

LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office SOP-1032 LU

Archiving of Essential Documents for NHS Research Sponsored by Loughborough University

Effective Date: October 2015

1.0 Introduction

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

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

2.0 Scope

This SOP applies to all research studies that are covered by the [Research Governance Framework \(v2 2005\)](#) and sponsored by LU. At the time of writing (July 2015) there are no studies sponsored by LU which use 100% electronic TMF so this SOP refers only to paper filing systems.

3.0 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 trial, the integrity of the trial data and the compliance of the trial with GCP and applicable regulatory requirements to be evaluated. LU SOP - 1015, Essential Documents and Trial Filing for Research Sponsored by LU, provides more information on the requirements for the TMF.

4.0 Individual Responsible for Archiving

The CI is responsible for the completeness and the quality of the documentation that makes up the TMF.

5.0 Archiving Arrangements

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. The TMF may be filed locally if suitable facilities are available or alternatively off-site through a Sponsor-approved external archiving facility.

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. It will usually be undertaken by the trial monitor but may also be undertaken by other appropriate 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.

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 appropriate 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.

6.0 Responsibilities

Responsibility Undertaken by		Activity	
1	LU Research Governance Officer & CI	LU Research Governance Officer & CI	Agree the provisional arrangements for archiving and the costings (if any) during the Sponsor review process.
2	CI	CI	Responsible for Archiving TMFs.
3	CI	CI	Responsible for costs of archiving using an external archive facility.
4	CI	CI or delegate	Responsible for the contents of the TMF.
5	CI	CI	Appoint another person responsible for the TMF and inform the Sponsor if they are no longer able to be responsible.

Responsibility Undertaken by		Activity
6	CI	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:	Jackie Green		Job Title: Research Governance Officer
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