




Research Governance Office Sponsorship Standard Operating Procedures

Insurance and Indemnity Arrangements

SOP Reference	S-1017
Version and Date	V5.0 April 2026
Author	
Name	Dr Cat Taylor
Job Title	Head of Research Governance
Reviewer/Approver	
Name	Emma Freeman
Job Title	Insurance Manager
Signature	
Date	28 April 2026
Effective Date*	28 April 2026
Next Review Date	April 2029

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1.0 Introduction and Scope

This Standard Operating Procedure (SOP) outlines the procedures undertaken by the Research Governance Office (RGO) for assessing and securing appropriate insurance and indemnity arrangements when the University of Leicester (UoL) acts as a Sponsor for research governed by the UK Policy Framework for Health and Social Care Research.

This SOP applies to;

- Substantively employed UoL staff and students;
- Student research where the main supervisor is a substantively employed UoL staff member; and
- Any research (referred to as 'trial' hereafter) sponsored by the UoL.

The RGO will complete a set of proportionate actions to determine the risk posed by a study. If risks are manageable, and the insurance and indemnity arrangements are deemed appropriate, the trial moves forward toward regulatory approvals.

The outcome is that Sponsorship is granted 'in principle' and is subject to the relevant regulatory approvals and Sponsor Green Light being issued.

2.0 UoL Insurance Policies

Whenever the UoL is the Sponsor of a trial as defined and governed by the UK Policy Framework for Health and Social Care Research, the UoL must have (or arrange) adequate insurance or indemnity to cover liabilities which may arise in relation to the design, management and (where applicable) the conduct of the trial.

2.1 NHS Indemnity and Commercial Insurance

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

2.2 Negligent and Non-Negligent Harm

The UoL insurance routinely provides cover for negligent harm. Where arrangements for non-negligent harm cover are required, the Insurance Office will contact insurers for further advice.

3.0 Procedure for Assessing Insurance and Indemnity Requirements

The RGO should be contacted at the earliest opportunity (ideally during the grant application and costing stage) to discuss the risk(s) associated with a trial in order to evaluate whether:

- The UoL standard insurance is sufficient;
- The trial requires specific referral to insurers; and/or
- There any additional insurance requirements.

The cost for trials that attract an additional premium must be covered by the research grant.

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Research activity involving the below are only covered following referral to the Insurance Office and satisfactory review of the protocol/ICF, and may be subject to additional premium;

- Clinical trials (CTIMPs) or other interventional studies which aim to enrol pregnant women
- Clinical trials (CTIMPs) or other interventional studies where participants are under 5 at the time of entry to the study.
- Clinical trials (CTIMPs) or other interventional studies with international trial locations
- Interventional trials which enrol more than 5000 research participants.
- Covid trials
- Therapies targeting the brain, blood-brain-barrier or cerebrospinal fluid
- Gene and cell therapy including gene editing (researchers conducting this type of trial must contact rgosponsor@le.ac.uk immediately for further information).

The Insurance Office will confirm whether or not cover will be provided, and where applicable the anticipated costs of additional premiums.

Where cover can be provided, Sponsorship will be granted 'in principle' and is subject to the relevant regulatory approvals and Sponsor Green Light being issued.

In the event that the University is not able to provide or arrange cover, the University will be unable to sponsor the study.

In all other instances, the insurance and indemnity arrangements will be determined during the Sponsor Review process as follows;

- Upon completion of a Sponsor Review, the RGO will request indemnity.
- The Insurance Office is responsible for the assessment of the insurance and indemnity requirements and where required, referral of the trial to the insurers if this has not already been completed or where the design, management or conduct of the trial has changed significantly since the initial referral.
- The Insurance Office will issue a trial-specific letter of indemnity which confirms the Insurer's acceptance. This will be issued via Infonetica.

Two 'To Whom It May Concern' (TWIMC) letters are used to evidence the level of insurance the UoL holds. When the RGO confirms that you are ready to submit your trial for regulatory approvals, you will need to download these documents from the RGO website. The link is provided in the communication issued via Infonetica.

- Modifications are communicated to the Insurance Office on a monthly basis and are noted and actioned accordingly. Modifications may be referred to the Insurers, and where necessary, an updated letter of indemnity and/or the cost of additional premiums will be issued (i.e., where the Chief Investigator is changed and/or significant changes are made to the design, management or risk of the trial).

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4.0 Placing 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 trials, the cost of insurance for the trial will be met centrally by the UoL. In certain circumstances, trials may attract an additional premium. The Insurance Office does not hold a central fund for the payment of additional premium costs and therefore the investigator must meet the cost of any additional premium.

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

- The Insurance Office will communicate this to the Chief Investigator (CI) who will confirm whether adequate funding is available.
- If the trial is to commence, the CI shall notify the Insurance Office that cover is required confirming the activity start date, the activity duration and an appropriate charge code.
- The Insurance Office will confirm commencement with Insurers and issue appropriate documentation.
- Insurers will issue an invoice to the Insurance Office who will recharge to the code provided.

In the event that the CI 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 Indemnity arrangements at research locations

The indemnity requirements for research conduct vary depending on the type of research location you intend to use and their geographical location within the UK.

The tables below provide an overview of the different clinical negligence indemnity requirements. In all cases, copies of the indemnity certificates and all communication with the location must be filed in the relevant Investigator Site File (ISF) and Trial Master File (TMF). These records must be available upon request in the event of a claim.

It is the responsibility of the CI to ensure the appropriate indemnity is in place for each research location. This includes notifying all Principal Investigators (PI) or responsible persons at a research location of these requirements.

5.1 NHS Trusts and GP Practices – Indemnity for Clinical Negligence

Type of research location	Indemnity requirements where locations are based in England and Wales	Indemnity requirements where locations are based in Scotland	*Requirements within Standard IRAS Section A76-3 or Combined review IRAS 'Management of Research' Section E Q5
NHS Trust	The Clinical Negligence Scheme for Trusts (CNST) applies ¹	The Clinical Negligence and Other Risks	<ul style="list-style-type: none"> • Select 'NHS Indemnity'

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		Indemnity Scheme (CNORIS) applies ¹	
General Practice (GP)	The Clinical Negligence Scheme for General Practice (CNSGP) applies ¹	The practice must be covered by the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) ² or location specific insurance must be provided ³	<ul style="list-style-type: none"> Select 'other arrangements apply'. Within the detail section confirm the relevant insurance for the specific location e.g. CNSGP applies.

5.2 Universities, Community venues and private practices – Indemnity for Clinical Negligence

Type of research location	Indemnity Requirements	*Requirements within Standard IRAS Section A76-3 or Combined review IRAS 'Management of Research' Section E Q5
University of Leicester	University Insurance Applies however this is limited to specific buildings and rooms within the University. The location of the research must be clarified and agreed in order for insurance to be approved.	<ul style="list-style-type: none"> Select 'other arrangements apply'. Within the detail section state that 'University of Leicester Insurance applies'.
Other non-NHS locations (e.g., community centres, Pharmacies)	Location specific insurance must be provided ³	<ul style="list-style-type: none"> Select 'other arrangements apply'. Within the detail section confirm the relevant insurance for the location (e.g., 'public liability will be in place at the location prior to any research activity taking place').
Private Practices	Location specific insurance must be provided ^{3,4}	<p>A76-3</p> <ul style="list-style-type: none"> Select 'other arrangements apply'. Within the detail section confirm the relevant insurance for the location (e.g., 'public liability will be in place at the location prior to any research activity taking place').
<p>Key</p> <p>¹ Provision of evidence is not required.</p> <p>² A list of the practices covered is available from the following website</p> <p>³ Insurance must meet the following;</p> <ul style="list-style-type: none"> Public Liability - 10 million per any one claim Professional Indemnity – 10 million per any one claim Medical Malpractice (sometimes referred to as treatment liability and wording cannot exclude involvement in clinical trials) – 10 million per any one claim <p>⁴ Please note that where private practices are conducting research activities these are not covered by the NHS indemnity scheme, even if those research activities are conducted on NHS premises. Private practices will need to provide evidence of their own cover.</p> <p>* Considerations</p> <ul style="list-style-type: none"> The indemnity requirements listed above relate to the clinical negligence aspects of patient care during a trial. The design and management of the trial require separate indemnity arrangements which are provided by the University of Leicester. These are captured by selecting the following within IRAS, For section A76-1 and A76-2, select 'other arrangements apply' and write 'University of Leicester Insurance Applies'. Where you are involving multiple different location types, select all the applicable answers within IRAS. 		

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5.3 Other useful insurance considerations

Private practice activities aren't protected by either the CNST or CNORIS, even if the activity being undertaken is carried out in an NHS hospital.

In most cases, GPs are independent practitioners who are contracted to provide NHS care. As such, in Scotland, they, and the staff employed by them, aren't covered by NHS indemnity (CNORIS) and the practice must bear responsibility for the acts and omissions of staff. However, Health Boards have the power to establish GP practices. In these cases, the GP practice would be covered by NHS indemnity. A list of all members of the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) is available [here](#).

6.0 Further Information

6.1 UoL Insurance Office

In the first instance, the RGO should be contacted for advice about insurance and indemnity requirements (rgosponsor@le.ac.uk). The RGO will facilitate and manage referrals to the UoL Insurance Office where further advice is needed.

6.2 UoL Insurance Broker

Under no circumstances should researchers contact the UoL Insurance Broker directly. All communication with the Brokers must be via the UoL Insurance Office.

7.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	5.0	<ul style="list-style-type: none">Administrative changes.Updates to wording in Introduction, scope and procedures section.Additional guidance added regarding the indemnity requirements at locations conducting research.Terminology changes e.g. reference to trial 'sites' changed to trial 'locations' and 'amendments' to 'modifications' as per UK CTR 2026 guidelines.Removal of insurance cover for non-substantive staff.Removal of Appendix 1 (flowchart).Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive

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