Clinical Directorate Clinical Research Governance Team

Standard Operating Procedure

Requirements for Insurance for University Sponsored researc

SOP030

Author	**Date of Approval**
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Approved on behalf of ratifying committee	**Date of Approval**
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Document Control

Issue Date	08/08/2023
Effective Date	9th August 2023
Review Date	8th August 2025
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Document History can be viewed on Q-Pulse

Review Process Prior to Sign Off

Name of Committee	**Date**
Clinical Trials Oversight Committee	10th January 2022
SPARK Sponsorship Committee	17th February 2022
Chair of SPARK Sponsorship Committee	8th August 2023

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1. Introduction

It is a requirement of the Medicines for Human Use (Clinical Trials) Regulations 2004 (Regulations) that all Sponsors have appropriate insurance and indemnity in place for the research. The Research Governance Framework Principle 13 also states that Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

NHS bodies are liable for clinical negligence and other negligent harm to individuals covered by their duty of care. Institutions employing researchers are liable for negligent harm caused by the design of studies which they initiate. Manufacturers have liability for faulty medicines.

2. Scope of Procedure

This procedure details the requirements for insurance for University Sponsored research, including automatic provision of cover, where research needs to be referred for review and how the University will decide if a study can be conducted "at risk".

3. Who

This SOP is aimed at Chief Investigators, students, trial coordinators and other members of University Staff involved in University Sponsored research.

This SOP is aimed at staff within the University Clinical Directorate who are involved in the oversight of University Sponsored research.

4. When

The SOP should be referred to when applying for University sponsorship or when completing any steps of the sponsorship approval process.

5. University of Liverpool Insurance Provision

The University holds Clinical Trials Insurance cover for research Sponsored by the University, unless research falls under the below referral categories. If research falls outside of the remit of requiring Sponsorship by the University (see POL001), or it is not Sponsored by the University, then it **must not** be assumed that the research has adequate insurance cover. Please refer to the University Insurance webpages for further advice.

5.1 Referral Categories

Certain types of research require referral to the insurers and extra insurance cover may need to be purchased. These are detailed below;

- Recruitment of participants in the following groups into interventional studies or observational studies involving the taking of tissue samples for research purposes;
    - Children under the age of 5

  - Pregnant Women

- First in Man CTIMPs
- Clinical Investigations of Medical Devices
- Research involving Cell Gene Therapy
- Therapies targeting blood, blood-brain barrier or cerebrospinal fluid
- Research involving Blood borne pathogens
- Research involving the use of Opioids
- Human Health related based Studies taking place at international sites

The allocated Sponsorship Officer will assess the need for referral when validating a Sponsorship application and liaise with the University Insurance Manager to assess insurance need. The allocated Sponsorship Officer will then feedback any requirements to the CI. It is likely that UK based research will be covered under the master policy, but Human Health related based Studies taking place at international sites usually require additional insurance to be purchased.

Investigators must be aware that they must meet the cost of any extra insurance cover required from their research grant or from Departmental funds. It is recommended that insurance requirements are assessed when submitting a research grant to ensure appropriate costs are included.

For investigators undertaking research at International sites Travel Insurance must also be gained from the Legal and Governance Department by completing the Record of Travel form located in TULIP.

6. Undertaking International Research “at risk”

As noted above the University Insurance Brokers may direct Human Health related based Studies taking place at international sites to purchase additional insurance cover. In certain circumstances the University may allow sponsored international research to proceed “at risk”, without purchasing additional insurance cover.

Once a referral has been made and quotes for additional cover obtained the CI may discuss with their Sponsorship Officer the wish to undertake research “at risk”.

6.1 Exclusions

There are certain automatic exclusions to research being able to be conducted at risk;

- Clinical trial of an investigational medicinal products, Clinical investigations of a medical device and Combined trials of an investigational medicinal product and an investigational medical device **must** purchase additional insurance cover if directed.

- If local regulations or ethics requirements dictate that specific insurance must be purchased, then additional insurance cover **must** be purchased as directed.

6.2 International Insurance Sponsor Risk Algorithm

FORM016 International Insurance Sponsor Risk Algorithm will be completed by the Senior Clinical Research Governance Manager, with attention paid to the type of Study, any Study Procedures, reason for Insurance referral, local requirements for Insurance and the quotes received. The funder and funding amount will also be detailed.

The algorithm will detail the risk level of the study - Low Risk Study, Medium risk Study or High-Risk Study.

If the algorithm details the study as being High Risk, then additional insurance cover **must** be purchased as directed.

If the algorithm details the study as being medium or low risk then the protocol, application form and algorithm will be provided to the Associate Pro-Vice-Chancellor for Clinical Research, Head of Clinical Operations, Chair of the SPARK Sponsorship Committee and the University Insurance Manager for review and final decision. The Associate Pro-Vice-Chancellor for Clinical Research will make the final decision.

The decision will be documented in the Sponsor file for the study and provided to the CI and research team (where appropriate).

7. Roles and Responsibilities

It is the responsibility of the responsible Sponsorship Officer to identify where a study requires referral to the Insurance Manager and ensure this is done.

It is the responsibility of the Senior Clinical Research Governance Manager or Sponsorship Manager (as deputy) to complete FORM016 in the event a study may need to proceed “at risk” without insurance. It is also their responsibility to provide the completed FORM016, and any supplementary documentation to Associate Pro-Vice-Chancellor for Clinical Research, Head of Clinical Operations, Chair of the SPARK Sponsorship Committee and the University Insurance Manager for review and final decision.

The responsible Sponsorship Officer will then provide the final decision to the Chief Investigator and study team

8. Associated Documents and References

POL001 Sponsorship of Research - Statement of Policy

FORM016 International Insurance Sponsor Risk Algorithm

UK Policy Framework for Health and Social Care Research - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/

The Medicines for Human Use (Clinical Trials) Regulations 2004 - https://www.legislation.gov.uk/uksi/2004/1031/contents/made

9. Training and Resources

CIs, students, trial coordinators and other members of University Staff involved in Sponsored research should be aware of and familiar with this SOP. Training can be provided by the Clinical Research Governance Team upon request.

10. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.