



UNIVERSITY OF LEICESTER

JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

**University of Leicester (UoL) Research Governance Office
SOP S-1017 UoL**

**Process for Application for Indemnity for Studies
Sponsored by University of Leicester**

OFFICE BASE

Research Governance Office
University of Leicester
Academic Department
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

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1.0 Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office within University of Leicester (UoL) when completing a Sponsor risk assessment for the purpose of assessing and providing indemnity for research involving the NHS, therefore governed by the Research Governance Framework.

The outcome is that the Research Governance Office has a set of proportionate actions to complete the Sponsor Decision process and provide an in principle decision to sponsor the Study where it is possible to manage the risk appropriately, once satisfied that appropriate indemnity arrangements have been placed.

2.0 Scope

This SOP applies to all University of Leicester staff, students and any external individual who approach the UoL to request that the organisation act as Sponsor for research activity.

3.0 Purpose

This SOP will detail the process for ensuring appropriate insurance arrangements are in place for any research activity involving the University. Specifically this SOP will detail process for

- ensuring the appropriate university insurance is in place
- assessing whether the research activity requires specific referral to insurers
- referring the research activity to insurers

4.0 Procedures

Whenever the University is deemed to be involved in specific research activity involving the NHS, and therefore governed by the Research Governance Framework, the University must have appropriate insurance in place.

NHS and Commercial indemnity

Neither NHS nor Commercial Sponsors indemnify the University of Leicester should an injured party sue the University AND the NHS or the University AND the commercial company. In such cases the University requires its own insurance to cover itself should the University be found responsible for that harm (i.e. the University has been negligent) or have to pay defence cost to successfully defend any claim.

Negligent and Non-Negligent Harm.

The University's insurance cover routinely provides for negligent harm. Where arrangements for non-negligent harm cover are required the Insurance Office shall contact insurers for further advice.

- a) On receipt of an application for sponsorship the UOL Research Governance Office will forward this to the Insurance Office.
- b) Once the information has been received, the Insurance Office shall be responsible for assessment of the insurance requirements and where required, referral of the research activity to insurers.
- c) All sponsor applications will be reviewed by the Insurance Office on a case by case basis. In the majority of applications, the cost of insurance for the trial will be met centrally by the University. In certain circumstances proposals may attract an additional insurance premium. The following are examples of such types of trial:
 - Phase I/II Clinical Trials Research participants are under 5 years of age
 - Research participants that are pregnant
 - The research interferes with the process of conception
 - Clinical trials studying hepatitis/HIV
 - Clinical trials studying Creutzfeld-Jakob Disease
 - Clinical trials studying Genetic Engineering
 - Clinical Trials of unlicensed products
 - International Sites – where there may be a requirement to place local cover
 - Association of British Pharmaceutical Industries (ABPI) standard indemnity is not in place for research sponsored/funded by a Pharmaceutical company.
- d) The Insurance Office will issue a letter which is study specific, and confirms Insurers acceptance, to the Research Governance Office who will, in turn, forward it to the Investigators.
- e) A 'To Whom It May Concern' letter will also be issued, via the Research Governance Office, detailing the level of insurance the University holds. This letter is renewed annually on 1 August.
- f) The documents as defined in d) and e) above will be issued to the applicant/investigator by the UOL Research Governance Office.
- g) Amendments that increase the number of sites, or have a significant impact on the protocol inclusion/exclusion criteria will be communicated by the Research Governance Office to the Insurance Office. A communication confirming that the insurance remains valid will be required as part of the amendment sponsor green light process.
- h) In the event that the Insurers are not able to provide cover, the University will be unable to sponsor the study.

This process is detailed in the Insurance process flowchart – [Appendix 1](#).

Effecting Cover Where Additional Premium Is Required

The Insurance Office does not hold a central fund for payment of additional insurance costs and therefore the investigator must meet the cost of any additional premium.

Should a trial attract a specific additional premium, the Insurance Office will communicate this to the UOL Research Governance Office who will confirm that adequate funding is available.

If the trial is to commence the UoL Research Governance Office shall notify the Insurance Office that insurance cover is required confirming the research activity start date, the research activity duration and a University charge code.

The Insurance Office will confirm commencement with Insurers and issue appropriate documentation.

Insurers will issue an invoice to the University Insurance Office who will recharge to the code provided.

In the event that the investigator is unable to meet the cost of an additional premium, or the insurers are unwilling to provide insurance, the University will be unable to sponsor the study.

5.0 Responsibilities

Communication with University Insurers

All communication with the University Insurers should be via the University Insurance Office.

6.0 Further information

- 6.1 [Sponsor Risk Assessment Tool](#)
- 6.2 [UoL Insurance Office](#)
- 6.3 [SOP S-1003 UoL, Sponsor Risk Assessment and Management of Research Sponsored by University of Leicester](#)

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

7.0 Development and approval Record for this document

Author / Lead Officer:	Wendy Gamble / Sue Banbury
Job Title:	Research Governance Manager / Insurance and Risk Manager
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	10/04/2017

8.0 Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
October 2013	2	W Gamble S Banbury	Version 1 amended, and re-numbered, following review of Sponsor processes
April 2016	3	W Gamble S Banbury	Version 2 reviewed and amended to make minor changes to wording , including adding in clinical trials of unlicensed products into the "trigger" criteria