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| **SOP010 Archiving Essential Documents for LJMU Sponsored Clinical Research** | |
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| **Relevant to:** | Staff and students conducting clinical research |
| **Approved by:** |  |
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| **RELEVANT DOCUMENTS** | |
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| **RELATED POLICIES & DOCUMENTS** | |
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# Introduction

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 the above principles and the possibility of inspection by the Department of Health, it is therefore good practice to archive essential research documentation and LJMU requires that for Sponsored studies essential documentation must be retained for a period of at least 5 years or as defined by the funder.

# Scope of Procedure

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

# Procedure

## Who

The SOP is aimed at CI’s, Principle Investigators (PI’s) and any other members of a study team who are responsible for maintaining and archiving essential study documents.

The SOP is also aimed at staff within LJMU REG who are involved in the sponsorship of studies.

## 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 participant entered onto the study has had their last study visit.

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

## How

* + 1. **What documents should be archived?**

All Essential Documentation as defined in ICH-GCP Guidelines (Section 8). It is presumed that this will be the entire Study Master File.

The CI will need to 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.

* + 1. **Archiving Arrangements (paper records)**

To transfer documents to the LJMU Records Management Centre, the designated archivist should contact the Records Management staff in the first instance to discuss requirements and agree the transfer.

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. The Records Management Service Records Transfer List must be fully completed and placed in the top of the box.

The CI or designated archivist should inform the Sponsor of planned arrangements for archiving of essential documents as soon as possible and within one year of the end of the trial.

Once archived essential documents 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 LJMU REG

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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 once written permission has been obtained from all of the following, in accordance with the study protocol requirements, and sponsor SOPs.

* + - * Sponsor
      * Designated Archivist

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.

* + 1. **Archiving Arrangements (electronic records)**

The use of electronic systems for study activities can mean that essential documentation is not able to be stored with the paper SMF 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.

LJMU provides electronic archiving via the Data Catalogue Service. 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.

* + 1. **How long should documents be archived for?**

The CI should ensure that the documents contained, or which have been contained, in the study master file are retained for at least 5 years after the conclusion of the study and that during that period documents are:

1. Readily available to the licensing authority on request; and
2. Complete and legible”

The LJMU retention schedule should be referred to for advice prior to archiving of research materials.

# 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.

# Abbreviations

**CI** Chief Investigator

**CTIMP** Clinical Trial of an Investigational Medicinal Product

**LJMU REG** LJMU Research Ethics and Governance

**PI** Principle Investigator

**SOP** Standard Operating Procedure

# Associated Documents and References

To be completed

# Monitoring and Audit

Compliance with this SOP will be audited periodically as part of the LJMU REG audit plan.

# Change History

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| Version No. | Effective date | Significant changes | Previous version No. |
| 1.0 | See page 1 | This is the first version of this SOP | n/a |