



Archiving of Essential Documents for Research Studies Sponsored by the University of Leicester with SOP S-1032 UoL

This document must be completed during the Sponsor application process where a request has been submitted to the University of Leicester (UoL) to act as the sponsor for a research study. This form only needs to be completed if the intention is to archive Trial Master Files (TMFs) in alternative storage facilities other than Stor-a-file. Once completed the document must be sent to the Research Governance Manager and a copy stored in the Trial Master Files (TMFs).

The purpose is to ensure that the TMF for research studies are readily available at all reasonable times for inspection by the MHRA or any person appointed by the UoL to audit the study.

Please complete the form clearly and if not using typescript, please PRINT the words to enable legibility.

Table with 2 columns: Field Name, Value. Fields include Full Study Title, Study Reference Number, Chief Investigator, and Point of Contact (contact details).

Table with 2 columns: Question, Answer. Questions include: Is the storage facility on or off site? Where is the storage facility located? How long is this study documentation to be stored for? Which individual is responsible for the day to day management of the facility? Who has access to the storage facility? Are the rooms/ cabinets lockable? Confirm the facilities are secure, with appropriate environmental controls and adequate protection from fire, flood, rodent, pest and unauthorized access.

NB: if the investigator becomes unable to store their essential documents, the sponsor should be notified in writing so that alternative storage arrangements can be agreed. If the Investigator is no longer able to maintain custody of the essential documents, the sponsor should be notified in writing to arrange an appropriate alternative.

Chief Investigator:.....Date:

Sponsor:Date: