



**UNIVERSITY OF LEICESTER, UNIVERSITY OF LOUGHBOROUGH
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1000 UoL**

Version 5, March 2018

**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

Research Governance Office
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Effective Date: April 2018

1. Introduction

Standard Operating Procedures (SOPs) are method sheets sufficiently detailed to be unambiguous, but not so detailed and inflexible that continuous amendments are required. They are intended to outline the processes and / or procedures for a given purpose or policy application.

The Research Governance SOPs will be used for reference and the training of UoL research active personnel. They are also used as evidence to assure compliance with the regulatory agencies and frameworks necessary to govern research.

SOPs describe working practices, which should be adhered to. However, occasionally specific circumstances may require variations from an SOP. Formal written explanations / justifications of such deviations must be recorded in the appropriate research site files, and where necessary, revised SOPs drawn up and implemented appropriately.

The aim of this SOP is to define the procedures for preparation, approval, distribution, amendment and storage of Standard Operating Procedures used for the purposes of Research Governance or research activity that requires a Sponsor, according to the Research Governance Framework, within the University of Leicester.

2. Scope

This SOP applies to all staff, and any external individuals who conduct research within the University of Leicester.

3. Procedure

The University of Leicester and the University Hospitals of Leicester NHS Trust work as a Joint R&D Support Office and each organisation has their own suite of SOPs. Each SOP will be identified with an SOP number and paginated as appropriate. SOPs will be numbered sequentially starting from 1000.

Each new or revised SOP will be reviewed by the UoL Research Sponsorship, Management and Operations Group (RSMOG) and signed off by the Chair of the UoL Research Sponsorship Committee (RSC).

SOPs will be published on the UoL College of Medicine, Biological Sciences and Biology website, Research Governance webpages.

All SOPs will be reviewed on a two yearly basis by the Research Governance Manager or their delegate.

4. Study specific SOPs

As a general rule, there should be no study specific SOPs. Study specific processes or procedures should be detailed within the Protocol.

Where it is necessary to produce procedural documents they must be written in accordance with this SOP.

5. Responsibilities


Number	Responsibility	Undertaken by	Activity
1	Sponsor	Research Governance Manager or their delegate	Ensure SOPs written in accordance with SOP S-1000 UoL
2	Sponsor	Research Governance Manager or their delegate	Circulate all new and revised SOPs to RSMOG for review and ensure appropriate sign off prior to publishing
3	Sponsor	Research Governance Manager or their delegate	Review all Research Governance SOPs every 2 years following the process detailed in SOP S-1000 UoL

6. 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	Research Governance Manager

7. Development and approval Record for this document

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Author / Lead Officer:	Wendy Gamble
Job Title:	Research Governance Manager
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	16/04/2018

8. Review Record

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.
Mar 2018	5	Michelle Muessel	Change of address

9. Distribution Record:

Date	Name	Department	Received