University of Leicester and University Hospitals of Leicester NHS Trust joint Research Support Office Standard Operating Procedures

University of Leicester Research Governance Office
SOP S-1000 UoL

Process for Writing Standard Operating Procedures (SOPs) for Research Governance Procedures for Research Sponsored by the University of Leicester (UoL)
(SOP for SOPs)

Office Base

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Version 6.0, September 2023

Effective date: October 2023

This SOP will be implemented in line with the document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

1.0 Introduction and Scope

Standard Operating Procedures (SOPs) are method sheets designed to achieve uniformity in the performance of specific functions. They should be clear, concise and must be adopted by the users.

Staff performing relevant activities must be trained in the process described in the SOP and this training should be documented.

The Research Governance SOPs will be used for reference, and for the training of personnel working on University of Leicester (UoL) sponsored research studies. They are also used as evidence to assure compliance with the regulatory agencies and frameworks necessary to govern research.

The aim of this SOP is to define the procedures for the creation, approval, issue and control of SOPs used for the purposes of Research Governance or research activity that requires a Sponsor, according to the UK Policy Framework for Health and Social Care Research, within the UoL.

2.0 Definitions

Author
Individual who prepares and writes the SOP. The author should be an individual who is appropriately qualified and experienced to ensure that the SOP describes a workable record of what actually happens.

Approver
A senior individual with appropriate experience and designated authority to approve the SOP for use.

Instruction Manuals
An instruction manual (e.g. lab or sample manual) is a controlled document to be used when a SOP is not sufficiently detailed to provide working instructions (e.g. sample collection and processing instructions).

Research Sponsorship, Management and Operational Group (RSMOG)
A group involved in the oversight of clinical research within the UoL and University Hospitals of Leicester (UHL), senior management members within the research governance office and external members from the UHL NHS Trust. The group meet regularly to share best practice across the University and to develop and maintain the UoL Sponsor SOPs.

Standard Operating Procedures
Detailed, written instructions to achieve uniformity of the performance of a specific function, communicate procedures to those who will undertake them, underpin training and form a permanent record of the methodology employed.

Study Specific SOPs
SOPs generated and issued by individual research teams/units within the UoL that provide instruction that is specific to a units/study's operations.

Researchers should assess both the UoL Sponsor SOPs and host NHS SOPs to determine where supplementation with details of study specific processes is required. Where more information is needed, it should be considered whether specific processes or procedures should be detailed within the Protocol or if an SOP or instructions manual are required. Manuals to support sample and/or data management, or support services (i.e., pharmacy, laboratory, scanning) can be produced but should utilise the same preparation, approval, distribution, amendment and storage practices as described in this document.

UoL Sponsor SOPs
UoL Sponsor SOPs issued by the UoL RGO, for use in clinical research which are reviewed by RSMOG. These SOPs must be followed where the UoL is the Sponsor of a research study and may also be used where the UoL act as the host institution.

3.0 Responsibilities

All staff
- Follow the procedure described in the SOP.
- Inform the author or RSMOG if errors or deviations from current/best practice are identified in the SOP that will require a review be undertaken or if the process described in the SOP requires updating.

Author
- Generates the draft SOP.
- Ensures that the appropriate individuals review the SOP and ensures review comments are incorporated as appropriate.
- Assesses the need for revision.

Approver
- Authorises the SOP for issue and use.

RSMOG
- Acts as the reviewers for the UoL Sponsor SOPs.
- Once the group is satisfied with the content of the SOP the group approves the SOP prior to it being sent to the approver.

4.0 Procedure

4.1 Identification of Need
All procedures for the conduct and quality of clinical research must be defined within an SOP or similar controlled document.

Any member of staff may identify the need for an SOP, where such a request is received it must be assessed to determine whether the process is already covered in an existing document or whether a new SOP is required.

If a new SOP is required, an author must be assigned to draft the document.

4.2 Numbering, version control and Format
Every SOP should be assigned a reference number and should be paginated appropriately. Each iteration of an SOP should be clearly version and date controlled,

typically minor revisions to an SOP should result in a .1 increase to the version number whereas more major revisions should result in an increase of 1.0.

A table documenting the version history of the document and changes made with each revision should be present within the SOP.

4.3 Content and authorship

SOPs should be written in a clear and concise manner and be as instructive as possible so that any trained individual can complete the SOP activity effectively.
Content should not include reference to data which may change on a regular basis (e.g. staff names and phone numbers).

Wherever reference is made to an activity covered by another SOP, the name/reference number of that SOP should be listed.

Once the draft of an SOP has been written it should be reviewed to ensure that it complies with all relevant regulations and guidelines.

4.4 Approval

Once the final version of an SOP has been produced it must be formerly approved. UoL Sponsor SOPs must be agreed by the RSMOG and must be approved by the Chair of the UoL Research Sponsorship Committee (RSC).

The effective date must allow time for user notification, training and implementation.

4.4 Notification and Training

SOP users must be trained in the relevant SOPs to their job role/delegated tasks as per the Delegation of Authority and Signature Log prior to performing the activity. Training must be recorded and appropriate training records maintained (e.g. SOP read logs S-1011).

4.5 Storage and Access

The UoL Sponsor SOPs are published on the Research Governance SOP webpages and are the only official version. Copies or print outs should be considered as uncontrolled versions.

4.6 Review of Issued SOPs

All SOPs should be current and fit for purpose and must be reviewed regularly. SOPs should state a ‘next review’ date, however, they may be reviewed or updated more frequently to reflect changes in practice or following the introduction of new regulations or procedures.

All UoL Sponsor SOPs will be reviewed as per the timeline stipulated on the individual SOP by the Head of Research Governance or their delegate but may also be subject to interim updates.

5.0 Additional Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Research	Ensure SOPs written in accordance with SOP S-1000 UoL

Responsibility	Undertaken by	Activity
	Governance or their delegate	
Sponsor	Head of Research Governance or their delegate	Circulate all new and revised SOPs to RSMOG for review and ensure appropriate sign off prior to publishing
Sponsor	Head of Research Governance or their delegate	Review all Research Governance SOPs as per timelines stipulated on the individual SOP following the process detailed in SOP S-1000 UoL

6.0 Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research SOPs written in accordance with SOP S-1000 UoL	Research Sponsorship and Management Operational Group (UoL)	Checks conducted on review of SOPs	Head of Research Governance

7.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	29/09/2023

8.0 Review record

This table is used to track the changes made on revised / reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
Feb 2014	2	Wendy Gamble	Document revised during review of processes following MHRA inspection. Document re-named and revised as a University document. Now version 2.
April 2015	3	UoL RSMOG	Document reviewed and revised. Removal of UHL logo and minor administrative amendments to dates / footer. Addition of Loughborough University to front page.
Dec 2016	4	Diane Delahooke	Logo change and RGO address change.
March 2018	5	Michelle Muessel	Change of address
Sept 2021	5.1	Cat Taylor	Administrative changes
September 2023	6.0	Cat Taylor	Administrative and formatting changes to improve accessibility of SOP Major updates to the wording to provide clarity around the creation, review and issue of both UoL Core and unit/study specific SOPs. Update to SOP review schedule form '2 yearly' to 'as per the timelines stipulated on the individual SOP'.