Research & Innovation Office

Standard Operating Procedure

Archiving of Essential Clinical Research Documentation

SOP Number	SLHSOP002	**Version Number**	1.0
Date Effective	23/06/2025	**Author**	Clare Pye Research & Innovation Manager
Related SOP's: Research Policies & procedures. V3. Dated 21/01/2025 SLHSOP004 – Maintaining a study site file – V1 dated 23/06/2025		**Document Summary:** Describes the processes for the storage and archiving of research studies.	
Approved by (name & Role)	Dr Paul Taylor Head of Research - SLH	**Date**	14th April 2025
Review date – 3yrs from date effective			

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Standard Operating Procedure: Research & Innovation Office

Archiving Procedures

Acronyms

CI – Chief Investigator
PI- Principal Investigator
CTIMP - Clinical Trial of an Investigational Medicinal Product
HRA – Health Research Authority
ICHGCP - International Conference on Harmonisation of Good Clinical Practice
MHRA - Medicines & Healthcare Products Regulatory Agency
SOP – Standard Operating Procedure
R&IO – Research & Innovation Office
SLH – St Luke's Hospice

Introduction

The Department of Health's UK Policy Framework for Health and Social Care Research (2023) and the Medicines for Human Use (Clinical Trial) Regulations (2004) require that Sponsors make the appropriate arrangements for the retention of research and clinical trial documentation for sufficient periods, to ensure availability for future audit (for legal, regulatory or governance reasons). While St Luke's Hospice is not currently performing the role of sponsor it does have a responsibility for the safe storage of research data.

Purpose

To ensure that all research documentation is archived appropriately and for sufficient periods of time.

Roles & Responsibilities

Duties within the organisation

It is the responsibility of the Research & Innovation Office (R&IO) to ensure the Research & Innovation (R&I) SOPs are available to all research active staff working on hospice approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Hospice R&I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File (electronic or hard copy) or a file note is documented that links to the filing of the SOP (Appendix 1) and are available to research staff, and to inform the Research & Innovation Office (R&IO) of the names of all research staff involved in a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example, those of a Clinical Research Network, University or commercial sponsor.

If there is significant conflict between the external SOP and the Hospice R&I SOP it is the responsibility of the CI or PI to resolve these with the R&IO prior to starting the study.

It is the personal responsibility of all staff to follow Hospice (or the designated alternative organisation's) procedural documents. The R&IO is responsible for managing Hospice R&I SOPs including their approval, dissemination and archiving.

All Hospice R&I SOPs will be published on the Hospice website.

Specifics of this SOP

The CI/PI will ensure that study data is stored in a secure environment and archived in accordance with legislation and this SOP. They will inform the R&IO of archiving arrangements, including location and date of destruction, so a record can be held within by the R&IO Research Register. The Sponsor will ensure archiving arrangements are detailed in the sponsor agreements so it is clear from the outset whether archiving will be onsite, off-site or electronic. Any associated costs will also be included within the agreement.

The CI/PI & the R&IO within the Hospice will be fully responsible for:

- The administration and retention of data relating to archiving
- The retrieval (as required) and/or destruction of archived material
- Adherence to this SOP

The R&IO will coordinate the archiving process for the Hospice, including keeping a database within the Research Register of all archived study data

Details of procedures

Research register details

The R&IO must be made aware of the following details which will be stored in the St Luke's Hospice (SLH) Research Register at the beginning of any study:

- PI/CI Name
- Job title
- Tel Number
- Email Address
- Study title
- (SLH) Study Number
- Sponsor
- Period of Archiving
- Place of storage (If outside the R&IO)
- Funding arrangements (if applicable)
- Contact details of Sponsor

The CI/PI must inform the R&IO of the location of the archive(s), to enable audits to be carried out, and the date that the records can be destroyed. They must also inform the R&IO if they are transferring this responsibility to another.

Archiving procedure

Archiving is the responsibility of the Sponsor but may be delegated to the Hospice//CI/PI within a contract/agreement. Research records can either be archived by the Sponsor, research team, or by the R&IO, as agreed in the contract or as indicated in the Protocol.

Investigators must ensure that all documents pertaining to a study and applicable clinical data are archived in a secure facility (this includes the Investigator Site File, Pharmacy Site File (these should be archived with the study and not separately in

pharmacy), and the Case Report Forms. All versions of documents must be archived, including CVs of investigators.

Environmental Conditions/Impact

The minimum requirement is for documentation to be stored in conditions that minimise the risk of damage or loss of information. The risk of damage from water should be reduced by storing documentation above floor level and away from overhead water pipes. Documentation should be located in areas with minimal variation in temperature and humidity if stored for long periods of time.

St Luke's Hospice believes being environmentally friendly and reducing paper use go hand in hand in creating a more sustainable world. By adopting a "paper-light" approach, we cut down on deforestation, decrease greenhouse gas emissions from paper production, and reduce the energy used in recycling and disposal processes. Therefore, where possible please complete and file the attached file note in **Appendix 1** and file within your electronic or hard copy site file to comply with the procedures outlined in this document and in accordance with SLHSOP004 – Maintaining a study site file and the NIHR Trial Master File Toolkit - Trial Master File | Clinical Trials Toolkit documenting essential study documents.

Hard copy Archiving

Hard copy documents will be being stored in the locked R&IO in a locked cabinet.

Electronic Archiving

Electronic archiving can be facilitated for all studies via - S:\Research Shared\12 Archived studies. It is important that drives are backed up regularly and checked periodically by the research team to ensure short term (5 years) digital data preservation is successful.

Details of electronic archiving and location of data has to be made available to the R&IO by the sponsor to facilitate retention requirements monitoring and data destruction.

Archiving costs

Wherever possible any costs of archiving should be obtained from the research grant/sponsor.

Destruction of data

When the date of destruction is reached the Sponsor should be notified of the action to be taken regarding disposal (as per earlier received instructions).

Security of premises

All research data should be stored in locked cabinets in the R&IO or another locked cabinet within the hospice and recorded in the research register. The offices should be locked when not occupied and the buildings secured by key fob or keypad entry.

Retention periods

The Hospice will follow the retention periods depending on the study type and associated governance requirements

• All Clinical Trials of Investigational Medicinal Products or Devices (Non-commercially sponsored) - The Clinical Trials Regulations and specifically, Regulation 31A of the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, define the archiving requirements for Clinical Trials of Investigational Medicinal Products (CTIMPs). At least 5 years or longer if required by the sponsor.

• All Clinical Trials of Investigational Medicinal Products or Devices (commercially sponsored) - At least 5 years or longer if required by the sponsor.

• Non CTIMPS - any other studies delivered by the hospice (regardless of risk and including low risk) – 5 years from completion of the study or submitting final report.

The Research Office will notify any changes to this policy to the research community as required. It is the responsibility of the CI/PI to ensure that trial specific records

are retained for the amount of time specified in the related legislation or study protocol

References

UK Policy Framework for Health & Social Care Research (2023): UK Policy Framework for Health and Social Care Research - Health Research Authority

Records Management Code of Practice for Health and Social Care (2023): Records Management Code of Practice - NHS Transformation Directorate

The Medicines for Human Use (Clinical Trials) Regulations 2004 (Plus subsequent amendments: The Medicines for Human Use (Clinical Trials) Regulations 2004

ICH – Good Clinical Practice guidelines: ICH Official web site : ICH

NIHR Trial Master File Toolkit - Trial Master File | Clinical Trials Toolkit

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 - https://www.legislation.gov.uk/uksi/2006/1928/regulation/18/made

Appendices

Appendix 1

File note for the storage and tracking of SLHSOP002 – Archiving of Essential Clinical Research Documentation during study performance

Study Name:			
SLH study number:			
CI/PI			
Description: The Archiving of Essential Clinical Research Documentation for the above referenced study will be performed in accordance with SLHSOP2- Archiving of Essential Clinical Research Documentation which is filed in S:\Research Shared\Active\Closed or Archived study folder depending on the status of the study			
	Print Name:	**Signature:**	**Date:**
CI/PI			