period of 10 years for non-implantable devices and 15 years for implantable devices is required, starting after the date the device is placed on the market.

3.6 Preparation for archiving

Prior to archiving, the essential research documentation should be prepared accordingly, and the pre-archiving checklist (T1038) should be completed. This should be done by the research team delivering the trial.

- Before archiving, the contents of the trial documentation should also be assessed for any records that could be disposed of (for example, duplicates) and those that may be subject to rapid deterioration and will therefore require transferring to a more robust media prior to archiving.
- Please remove, lever arched binders, polly pockets, paperclips, staples, treasury tags if metal.
- Patient medical records will be subject to arrangements within the NHS Organisation that owns them, but clear identification that the patient has been involved in a Clinical Trial must be evident, e.g. a sticker on the front of the records. In addition, it must be clear if the record must be retained and not destroyed before a specified date.
- It is important that where centralised records have been held, for example staff training records or CVs, that these are considered in the arrangements for archiving and retention as they may be required to be produced in addition to the TMF to demonstrate compliance.
- Documentation and records from supporting services such as laboratories are required to be archived alongside the TMF, where appropriate. This includes any pharmacy documentation.
- Only one study should be filed per box.
- Redaction would hinder any essential reconstruction of the trial and is for this reason is not permitted in the ISF. It is expected therefore that the ISF will contain personal identifiers.
- There should however be no participant identifiers or personal information held in the TMF or held by the Sponsors, and the control of any source documents must remain with the local PI unless specific consent has been obtained from trial subjects for their personal information to be released from the trial site.

3.7 Archiving of electronic data and documentation

Where electronic systems are utilised for activities such as data management (e-CRFs), statistical analysis and storing scanned copies of documents, the electronic data/documentation needs to be retained. This data may be on a server. There must be a backup of any electronic data. The medium for electronic data storage should not become obsolete during the archiving period. The use of USB sticks/floppy discs is not supported at UHL for this reason. Archived electronic data should be transferred to a newer more appropriate media if necessary. Access to electronic data must be suitably restricted and the data must be protected from unauthorised changes to maintain authenticity.

3.8 Off-site archiving

UHL has a contract with an off-site archiving facility called Stor-a-file. Any alternative off-site archiving facility used must be assessed and approved by the sponsor, with the appropriate contracting in place.

To utilise Stor-a-file, a designated individual within the research delivery team must be assigned to take ownership of the archiving process. Please follow the following process;

Contact R&I admin team directly (via riadmin@uhl-tr.nhs.uk) to request current costs (please note that all archiving related costs are to be paid by the PI or CI as appropriate, invoices will be sent to the billing addresses provided and must be paid promptly)

- Complete https://forms.office.com/e/cCdBKqwYmU to request boxes and barcodes. The R&I Office will contact Stor-a-file to arrange the delivery of the printed barcodes and boxes to a specified location. A minimum of 10 boxes and Bar Codes will be provided at each request.
- Once the steps outlined in section 3.6 and the pre-archiving checklist (T1038) have been completed, the boxes can be filled along with a copy of the checklist. The boxes must be checked by a delegated manager in the specialty area.
- The research team must then complete the following Microsoft form to request the collection of the packaged boxes for transfer to the off-site storage facility; https://forms.office.com/e/cCdBKqwYmU The research delivery team should retain a copy of Form B for their records. A copy of the sheet noting the LMB barcodes and contents should also be retained and there should be a copy left with the boxes to be archived.
- The R&I office will then contact Stor-a-file who will arrange the date and time of collection with the contact person on the form.

3.9 Change of ownership of essential research documentation

There may be occasions where change of ownership may be required, for example investigators may retire or CTU/external may close. The sponsor must be notified of any transfer of ownership so that the essential research documentation is available for inspection throughout the retention period.

3.10 Retrieval of archived documentation

The R&I Office will facilitate all requests for retrieval of archived documentation. Only authorised personnel are permitted to request retrieval. Please complete; https://forms.office.com/e/cCdBKqwYmU to arrange retrieval. The request will be sent via R&I Admin through to Stor-a-file with the details of delivery point and responsible person. On arrival of the box(es), the receiver must notify the R&I Office of arrival. The box(s) can be logged out for a period of one month only for Investigator File/Case Notes and therefore must be returned within a maximum of one month unless express arrangements have been made with the R&I Director of Operations in advance, for the documentation to be retained out of storage for longer periods.

To return the boxes to Stor-a-file, please complete; https://forms.office.com/e/cCdBKqwYmU It is essential that the documents retrieved are returned in full and R&I are informed of the completed collection.

3.11 Destruction

It is the responsibility of the sponsor to notify investigators when the archiving period has expired for their study. In the absence of this notification, the site can seek authorisation from the sponsor to destroy the archived study documentation. The site should reasonably try 3 times to acquire sponsor authorisation and if this is not received, the R&I Director of Operations can be approached alternatively for authorisation to destroy. It is the responsibility of the investigator or delegated member of the research team to complete the destruction of the documentation in accordance with UHL or their local policies and procedures as applicable.

For multi-centre studies, it is the responsibility of the CI/PI/Delegated individual to ensure that all sites have destruction confirmed via the Microsoft form https://forms.office.com/e/w5SwUhKJ2R and the CI must retain this confirmation post destruction.

4. Supporting Documents and Key References

T1038 Pre-Archiving Checklist

5. Key Words

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

6. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Sponsor Audit	Randomly chosen for audit	Carolyn Maloney	As and when	A report will be produced

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

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