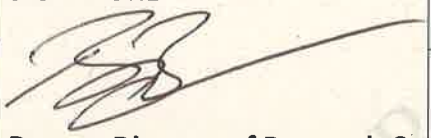
The Centre for Health Research & Innovation
Our Research Our Care

NHS
Lancashire Teaching Hospitals
NHS Foundation Trust

STANDARD OPERATING PROCEDURE
Establishing and Maintaining an Investigator Site File

AUTHOR.	AUTHORISED BY	DATE AUTH	RISK MANAGEMENT PROCEDURE NUMBER
NAME **Kina Bennett**	NAME **Paul Brown**	13/07/2023	**RDCLI14**
SIGNATURE  **Head of Research & Development**	SIGNATURE  **Deputy Director of Research & Innovation (Operations)**	REVIEW DATE 13/07/2025	

RESEARCH AND INNOVATION

R & I

BACKGROUND

The conduct of a clinical trial or research study must be able to be reconstructed, both during the trial or study and for some time after its completion, from the documentation which is filed and retained within the investigator site file. Maintenance of the correct and appropriate documentation in a manner suitable for managing the conduct of the trial and enabling evaluation by audit or inspection is essential for Good Clinical Practice compliance.

PURPOSE

This document describes the procedure for establishing and maintaining an Investigator Site File (ISF) and has been produced in accordance with the principles of Good Clinical Practice.

SCOPE

- All research carried out at Lancashire Teaching Hospitals NHS Foundation Trust must have a Site File which contains all essential documents.

- This SOP applies to all Investigator Site Files for studies sponsored by Lancashire Teaching Hospitals NHS Foundation Trust and can be used as guidance for externally sponsored studies.

The investigator site file contains the essential documents necessary for the investigator and the research team.

'Essential Documents are those documents which 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 Good Clinical Practice and with all applicable regulatory requirements' (ICH GCP, 2006).

PROCEDURE

1. WHO?

The responsibility for setting up, maintaining, storing and archiving the ISF rests with either the Chief Investigator (CI) or Principal Investigator (PI) who is the lead investigator at the site. The CI or PI may delegate this duty to a qualified member of the research team. This delegation must be formally documented on the delegation of duties log (see RDCLI13 Delegation of Duties SOP (Q-Pulse) and RD-TMP-04 Delegation of Duties Log (intranet)).

2. WHEN

The investigator or delegated research personnel must ensure there is an up to date site file at the beginning of the trial or study, prior to patient recruitment. This may be provided by a study sponsor, in which case the site file provided must be used and any study specific guidance should be followed. If no site file is provided, then this Standard Operating Procedure must be followed.

3. HOW

Establishing an Investigator Site File

1. The Investigator Site File must be set up using the Lancashire Teaching Hospital investigator site file index template RD-TMP-01 available on the Intranet.

2. All essential documents generated in a clinical trial or study must be stored within the investigator site file using a file index. This facilitates audit, inspection and trial management.

3. If the investigator site file is a physical paper file, this must be stored in a lockable cabinet or room, with restricted access. Members of the research team must have access to the file to complete any delegated duties, including audit.

4. If a document is not located in the investigator site file, a file note (RD-TMP-02) must be made to detail the location and to explain the reason for this decision.

5. The investigator should ensure all essential documents are filed in date sequential order (usually with the most recent on top) unless specified otherwise, to enable a clear audit trail. This includes email correspondence which should be printed out and filed in the site file. It is also acceptable to upload correspondence onto Edge, ensuring the emails have a clear title and a file note is included in the site file to reference the location of the correspondence.

Electronic Investigator Site File (eISF)

There is an increase in the number of Sponsors requesting electronic Investigator Site Files (eISF) as opposed to the traditional paper investigator site files. There are advantages to eISF's in terms of storage and space, as well as support for version control. Likewise Sponsors may use shared platforms and can audit the site file remotely. If a study will use an eISF this will need to be approved by the Trust's IT service and IG teams as appropriate, as part of feasibility and set-up.

Where sponsors do not provide a specific eISF but agree for us to use an eISF, the use of the Edge Document Management system (SOP RDADM04) can be used. When Edge is used, it is accepted that a small paper working file may also be required which should be managed as per standard paper files. A file note should be included to reference the location of the main eISF. Likewise a file note should be included in the eISF to explain the use and purpose of any paper working files.

Maintaining an Investigator Site File

1. The investigator is responsible for updating the investigator site file with any relevant and applicable documentation as the trial progresses. This duty can be delegated to an appropriately trained member of the research team on the delegation of duties log (RD-TMP-04 Delegation of Duties Log).

2. The investigator should file documents in a timely manner and file superseded documents in the appropriate section of the investigator site file. All previous documents must continue to be filed in the investigator site file. The version and date of the newer version must be clearly marked on the previous version in black ink and must be signed by the investigator or delegated person.

3. The investigator site file must be available to the R&I audit team, Sponsor, trial monitors, representatives of the Medicines and Healthcare products Regulatory Agency (MHRA) and other regulatory bodies, upon request.

4. The investigator should carry out regular checks to ensure the contents are up to date.

5. The investigator is responsible for ensuring the final study report is filed in the investigator site file at the study closure.

Archiving an Investigator Site File

- Once the trial is finished, the investigator is responsible for reviewing the investigator site file to ensure that all the required documents are present.
- The investigator site file must be archived in accordance with Archiving SOP RDADM08.
- The investigator site file must be archived for at least five years, or for a longer period if determined by the sponsor.

4. OTHER RELATED PROCEDURES

SOP RDCLI13 Delegation of Duties
SOP RDADM04 Edge Study Document Management
SOP RDADM08 Retention of Data, Off–Site Archiving and Destroying Documents
RD-TMP-01 Investigator Site File Index
RD-TMP-02 LTHTR RD file note
ICH GCP Topic E6

Sign Off			
Lead Author:			
Name and Position	Kina Bennett, Head of Research & Development		
Signature	KB H	**Date**	13/07/2023
Reviewed and approved by:			
Name and Position	Research & Innovation Committee Representative		
Signature		**Date**	13/07/2023
Authorised for release by:			
Name and Position	Rebecca Wilby, Research Access Project Manager		
Signature		**Date**	13/07/2023

Controlled Copy Authorisation			
Copy Number			
Location			
Authorised signature		Date	
Print-out only valid with original authorised signature			