1. Introduction

This Standard Operating Procedure (SOP) describes the creation of an audit trail through the retention of essential documents in the Investigator Site file (ISF) for all research Hosted by University Hospitals of Leicester NHS Trust (UHL) or where UHL is a Site.

The Essential Documents relating to a research study are those documents which individually and collectively enable both the conduct of the research study and the quality of the data produced to be evaluated. These documents serve to demonstrate compliance with the relevant Principles of Good Clinical Practice (GCP) and with all regulatory requirements.

All clinical information must be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of the study subjects remains protected.

2. Scope

This SOP applies to all staff conducting research where the UHL is a HOST organisation or a Research SITE.

3. Investigator Site File (ISF)

The ISF consists of essential documents relating to the specific investigator site, before the study commences, during study conduct and after completion of the study. It is the responsibility of the Principal Investigator (PI) to establish and maintain an ISF for each research study they participate in. It can take the form of a paper and/or electronic file as agreed by the sponsor and both formats must adhere to the basic requirements set out in this SOP.

A tabulated guide to ISF documents is contained in Appendix 1, 1a (ISF Index for CTIMP studies and Non UKCA/CE marked medical device studies) and Appendix 2 and 2a (ISF Index for Non CTIMP studies and UKCA/CE marked medical device studies.). The Index may be adapted to reflect specific study requirements. The Index may vary if the Sponsor has a template to be used It is expected that all ISF are 'inspection ready' at all times. Where areas of concern and/or Non-compliance have been identified they will be escalated in accordance with the non-compliance SOP C-2013 UHL or SOP S-1016 UHL as appropriate.

It is a legal requirement that researchers retain the ISF and all other study related documentation for a minimum of 5 years following completion of the study, or as directed by the Sponsor. SOP C2017 Archiving of essential documents.

4. Procedure

a. Responsible Personnel

The PI will be responsible for establishing and maintaining the ISF and may delegate these activities to a research team member. This must be recorded on the Delegation of Authority Log S1006 appendix 1.The files must be actively maintained until the study is formally closed.

b. Storage of ISF

All essential documents must be appropriately stored at all times. The ISF must be stored in a secure location, preferably in a lockable cabinet, but within a secure locked area with minimal staff access, other than research staff. The PI must be able to demonstrate that all reasonable measures have been taken to ensure its security and to protect confidentiality and data integrity. It may not be possible for all documentation to be stored in one file. Where separate file/s, including electronic versions of documents are required / maintained, a file note must be made in the ISF which clearly documents the location and title of the additional file/s. Where a separate pharmacy file is created for the purposes of study management, this remains part of and should be archived with the ISF.

c. Version Control

All documents must be version controlled, signed and dated where appropriate. To record version management, a version control log can be utilised(Appendix 3)All previous versions of documents must be retained, but marked as superseded by striking through the front cover with a single line in pen and marking as superseded by the later version. A file note (signed and dated by the PI) must be placed in the file giving details of any missing or unavailable documents.

d. Archiving

Archiving of the ISF and all associated essential documents must be undertaken as per arrangements made with the Sponsor. Archiving provisions must be catered for at the beginning of the study and will be a requirement of Trust Authorisation. Details of the location and required ISF archiving timescale as informed by the Sponsor must be provided at the end of the site involvement in the study to Corporate R&I office.

5. Non Compliance

Failure to demonstrate compliance to this SOP will result in implementation of the SOP C-2013 UHL Non Compliance SOP at a minimum of a MAJOR Finding.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Principal Investigator	PI/Study Team	Establishing the ISF at the beginning of the study
2.	Principal Investigator	PI/Study Team	Maintaining the ISF during the life of the study.
3.	Principal Investigator	PI/Study Team	Ensure the safe storage of the ISF at all times.
4.	Principal Investigator	PI/Study Team	Ensure the TMF/ISF is archived as per the arrangements with the Sponsor

7. Who Guideline Applies To

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

8. Education and Training

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

9. Education and Training

None

10. 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

11. Supporting Documents and Key References

SOP C-2009 Appendices 1, 1a, 2, 2a, & 3.

SOP C-2013

SOP S-1016

SOP C-2017

12. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, ISF, TMF, CTIMP, Essential Documents

13. 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**	

14.

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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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Approved by:	**Professor Nigel Brunskill**	**Date Approved:** 09/07/2021.

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
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February 2017	3	CM	Update to Logo.
February 2019	4	CM, LW	Consistency check. Logo Change.
April 2021	5	LW JJ	Update for archiving reporting requirements, Update to new template

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