University of Leicester and University Hospitals of Leicester NHS Trust joint Research 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

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Version 4.0 May 2023

Effective Date: May 2023

This SOP will be implemented in line with this 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.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office (RGO) within the University of Leicester (UoL) when completing a Sponsor review, including a risk assessment, for the purpose of assessing and providing indemnity for research governed by the UK Policy Framework for Health and Social Care Research.

The outcome is that the RGO will complete a set of proportionate actions to determine the risk posed by a study. Where it is possible to manage the risk appropriately, and once satisfied that appropriate indemnity arrangements are in place, applications for Sponsorship will progress through to obtaining regulatory approvals.

Sponsorship is 'in principle' and is subject to the necessary and relevant regulatory approvals and Sponsor Green Light being issued.

2.0 Scope

This SOP applies to substantively employed UoL staff and students. Any individual who is not substantively employed by the UoL must hold a minimum 0.2 FTE UoL contract for the UoL to consider acting as the Sponsor for their research activity. Where the research activity is student research, the main supervisor must be a substantively employed UoL staff member.

3.0 Purpose

This SOP details the process for:

- ensuring appropriate indemnity arrangements are in place for research Sponsored by the UoL or where the UoL is acting in the capacity of a UK Coordinator for an external Sponsor
- assessing whether the research activity requires specific referral to insurers,
- referring the research activity to insurers.

4.0 UoL Indemnity Policies

Whenever the University is deemed to be involved in specific research activity governed by the UK Policy Framework for Health and Social Care Research, the University must have appropriate indemnity in place.

4.1 NHS and Commercial indemnity

Neither the NHS, nor Commercial Sponsors, indemnify the UoL. Should an injured party sue the University **and** the NHS, or the University **and** the commercial company, the University has its own indemnity should the University be found responsible for any negligent harm, or have to pay defence costs to successfully defend any claim.

4.2 Negligent and Non-Negligent Harm.

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

5.0 Procedure

a) Research activities that are deemed to be of 'higher risk' or are likely to attract an additional indemnity premium, will be referred to the Insurance Office prior to the Research Governance Office commencing the initial Sponsor review.

The following types of studies will be referred:

- Phase I 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, Human T-Cell Lympotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants, derivatives or variations thereof of Acquired Immune Deficiency Syndrome (AIDS) or any syndrome or condition of a similar kind
- Clinical trials studying Transmissible Spongiform Encephalopathy (TSE), Creutzfeidt-Jacob Disease (CJD), variant Creutzfeidt-Jacob Disease (vCJD) or new variant Creutzfeidt-Jacob Disease (nvCJD)
- 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
- COVID-19 related research
- Patients who lack capacity to consent
- Those applying for HRA's Confidentiality Advisory Group Approval which involves accessing personal identifiable data without consent
- Trials involving 5000 or more participants
- Gene and cell therapy clinical trials (researchers conducting this type of trial **must** contact htaenquiries@le.ac.uk immediately for further information)

The Insurance Office will confirm whether or not indemnity cover will be provided, and where applicable the anticipated costs of additional indemnity premiums. **In the event that the Insurers are not able to provide cover, the University will be unable to sponsor the study.**

b) Upon completion of a Sponsor review, the RGO will forward the relevant documents as per Appendix 1 to the Insurance Office.

c) The Insurance Office are responsible for the assessment of the indemnity requirements and where required, referral of the research activity to the insurers if this has not already been completed or where the design, management or conduct of the study has changed significantly since the initial referral.

d) The Insurance Office will issue a study-specific letter of indemnity which confirms the Insurer's acceptance.

e) A 'To Whom It May Concern' letter will also be issued detailing the level of indemnity 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 RGO.

g) Amendments are communicated to the Insurance Office on a monthly basis and are noted and actioned accordingly. Amendments may be referred to the Insurers, and where necessary, an updated letter of indemnity and/or the cost of additional indemnity premiums will be issued.

This process is detailed in the Indemnity Process for Sponsored Studies flowchart – Appendix 1.

5.1 Effecting Cover Where an Additional Premium is Required

All Sponsor applications will be reviewed by the Insurance Office on a case-by-case basis. For the majority of applications, the cost of indemnity for the research activity will be met centrally by the University. In certain circumstances, research activity may attract an additional indemnity premium. The Insurance Office does not hold a central fund for the payment of additional indemnity premium costs and therefore the investigator must meet the cost of any additional premium.

Should a study attract an additional premium, the following process will be followed;

a) the Insurance Office will communicate this to the RGO who will confirm whether adequate funding is available.

b) If the study is to commence, the RGO shall notify the Insurance Office that indemnity cover is required confirming the research activity start date, the research activity duration and an appropriate charge code.

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

d) 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.

6.0 Responsibilities

Communication with University Insurers

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

7.0 Further information

7.1 Sponsor Risk Assessment

For further guidance on the Sponsor Risk assessment please refer to SOP S-1003 ‘Sponsor Risk Assessment and Management of Research Sponsored by University of Leicester’ and its associated appendices.

7.2 UoL Insurance Office

Contact the University's Insurance Office via insurance@le.ac.uk

8.0 Development and approval record for this document

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

Author / Lead Officer:	Cat Taylor/Sue Banbury
Job Title:	Head of Research Governance/Insurance and Risk Manager
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	18/05/2023

9.0 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)
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
September 2021	3.1	Cat Taylor	Administrative changes
May 2023	4.0	Sue Banbury/ Cat Taylor	Update to list of trial types which may require additional premiums. Update to the effect of study amendments on indemnity. Update to contractual requirements of non substantively employed UoL staff Administrative changes and clarification of text to improve understanding. Update to the flowchart (Appendix 1).