



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 storage facility location, duration, management, access, and security. Includes a note (NB) at the bottom regarding investigator notification.

Chief Investigator:.....Date:

Sponsor:Date: