Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Archiving of Essential Documents for University Sponsored Studies

SOP020

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1. Introduction

To ensure that results from Clinical Trials of Investigational Medicinal Products (CTIMPs) can be examined and subject to internal and regulatory audits, it is necessary for the Chief Investigator (CI) and the Sponsor to maintain accurate records throughout the lifecycle of the study and that this information is appropriately retained following study completion. The documents that must be maintained throughout the study and retained following the study completion are the 'Essential Records'. The MHRA recognises the ICH GCP E6 (R3) definition of essential records:

'Essential records are the documents and data (and relevant metadata), in any format, associated with a clinical trial that facilitate the ongoing management of the trial and collectively allow the evaluation of the methods used, the factors affecting a trial and the actions taken during the trial conduct to determine the reliability of the trial results produced and the verification that the trial was conducted in accordance with GCP and applicable regulatory requirements…'.

Appendix C of ICH GCP E6 (R3) gives further guidance on what records should be considered essential and therefore require retention.

There is no legal requirement to archive essential documentation for non- CTIMPs, however the principles established in the ICH GCP Guidelines *"may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects."* The Guidelines state that *"the Sponsor or owners of the data should retain all of the sponsor-specific essential documents pertaining to the trial."*. In light of this principle and in line with the University of Liverpool Records Retention Schedule records documenting the conduct of research projects, including things such as protocol, consent procedure, participants and adverse effects should be retained for a minimum of 6 years.

2. Scope of Procedure

This Standard Operating Procedure (SOP) describes the requirements for archiving of essential documentation relating to studies sponsored by the University.

3. Who

This SOP is aimed at Chief Investigators, students, trial coordinators and other members of University Staff involved in the end of study and archiving processes for University Sponsored research.

This SOP is aimed at staff within the University Clinical Directorate who are involved in the end of study and archiving processes for University Sponsored research.

4. When

This SOP should be referred to at the end of the study. The end of the study should be defined in the protocol, for example, when the last patient entered onto the study has had their last study visit. Refer to SOP021 for more information on end of study procedures.

Essential records should be archived as soon as practicable after the completion of the study.

5. What documents should be archived?

All Essential Documentation as defined in ICH GCP E6 (R3) Guidelines (Appendix C), including minutes from all trial related meetings, must be retained. It is presumed that this will be the entire Trial/ Study Master File.

The CI should appoint a designated archivist for the study who will have oversight of the archiving procedure. If one is not named it will be assumed this is the CI. The designated archivist for the study should check the contents of archived material prior to sending to archiving and keep a copy of the contents list and record location of storage.

6. Archiving retention periods

All essential records relating to conduct of a CTIMP must be archived in accordance with the requirements of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 to enable evaluation of trial conduct and data quality.

Regulation 31A of the clinical trials regulations mandates retention of essential records and participant medical files for at least 25 years from the conclusion of the trial, or longer if required for marketing authorisation purposes.

ICH E6(R3) Good Clinical Practice requires essential records to be complete, legible, and readily available for inspection throughout the retention period.

All essential records relating to conduct of a non-CTIMP must be retained in accordance with the University of Liverpool Records Retention Schedule. This includes documents such as protocol, consent procedure, participants and adverse effects should be retained for a minimum of 6 years but retention decisions need to be made on a case by case basis, bearing in mind the stated or implied requirements of the funder.

Research data defined as 'any recorded information necessary to support or validate a research project's observations, findings or outputs, regardless of format' should normally be retained for 10 years OR the period specified by the funder, making open and accessible in a timely manner where possible.

The University retention schedule[1] should be referred to for advice prior to archiving of research materials.

The planned retention period of essential records should be defined within the protocol.

7. General Principles

Essential records are defined as "those documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced. These documents

[1] https://tulip.liv.ac.uk/pls/new_portal/webwise.rec_box_sys_maint.maintain_retention_schedule

serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice and with all the applicable regulatory requirements."

The clinical study report also needs to be included with the archived data when available. If there is a secure holding area available for temporary storage until the clinical study report is completed after the end of the study, this should be used and all documentation archived together. However, if this is not possible the clinical study report should be later filed along with the rest of the documentation to ensure that a complete record is maintained.

The CI or designated archivist should inform the Sponsor of planned arrangements for archiving of essential records as soon as possible and within one year of the end of the trial. Requests for this information will be made as part of the Sponsor End of Study processes and should be considered in advance of the study completion.

Once archived essential records should not routinely be retrieved and access to the material will be restricted to the Sponsor, the regulatory authorities and the designated archivist. Details of the archiving location and the designated archivist should be recorded by the CI and notified to the Sponsorship Team.

If archived study records are requested for review by Regulatory Authorities the request should be made via the designated archivist and permission must be gained from the Sponsor representative for the retrieval of an archived box. Whenever an item is retrieved from archive, the date, item and person retrieving the item should be documented, together with the date returned to archive.

Archived documentation can only be destroyed at the end of the retention period once written permission has been obtained from all of the following, in accordance with the study protocol requirements, and sponsor SOPs.

- Sponsor
- Designated Archivist and/or CI

This information is an important part of closing the study and provision of the information is covered by the Chief Investigator Sponsor Declaration. If this information is not received within 2 years of the Study Completion Date, the responsibility for any future queries related to these areas will sit with the CI, and their Institute and Department. The Sponsor will be unable to provide support for queries related to these areas, as we will not hold the required information. Failure to provide such information may impact on current and future applications for Sponsorship.

8. Archiving Arrangements for non-CTIMPs (paper records)

The University Semi-Permanent Records store should be utilised to archive non-CTIMP research records. Full details on this process can be found on their website.

All archived material should be stored in archive boxes that are not labelled or externally sealed in line with the requirements of the Records Management Centre. The material should be removed from ring binders and folders before being packaged within the archive box.

9. Archiving Arrangements for CTIMPs (paper records)

It is expected that where the University, as Sponsor, are responsible for, or a University Department have been delegated the function of archiving essential records for a CTIMP this archiving will be undertaken with RESTORE Document Management.

Where the University is not responsible, or has not been delegated the function of archiving, the contract with the Sponsoring Organisation should define how this will be undertaken. It is not expected RESTORE will be used in this occurrence. It is noted that the Liverpool Clinical Trials Centre (LCTC) have a designated archivist and local procedure. Other departments wishing to utilise RESTORE should contact the Senior Clinical Research Governance Manager in the first instance to discuss requirements.

- Documents to be archived must be logged using the RESTORE Web Portal. The person undertaking the process of archiving must have received appropriate training for this system. It is noted that the RESTORE Web Portal should be accessed via Internet Explorer for optimal functionality;
- All documents should be removed from lever arch files and placed into appropriate archive boxes, ordered from RESTORE;
- Documents should be stored in the same order as the TMF, and each section be clearly labelled;
- The designated archivist should check the contents of archived material prior to sending to archiving and keep a copy of the contents list;
- The following sections must be completed in the RESTORE Web Portal for each box;
    - Barcode – Must match the RESTORE provided barcode for that box
    - Owner – Department undertaking the archive
    - Trial Acronym – The recognised acronym used throughout the trial
    - End of Trial Date – The date the trial ended
    - Description – The sections of the TMF filed in the box (i.e. section 1-4)
    - Destroy Date – If the date of destruction is known please enter. This can be left blank (see section 3.7 - Destruction of archived material).
- The Senior Clinical Research Governance Manager should be contacted to arrange collection of boxes for archive.

10. Archiving Arrangements (electronic records)

The use of electronic systems for trial activities can mean that essential documentation is not able to be stored with the paper TMF for archiving. In instances where it is not possible or feasible to print

electronic records for paper storage the CI must employ suitable procedures for the appropriate archive of such records. Throughout the retention period the authenticity of the data must be maintained and so consideration must be paid to the following areas;

- Electronic records are held on a system that provides regular back-up to reduce the risk of loss of data;
- Access to archived electronic records must be suitably restricted to essential personnel only (e.g. the Designated Archivist and the Sponsor). The records must also be protected from unauthorised changes to maintain authenticity;
- Electronic records must be periodically retrieved to ensure continued accessibility to the data. Where required processes must be employed to transfer records from near obsolete media to newer media as technology advances. Such media transfer should be validated and documented to ensure the full audit trail is maintained, and it can be confirmed that there has been no loss, change or corruption to the data.

The University of Liverpool provides electronic archiving via the Data Catalogue Service (http://datacat.liverpool.ac.uk/). It is recommended that all researchers make use of this service to ensure secure storage of their data, and also to assist in ensuring open access requirements can be met. Where departments have established data archive facilities it is not a requirement to use the Data Catalogue, but the Sponsor may ask for further details on the system and processes used. The University Information Governance website can provide more information on archiving of electronic records.

11. Roles and Responsibilities

The CI has a responsibility to ensure the Sponsor is aware of the archiving arrangements and for ensuring that the Sponsor and regulatory authorities have access to the archived data. If the CI leaves the University during the archival period, the sponsor should be informed and, if appropriate, a new designated archivist identified.

The designated archivist is responsible for the arrangements for the archiving of study documents and maintaining accurate records relating to the location of the records, and details of when records have been accessed and the time at which they were returned to archive. If the designated archivist leaves the University during the archival period, the sponsor should be informed and a new designated archivist identified.

The Sponsor is responsible for providing permission for archived documents to be accessed.

12. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit

LCTC	Liverpool Clinical Trials Centre
SOP	Standard Operating Procedure

13. Associated Documents and References

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

ICH Harmonised Guideline for Good Clinical Practice E6(R3)

University of Liverpool Records Management

University of Liverpool Document Retention Schedule

University of Liverpool Information Governance

14. Training and Resources

CIs, students, trial coordinators and other members of University Staff involved in end of study and archiving processes for University Sponsored research should be aware of and familiar with this SOP. Training can be provided by the Clinical Research Governance Team upon request.

15. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.