Archiving of Clinical Trial Data and Essential Documentation

POLICY DETAILS	
Document Type	Standard Operating Procedure
Document name	KHP-CTO/CT/SOP 4.0 Archiving of Clinical Trial Data and Essential Documentation
Version	Final v7.0
Effective from	16 October 2025
Review date	16 October 2026
Owner	King's Health Partners Clinical Trials Office
Originally Prepared by	Stuart Hatcher, KHP-CTO Archivist
Reviewed by	Sophie Espinoza, Quality Manager, KHP-CTO
Approved by	Ann-Marie Murtagh, Director KHP-CTO
Superseded documents	v 6.3 – 27 Sep 2022
Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
9th Nov 2010	2.0	Transfer to King's Health Partner Livery and minor amendment to archiving process. Glossary update.	Jackie Powell
26th Feb 2013	3.0	Review of archiving process. Administrative change from JCTO to KHP-CTO.	Jackie Powell
10th Oct 2013	4.0	Amended to include archiving of traceability documentation for ATMPs.	Jackie Powell
28th Nov 2016	5.0	Update of Glossary terms, scheduled review, and inclusion of section on considerations for archiving electronic data (section 4.3) and adjustment of section 4.5 to apply only to paper data and documentation.	Jackie Pullen

8th May 2017	6.0	Amendment of section 4.5 to apply to paper and electronic data.	Jackie Pullen
1st Oct 2018	6.1	Minor amendment to include trials managed by KHP-CTO	Jackie Pullen
26th June 2020	6.2	Minor amendment to clarify scope and administrative changes	Jackie Pullen
27th September 2022	6.3	4.1.3 updated as per imminent new guidelines and current practice.	Jackie Pullen
16 October 2025	7.0	Scheduled review to clarify details of current process Amending retention period to 25 years in line with UK Clinical Trial Regulations coming into force April 2026	Ann-Marie Murtagh

Table of Contents

1.0 BACKGROUND AND PURPOSE

The purpose of this SOP is to define the local procedure for preparing clinical study records at an investigational site conducting a clinical trial sponsored, co-sponsored, managed or hosted by one or more of the Partner Organisations, and for their subsequent transfer to archive as required in the Regulations and the Good Clinical Practice (GCP) – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human participants.

2.0 SCOPE

This procedure applies to all commercial clinical trials and non-commercial clinical trials which are sponsored, co-sponsored or managed by the KHP-CTO Partner Organisations.

The archiving process may differ at host sites due to their local policy. However, archiving oversight will be maintained by the KHP-CTO on behalf of the Sponsor. This will include confirmation that the host site has, and adheres to, organisational SOPs that detail the principles described within this SOP to ensure compliance with Good Clinical Practice (GCP) – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human participants.

This SOP does not cover archiving of participant source data such as patient medical records for non-commercial studies. These are the responsibility of the host Trust and Trust processes should be followed.

3.0 PROCEDURE

Retention of Clinical Trial Data and Essential Documents must safeguard participant well-being, data integrity, and allow traceability. All data and essential documents relating to the clinical study must be archived in accordance with this KHP-CTO SOP and the requirements of the UK Regulations. This applies irrespective of the format in which it is generated, that is, electronic or paper.

3.1.1 Clinical Trials of Investigational Medicinal Products

1. TMF, Site Documentation and all Essential Documentation: for a minimum of 25 years or until at least 2 years after the last approval of a marketing application in a region where the ICH guideline applies.

And

2. Until there are no pending or contemplating marketing applications in a region where the ICH guideline applies.

Or

3. As defined in the Sponsor's protocol.

3.1.2 Clinical Trials of Advanced Therapy Medicinal Products (ATMPs)

Trial Sponsors, the tissue establishments/procurement organisation, the manufacturer and the Investigator site where ATMPs are developed, manufactured or administered, must keep their parts of the traceability for a minimum of 30 years after the expiry date of the product, or longer if required by the teams of the clinical trial authorisation or by the agreement with the Sponsor.

In the case of the tissue establishments, if that period is longer than provided in the Directives, the Sponsor will ensure through contractual agreements that the period for traceability record retention is accurately stated.

3.2 Storage of Paper Essential Documents

The KHP-CTO has a contract with an external company that can provide an archiving service for research departments within the Partner Organisations that wish to avail themselves of an archiving service, or have no archive facilities of their own or have unsuitable archiving facilities as assessed by the KHP-CTO. Access to archived data must be restricted, protected from unauthorised changes, and its lifecycle (collection through disposal) governed to ensure integrity and traceability to maintain authenticity.

Off-site archiving can only be arranged with the prior authorisation of the Named Archivist or delegate within the KHP-CTO.

3.3 Electronic Archiving

The use of electronic systems for such activities as data management, statistical analysis, reporting and trial management systems, means that electronic data also needs to be retained. The data may be held on a server or transposable media.

It is recommended that more than one copy is retained (e.g. a backup server or back-up media stored in a separate location is used). Consideration should be given to storing the data in different formats on different types of media or on the same media from different manufacturers.

Access to archived data must be restricted, protected from unauthorised changes, and its lifecycle (collection through disposal) governed to ensure integrity and traceability to maintain authenticity.

It is important that future access to records and data is maintained. Media used to store data may deteriorate or become obsolete. In these circumstances, the transfer of data to a new media as technology advances would need to be considered.

The appropriate new medium for the record will be decided on a case-by-case basis by the KHP-CTO Quality Manager or delegate.

The transfer process will be documented to confirm all data and records have been transferred and can be accessed from the new storage medium.

3.4 Preparation for Archiving

Before archiving, it is important to assess the contents of the TMF for any records that could be disposed of and those that may be trial participant to rapid deterioration or need special requirements in order for them to be retained e.g. electronic media, photographs, sample packaging, plastic wallets.

Records in formats which may deteriorate during storage should be copied to a medium suitable for archiving.

It is also essential to ensure that the entire TMF is archived i.e. pharmacy records, laboratory records, data management; statistics and Sponsor correspondence will form part of the TMF.

The location of any part of the TMF that is going to be archived separately must be documented in the TMF. In the case of electronic data, if the data has been migrated to a new format for archiving, then transfer should be validated and fully documented, so that it can be subject to audit, to ensure and demonstrate that there has been no loss, change or corruption to the data or metadata and that authenticity is maintained.

The CI or their delegate (for the TMF) or the PI or their delegate (for the ISF) is responsible for addressing any issues identified with the contents of the file prior to archiving.

When a KHP Research team or Researcher requests archiving, the following procedure applies:

1. Archivist or delegate will visit Research Department at the request of the Investigator team to assess the archiving requirements.
2. For non commercial studies Archivist or delegate will confirm that the close-out visit has been completed, database has been locked and Clinical Study Report has been finalised and published prior to archiving the trial Essential Documents.
3. For commercial studies the CTO Facilitators will ensure the study is closed and required confirmation from commercial sponsor is in place
4. A pre-archive review will be performed by a delegate of the KHP-CTO prior to the records being boxed up. This will be signed by the reviewer and filed with the TMF/ISF when it is archived.
5. Archivist or delegate will send archive materials, Clinical Trial Archive Document (see Section 5.1), barcodes, archive clips and archiving boxes to the Investigational site.

3.5 Archiving Process

The study documents will be prepared for archiving as follows and as per the Archiving Process Map (see Section 6.1):

1. Remove documentation from lever arch file(s)
2. Remove all paperclips or bulldog clips.
3. Place paperwork onto blue archive clips
4. Pack the TMF, ISF, if applicable all paper CRFs, and any electronic transposable media in standard archiving boxes with lids.
5. For commercial research studies, where the research team have requested archiving of participant source data such as patient medical records, these will be archived in a separate box and content clearly labelled
6. Prepare the Clinical Trial Archive Document (see Section 5.1).
7. Once the above actions are complete, the Named Archivist or delegate, will visit the research team to review the files and complete the Clinical Trial Archive Document. The original Clinical Trial Archive Document will be filed in each box, and copies given to the Investigator site for their records and also retained by the Archivist or delegate for CTO records.
8. The archive box will be sealed, by the Archivist or delegate, with archive cable ties ensuring that any unauthorised attempt to open the box will be evident.
9. Barcode(s) will be securely stuck onto the archive box where it will be clearly visible.
10. When archiving is complete and the box(es) are ready, the Archivist or delegate will arrange collection with external storage company and ensure that the clinical trial management systems (MATTS or EDGE) is updated.
11. The Clinical Trial Archive Document copy will be returned to the KHP-CTO offices to be retained within the KHP-CTO.

3.6 Retrieval of Archived Boxes

Archived boxes may be retrieved from storage by the study Site as per the Document Retrieval Process Map (see Section 6.2):

1. Essential trial documents must be available at all times for inspection by regulatory competent authorities and other regulatory bodies or for audit in accordance with study contract.
2. Retrieval for data sharing to meet research transparency expectations is also permitted.
3. Only the Named Archivist or delegate can instigate the retrieval of an archive box (for example, if required by an auditor). A written request for retrieval must be sent to the Archivist or delegate by the Investigational research department. Telephone requests will not be accepted. The required box(es) will be identified by the Archivist or delegate and sent by courier to the required Investigational research department.

3.7 Returning Archived Boxes to Storage

Following withdrawal, each archive box re-presented to the off-site storage facility for storage will be treated as a new consignment and any documents which are added or removed from the box must be clearly documented on the Clinical Trial Archive Document.

The archive box(es) will then be dispatched in compliance with Section 3.4 and 3.5 above.

3.8 Destruction of Clinical Trial Data and Archived Essential Study Documents

Archived documentation can only be destroyed once written permission has been obtained in accordance with the study protocol requirements, Sponsor company's SOPs and permission from the following (if applicable):

1. Sponsor or CRO (details of process to seek permission should be given in the study contract)
2. Investigator Site Host Institution

4.0 RELATED TEMPLATES

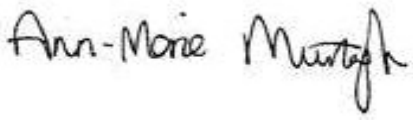
4.1 Clinical Trial Archive Document

5.0 RELATED DOCUMENTS

5.1 Archiving Process Map

5.2 Document Retrieval Process Map

6.0 APPROVAL and SIGNATURE



Ann-Marie Murtagh Date 16/10/2025

Director

King's Health Partners Clinical Trials Office

Appendix 1

GLOSSARY

Clinical Trial Archive Document – Document which must be completed for each clinical study box sent to archive. The form contains details of study, Investigator, archivist and box contents. A copy should be present in each box archived, with a copy held at the site and the original in the KHP-CTO.

Advanced Therapy Medicinal Product (ATMP) – A medicinal product which is either a gene therapy medicinal product, a somatic cell therapy medicinal product or a tissue engineered product.

Case Report Form: A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.

Chief Investigator (CI) – The chief investigator is the overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project

Clinical Trial - Any investigation in human participants, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal product or to identify any adverse reactions to one or more such products and to study absorption, distribution metabolism and excretion in one or more such products with the object of ascertaining the safety or efficacy of those products. The Medicines for Human Use (Clinical Trial) Regulations apply to all clinical trials conducted in the UK and Northern Ireland.

Good Clinical Practice (Good Clinical Practice (GCP) – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human participants. It ensures the safety, well-being, and rights of participants are protected while maintaining the credibility and accuracy of trial data. Good Clinical Practice (GCP) – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human participants.

International Council for Harmonisation (ICH) – a collaboration between regulators and the pharmaceutical industry in Europe, the United States and Japan to establish common standards for clinical trials. ICH Good Clinical Practice (GCP) – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human participants.

Investigator Site File (ISF) – A standard filing system which contains all essential documents held by Principal Investigator(s) conducting a trial which individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced.

King's Health Partners (KHP) – King's Health Partners brings together research, education and clinical practice across three NHS Foundation Trusts - Guy's and St Thomas', King's College Hospital and South London and Maudsley - and a world-leading university, King's College London.

King's Health Partners Clinical Trials Office (KHP-CTO) – Established in 2006 by King's College London, Guy's & St Thomas' NHS Foundation Trust, South London and Maudsley NHS Foundation Trust and King's College Hospital NHS Foundation Trust to provide a streamlined approach for all aspects of trial administration. The King's Health Partners CTO has two sections: the Commercial Team which provides a single interface for those wishing to conduct trials sponsored by the pharmaceutical industries and the Quality Team that supports investigators at King's Health Partners institutions who undertake CTIMP trials where King's Health Partners are the sponsor or co-sponsor

KHP-CTO Standard Operating Procedures (SOPs) - "detailed, written instructions to achieve uniformity of the performance of a specific function," SOPs are the basis against which Quality Systems and Processes are conducted and monitored.

MATTS – MedSciNet's Active Trial Tracking System. The electronic Clinical Trial Portfolio Management System used by the KHP CTO.

Medicines & Healthcare products Regulatory Agency (MHRA) – the UK's regulatory body responsible for ensuring the safety and effectiveness of medicines, medical devices, and blood components for transfusion. It operates as an executive agency sponsored by the Department of Health and Social Care

Named Archivist – Person responsible for ensuring archiving requirements are met. Referred to as "Archivist" in this SOP.

Partner Organisations – King's College London, Guy's & St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, South London and Maudsley NHS Foundation Trust and any other Organisations that may join the KHP Partnership from time to time.

Principal Investigator (PI) - the individual primarily responsible for the conduct of a research study at a specific research site

The Regulations – The Medicines for Human Use (Clinical Trial) Regulations 2004 which transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031**.** An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928. As amended from time to time.

Trial Master File (TMF) – A standard filing system which allows the effective storage and location of essential documents, that is the large volume of regulatory and approvals documents needed for clinical research. The filing system can be in the form of single project file or a number of files/filing cabinets, depending on what is deemed most appropriate for a particular clinical trial given its size and complexity. The regulatory and approvals documents within the TMF should be maintained alongside case report forms and source documentation.