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**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1032 UoL**

Version 2.1, September 2021

**Archiving of Essential Documents for Research Studies
Sponsored by the University of Leicester**

OFFICE BASE

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Effective Date: October 2021

1 Introduction

This Standard Operating Procedure (SOP) describes the requirements for archiving of all research sponsored by the University of Leicester (UoL). Its purpose is to ensure that Trial Master Files (TMFs) for studies are readily available at all reasonable times for inspection by regulatory authorities or any person appointed by the University of Leicester to audit the study.

Retention of the TMF (including the Investigator Site Files) for Clinical Trials of Investigational Medicinal Products (CTIMPs) and the medical records of subjects involved is a legal requirement. The Sponsor and Chief/Principal Investigator (CI/PI) must ensure that the documents contained, or that have been contained, in the TMF, as well as the medical files of trial subjects are retained for at least 5 years after the conclusion of a study and that they are complete and legible. Studies where the data are used to support a marketing application have further requirements as per Directive 2003/63/EC or the prevailing relevant legislation at the time. Subjects' medical records must be retained for at least 5 years in their original format and in accordance with the maximum period of time permitted by the institution to whom they belong.

Arrangements for retention of documents for non-CTIMP studies must be appropriate to the requirements for each individual study.

As most of the UoL sponsored research is hosted by UHL, UoL can take advantage of the UHL approved off site storage facility (Stor-a-file).

2 Scope

This SOP applies to all research studies that are sponsored by the UoL. At the time of writing (January 2017) there are no studies sponsored by UoL which use 100% electronic TMF so this SOP refers only to paper filing systems. Procedures for studies that contain electronic aspects of the TMF can be found at Appendix 2.

3 Definition

Clinical trial information must be stored in such a way that it can be accurately reported, interpreted and verified. The TMF is a collection of the documentation that allows the conduct of a clinical trial, the integrity of the trial data and the compliance of the trial with GCP and applicable regulatory requirements to be evaluated. UoL SOP S-1015, Essential Documents and Trial Filing for Research Sponsored by the University of Leicester, provides more information on the requirements for the TMF.

4 Individual Responsible for Archiving

The Research Governance Manager for UoL is the named person responsible for archiving of CTIMP documentation and for ensuring that access is restricted to themselves, their delegate, auditors and inspectors. The CI is responsible for the completeness and the quality of the documentation that makes up the TMF.

5 Archiving Arrangements

For all studies the Sponsor will inform the investigator(s)/institution(s) in writing of the need for record retention. The Sponsor delegates responsibility to the Chief Investigator (CI) for notifying the Research Governance Office) and the investigator(s)/institution(s) in writing when the trial related records are no longer needed and can therefore be archived.

The provisional arrangements and costings (if applicable) for archiving the TMF will be agreed between the CI and the Sponsor during the initial Sponsor review process. Costs for archiving are the responsibility of the CI and where possible must be included in an application for funding. The TMF may be filed locally if suitable facilities are available or alternatively off-site through a Sponsor-approved external archiving facility.

5.1 On Site Archiving

For all research including CTIMPs archived on site the proposed archiving area will be assessed by the Sponsor to ensure it is suitable unless the facilities and storage conditions are already known and approved by the Sponsor. This assessment must be documented using the Archiving Assessment Checklist (Appendix 1). It is possible that at the start of a study facilities may not be 100% ready to be used for archiving, but there must be a plan of action to ensure that by the time the study is ready for archiving the facilities are fit for purpose. Each iteration of Appendix 1 must be saved to show progress and will form part of the TMF and audit trail.

Before the TMF is archived, it is recommended that it is checked to ensure that it is complete and that all necessary documentation has been filed. This check should be comprehensively documented as described in SOP S-1024 UoL.

A checklist to aid the archiving process can be found at Appendix 3. It will usually be undertaken by the trial manager but may also be undertaken by other appropriate personnel. Preparation for archiving is expected to be completed by the study personnel.

Before archiving, the contents of the TMF should also be assessed for any records that could be disposed of (for example, duplicates) and those that may be subject to rapid deterioration and will therefore require transferring to a more robust media prior to archiving.

Patient medical records will be subject to arrangements within the NHS Organisation that owns them, but clear identification that the patient has been involved in a Clinical Trial must be evident, e.g. a sticker on the front of the records. In addition, it must be clear if the record must be retained and not destroyed before a specified date.

It is important that where centralised records have been held – for example – staff training records or CVs, that these are considered in the arrangements for archiving and retention as they may be required to be produced in addition to the TMF to demonstrate compliance.

In addition, pharmacy records and records of vendors or other agents of the Sponsor also form part of the TMF and arrangements must be made to ensure this documentation is stored appropriately for the required length of time and is retrievable if required.

The ultimate responsibility for the documents to be retained by the investigator or institution resides with the investigator or institution. If the investigator becomes unable to be responsible for their essential documents (for example due to retirement) the Sponsor should be notified in writing and informed to whom the responsibility has been transferred.

5.2 Off Site Archiving

For all research including CTIMPs archived off site and not using the UHL and Joint Office approved facility (Stor-a-file), the proposed archiving area will be assessed by the Sponsor to ensure it is suitable unless the facilities and storage conditions are already known and approved by the Sponsor.

This assessment must be documented using the Archiving Assessment Checklist (Appendix 1). It is possible that at the start of a study facilities may not be 100% ready to be used for archiving, but there must be a plan of action to ensure that by the time the study is ready for archiving the facilities are fit for purpose. Each iteration of the Archiving Assessment Checklist must be saved to show progress and will form part of the TMF and audit trail.

Before the TMF is archived, it is recommended that it is checked to ensure that it is complete and that all necessary documentation has been filed. This check should be comprehensive as described in SOP S-1024 UoL.

A flow chart detailing the process is available at Appendix 4.

5.3 Preparation for archiving

A checklist to aid the archiving process can be found at Appendix 3. This final check will usually be undertaken by the trial manager but may also be undertaken by other appropriate personnel. Preparation for archiving is expected to be completed by the study personnel.

Before archiving, the contents of the TMF should also be assessed for any records that could be disposed of (for example, duplicates) and those that may be subject to rapid deterioration and will therefore require transferring to a more robust media prior to archiving.

Patient medical records will be subject to arrangements within the NHS Organisation that owns them, but clear identification that the patient has been involved in a Clinical Trial must be evident, e.g. a sticker on the front of the records. In addition, it must be clear if the record must be retained and not destroyed before a specified date.

It is important that where centralised records have been held – for example – staff training records or CVs, that these are considered in the arrangements for archiving and retention as they may be required to be produced in addition to the TMF to demonstrate compliance.

In addition, pharmacy records and records of vendors or other agents of the Sponsor also form part of the TMF and arrangements must be made to ensure this documentation is stored appropriately for the required length of time and is retrievable if required.

The ultimate responsibility for the documents to be retained by the investigator or institution resides with the investigator or institution. If the investigator becomes unable to be responsible for their essential documents (for example due to retirement) the Sponsor should be notified in writing and informed to whom the responsibility has been transferred.

5.4 Arranging for archiving off site

Storage is available at Stor-a-file, Wenlock Way, Leicester, LE4 9HU (part of Leicester Micro Bureau Limited (LMB)) who have NHS relationships throughout England and Wales. They offer a fully comprehensive security system together with every possible retrieval and storage requirement, both now and in the future. Bar coding at the point of collection, together with full tracking facilities exist to ensure knowledge of wherever a particular set of data is at a particular time.

Arrangement for archiving can be done through the UHL R&I office. In order to request boxes for storage at the facility please complete FORM A.

All related costs in relation to the archiving process are at the Chief Investigator's expense e.g.:

- Boxes – minimum of 10
- Archiving to Stor-a-File
- Storage
- Retrieval

Relevant invoices will be sent to the billing address given on the attached form(s) and must be paid promptly.

5.5 Sending files to storage off site

A designated individual within the research team must take responsibility for the process for a specific trial. The Research & Innovation (R&I) Office must be contacted at the outset for details of current costings. Boxes and Barcodes may then be ordered on the attached 'Form A - Request for Boxes & LMB Barcodes for Archiving'.

The R&I Office will contact Stor-a-file to place the order and arrange delivery of printed Barcodes and boxes to a specified location. A minimum of 10 boxes and Bar Codes will be provided at each request.

Following receipt of the boxes and LMB barcodes and archive completion, the boxes must be filled in accordance with Appendix 3. Once the boxes have been checked by the Research Manager, a FORM B must be completed and forwarded to the R&I office.

A copy of all 3 sections of the form - numbered FORM B (1), (2) & (3) should be retained for your records and a copy of the sheet noting the LMB barcodes and contents of the boxes should be placed with the boxes to be archived.

The R&I Office will then contact Stor-a-file who, in turn, will arrange the date and time of collection with the contact person named on the form.

5.6 Retrieval of Archived documents off site

The R&I Office will facilitate all requests for retrieval of archived documentation. Only authorised personnel from the R&I Office are permitted to request retrieval. A test of the system is made annually.

In order to request retrieval of archived documents, FORM C must be completed and sent to the R&I Office using RIAdmin@uhl-tr.nhs.uk. On receipt, the request will be sent to Stor-a-file with details of delivery point and responsible person.

Once a request has been made, Stor-a-file will scan the stated LMB Barcode permitting 'exit from store'. The box can be tracked en route to stated location and on reaching its destination the same mechanism is used to identify that the box is now at that location. This ensures that the LMB database identifies retrieval from store and the date and time the box arrived at the requested location.

On arrival of the box, the receiver must notify the R&I Office of arrival. The R&I Office will then return Form C to the requester. The box(s) can be logged out for a period of one month only for Investigator File/Case Notes and therefore must be returned within a maximum of one month unless express arrangements have been made with the Head of Research Operations (UHL), in advance for the documentation to be retained out of storage for longer periods.

For return, Part 2 of the original FORM C must be completed and forwarded to the R&I office who in turn contact Stor-a-file regarding collection. It is essential that the documents retrieved are returned in full and R&I are informed of completed collection.


A flow map detailing the process is available at Appendix 5.

6 Responsibilities

Responsibility Undertaken by		Activity	
1	UoL Research Governance Manager & CI	UoL Research Governance Manager & CI	Agree the provisional arrangements for archiving and the costings (if any) during the Sponsor review process.
2	UoL Research Governance Manager	Research Governance Manager or delegate	Perform and document an assessment of proposed on-site archiving area if it is not already known to be suitable.
3	UoL Research Governance Manager	Research Governance Manager or delegate	Responsible for archiving TMFs.
4	CI	CI	Responsible for costs of archiving using an external archive facility.
5	CI	CI or delegate	Responsible for the contents of the TMF.
6	CI	CI	Appoint another person responsible for the TMF and inform the Sponsor if they are no longer able to be responsible.
7	CI	Monitor or other appropriate individual	Perform a TMF check prior to archiving.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions:

Development and approval Record for this document

Author/Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance
Reviewed by:	Research Sponsorship Management and Operations Group
Approved by:	Professor Nigel Brunskill 
Date Approved:	13/10/2021

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Jan 2017	2	Diane Delahooke	Logos updated. Text added to explain procedure for utilising off site archiving at Stor-a-file. Appendices added to bring in line with UHL process.
Sept 2021	2.1	Cat Taylor	Administrative changes

Distribution Record

Date	Name	Department	Received