Training and SOP Read Log – Guidance Page

How to use this document:

Staff working on UoL Sponsored research should use this Training and SOP Read Log to document both general and study/trial-specific training which has been completed.

- The **Sponsor SOP Read Log** is intended to be overarching and can be used to evidence SOP reading across multiple studies/trials and any general research training completed such as GCP and Informed Consent training.
- The **Training Log** is intended to be study/trial-specific and to evidence training for just the one study/trial. However, the page can be duplicated as many times as required so that a dossier of training can be created covering all studies/trials being worked on.

Training Requirement:

- All staff working on UoL Sponsored research are required to read Sponsor SOPs where these are relevant to their role and the type of study.
- A full list of Sponsor SOPs is available on the Research Governance Office website and suggested SOPs are listed below.
- Staff must read the SOPs prior to or at Study Initiation, or within 1 month of joining the study (i.e., being on the Delegation of Authority and Signature Log).
- Re-reading of SOPs should be undertaken regularly (i.e., annually) and/or when made aware by the Sponsor that a new version of an SOP(s) has been issued.

Chief Investigator required reading:

S-1010 UoL - Delegation of Responsibilities for Research Sponsored by the University of Leicester

Research Team suggested reading:

S-1007 - Monitoring of Research Sponsored by the University of Leicester
S-1009 - Processing and Reporting of Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions
S-1012 - Management and Production of Corrective and Preventative Action Plan (CAPA)
S-1013 - Identifying and Reporting Deviations and Serious Breaches of GCP
S-1015 - Creating and Maintaining a Trial Master File (TMF)/ISF
S-1020 - Training for Staff Engaged in Research
S-1021 - Informed Consent for Research

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Sponsor SOP Read Log

Name:		**Role:**	

Please use this Read Log to document which Sponsor SOPs you have read. This page can be photocopied and used across multiple studies/trials. Re-reading of SOPs should be undertaken regularly (i.e., annually) and/or when made aware by the Sponsor that a new version of an SOP(s) has been issued.

SOP S Number	SOP version	SOP Date (dd/mm/yyyy)	Date Read (dd/mm/yyyy)	Initials/Signature
S-	V__.__	__ /__ /_____	__ /__ /_____	
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S-	V__.__	__ /__ /_____	__ /__ /_____	
S-	V__.__	__ /__ /_____	__ /__ /_____	
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General Research Training Log

Please use this table to document any general research training (i.e., GCP, Informed Consent, Data Protection, HRA Human Tissue Act).

Name of Training	Date Completed (dd/mm/yyyy)	Expiration Date
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Study/Trial-Specific Training Log

Name:		**Role:**	
Sponsor Reference Number:		**Study Title / Acronym:**	
Principal Investigator:		**Site:**	

Please use this Training Log to document any study/trial-specific training. This page should be completed for each study/trial being worked.
A copy should be retained within the Trial Master File/Investigator Site File (as appropriate).

By completing the below, you are confirming that you have read/received training relevant to your role and that you understand your responsibilities in the conduct of the study/trial. Any amendments to the protocol/training topics listed may result in the requirement for retraining.

Research Team suggested training topics reading:

- Protocol
- Maintenance of Source Documents
- Maintenance of TMF/ISF
- Reference Safety Information (Investigator Brochure/SmPC)
- Informed Consent Procedures
- CRF/eCRF/Data Entry
- Handling/storage/shipping of Lab samples
- Study/trial specific SOPs
- Amendment and relevant associated documents (In the Document/Topic version column list the Amendment reference and Date e.g. SA01 01/01/2023)

Training Document/ Topic	Document/ Topic version and date	Date Completed
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