1. Introduction

This Standard Operating Procedure (SOP) describes the requirements for archiving of all research Hosted by the University Hospitals of Leicester NHS Trust (UHL). Its purpose is to ensure that Investigator Site Files (ISFs) for studies are readily available at all reasonable times for inspection by the MHRA or any person appointed by the UHL to audit the study.

Retention of the ISF for Clinical Trials of Investigational Medicinal Products (CTIMPs) and the medical records of subjects involved is a legal requirement. The Sponsor and Principal Investigator (PI) must ensure that the documents contained in the ISF, as well as the medical files of study subjects are retained for at least 5 years after the conclusion of a study and that they are complete and legible. Studies where the data are used to support a marketing application have further requirements as per Directive 2003/63/EC or the prevailing relevant legislation at the time. Subjects' medical records must be retained for at least 5 years in their original format and in accordance with the maximum period of time permitted by the institution to which they belong.

Arrangements for retention of documents for non-CTIMP studies must be appropriate to the requirements for each individual study.

2. Scope

This SOP applies to all research studies that are hosted by UHL.

3. Definitions

Clinical research study information must be stored in such a way that it can be accurately reported, interpreted and verified. The ISF is a collection of the documentation that allows the conduct of a research study, the integrity of the study data and the compliance of the study with GCP and applicable regulatory requirements to be evaluated. SOP C-2009 UHL provides more information on the requirements for the ISF.

4. Individual Responsible for Archiving

Head of Research Operations at UHL is the named person responsible for archiving of research documentation and for ensuring that access is restricted to themselves, Auditors and Inspectors. The PI is responsible for the completeness and the quality of the documentation that makes up the ISF & for ensuring that there is adequate funding available for appropriate archiving at the end of the study.

5. Archiving Arrangements

For all studies the Sponsor will inform the Investigator(s)/Institution(s) in writing of the need for record retention and again will notify the Investigator(s)/Institution(s) in writing when the study related records are no longer needed.

The provisional arrangements and costings (if applicable) for archiving the ISF will be agreed between the PI and the Sponsor during the initial Site Selection process. Costs for archiving are the responsibility of the PI. The ISF may be filed locally if suitable facilities are available or alternatively off-site through a Sponsor-approved external archiving facility.

Before the ISF is archived, it is recommended that it is checked to ensure that it is complete and that all necessary documentation has been filed. This will usually be undertaken by the study

monitor but may also be undertaken by other appropriate personnel. Before archiving, the contents of the ISF 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.

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 research study 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 records centralised 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 ISF to demonstrate compliance.

It is recommended that documentation and records from supporting services i.e. laboratories are archived alongside the main ISF.

In addition, pharmacy records and records of vendors or other agents of the Host/Sponsor also form part of the ISF and appropriate arrangements must be made to ensure this documentation is stored with the ISF for the required length of time and is retrievable if required.

The ultimate responsibility for the documents to be retained by the Investigator resides with the Investigator. If the Investigator becomes unable to be responsible for their essential documents (for example due to retirement) the Sponsor should be notified in writing and informed to whom the responsibility has been transferred.

6. Process for Archiving Hosted Study Files

In all cases, the Sponsor should be directing the PI and research team in accordance with the relevant Sponsor SOP. In the absence of this, the UHL SOP S-1029 UHL and associated appendices can be employed.

7. Responsibilities

	Responsibility	Undertaken by	Activity
1	UHL Head of Research Operations & PI	UHL Head of Research Operations & PI	Agree the provisional arrangements for archiving and the costings (if any) during the Site Selection process.
2	PI	PI	Responsible for costs of archiving using an external archive facility where required
3	PI	PI or delegate	Responsible for the contents of the ISF.
4	PI	PI	Appoint another person responsible for the ISF and inform the Sponsor if they are no longer able to be responsible.

8. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

9. Education and Training

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

10. Education and Training

None

11. 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

12. Supporting Documents and Key References

SOP C-2009

SOP S-1029

13. Key Words

Research, Innovation, EDGE, REC, HRA, Archiving, Storage, Data Protection, ISF, TMF

14. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

15.

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

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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
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July 2017	3	CM	Process for archiving Hosted study files added
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