



UNIVERSITY OF
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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-1003 UoL

Sponsor Risk Assessment and Management of Research Sponsored by University of Leicester

Version 7.2, September 2023

Office Base

Research Governance Office
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Effective date: October 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 and Scope

This Standard Operating Procedure (SOP) describes the process by which all studies Sponsored by the University of Leicester (UoL) will be assessed for risk. It describes when a risk assessment is required and when it is not and describes the procedure for the completion of a Sponsor risk assessment.

The outcome is that the UoL has completed a comprehensive review of a research application, has identified appropriate actions to mitigate any identified risk(s), and this enables the UoL to provide an “in principle” decision to sponsor the study and to begin the Sponsor Green Light Process.

The Sponsor risk assessments are the Sponsor’s responsibility to assure itself that all risks are known and managed.

2.0 Sponsor Review and Risk Assessment

The Risk Assessment Decision Flowchart (Appendix 4) should be consulted to identify the type of review and/or risk assessment required for a study.

Sponsor application documentation required to commence the Sponsor Review and (where necessary) Risk Assessment, and to begin the Sponsor process are listed on the Sponsor Application Form which must be downloaded from the Research Governance webpages each time a new Sponsor application is submitted to ensure that the most up to date version of the Sponsor Application Form is used.

For applications to be valid, all relevant sections of the Sponsor Application Form must be completed, and all relevant study documents attached.

2.1 Risk Assessment

The Risk Assessment Form (Appendix 1), which includes the Risk Analysis Matrix Tool helps to assess the potential risk(s) associated with a specific study. It is expected that the Risk Assessment Form be completed by the Head of Research Governance, or their delegate, in communication with the Chief Investigator, research team members and service managers as appropriate.

The risk assessment is dependent on an understanding of risks associated with the study and the capabilities of UoL (e.g. a high risk study by an experienced research team may be addressed by routine management processes, whereas a low risk study by an inexperienced research team may require additional management actions to mitigate risk, etc.).

The risk assessment also depends on current circumstances in UoL at that particular time, for example, if key resources or staff are available or unavailable, when the study is expected to be delivered.

The risk assessment is intended to ensure that risks are identified and addressed in a proportionate way. It is not intended to be overly intrusive and is designed to identify quickly and at an early stage any additional safeguards required for the management of a study. The key output is a list of actions required to manage any identified risks, and ensure the efficient delivery of the study to time and target.

In cases of research requiring a Risk Assessment the process will be started by the Head of Research Governance or their delegate. In order to progress the Sponsor decision, a meeting between the Chief Investigator, members of the study team, and service managers as appropriate will be a mandatory requirement. The purpose of this face-to-face meeting will be to discuss the Risk Assessment in detail, and to talk through any mitigation plans. The meeting will be followed-up by email, and further discussions may be conducted via email or telephone.

2.2 Risk Assessment Form (Appendix 1)

The Risk Assessment Form considers the following areas of risk for UoL from the perspective of a research Sponsor:

- Risks associated with CTIMP/Intervention/Device
- Risks associated with the design and methods of the trial
- Risks to participants
- Risks to the reliability of the results
- Other risks

Each area has a set of specific questions. The answers will be subject to a likelihood, impact and residual risk score (see Appendices a, b and c of the Risk Assessment Form for definitions). Mitigation strategies should be documented to address all concerns identified. The risk assessment will be used to inform the monitoring plan in conjunction with the risk based Monitoring Strategy Table (Appendix 2 to SOP S-1007).

The Risk Assessment Form will be repeated as risk mitigation is completed, and will be revisited during the life cycle of the study if any material changes are made to the study documentation, staffing or operational circumstances. The Risk Assessment Form completion, review and revision record should be completed and the form should be saved using the format Year/Month/Day i.e. 2013/11/19. There may be multiple revisions to the form during the life cycle.

2.3 Sponsor Review

A Sponsor review is required for studies whether a Risk Assessment is required or not. The Sponsor Review Checklist (Appendix 2 Risk Assessed Studies and Appendix 3 Non-risk Assessed Studies) will be completed by the Head of Research Governance or delegate.

A Sponsor review document will be written and sent to the Chief Investigator via email, which will detail all comments, questions, points of clarification and changes required prior to confirmation of Sponsorship.

3.0 Overview by the Research Sponsorship & Management Operational Group (RSMOG) and the Research Sponsorship Committee (RSC)

An overview of each study received for Sponsor review is presented to the RSMOG at each bi-monthly meeting. Any study that has high risk scores or any issues identified during the initial risk assessment can be discussed at the RSMOG and RSC and to confirm any mitigation decisions.

In some cases, the decision of the Committees may be that the risk to the UoL as Sponsor is too high. In these cases, Sponsorship will be refused.

4.0 Indemnity


The University of Leicester will provide indemnity in accordance with SOP S-1017 UoL.

5.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Research Governance or their delegate	Completion of Risk Assessment form.
Sponsor	Head of Research Governance or their delegate	Refer studies identified as having high likelihood of risk scores to both RSMOG and RSC.
Sponsor and Chief Investigator	Head of Research Governance or their delegate and the Chief Investigator	Develop proportionate risk mitigation actions as appropriate.

6.0 Development and approval record for this document

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

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	28/09/2023

7.0 Review record

This table is used to track any changes made on revised/reviewed versions

Date	Issue number	Reviewed by	Description of changes (if any)
October 2013	2	Wendy Gamble	Version 1 revised to reflect changes to Risk Assessment Process.
April 2015	3	UoL RSMOG	SOP reviewed and revised to include amendments to the risk assessment tool to include PPI, study registration, archiving, data going outside of UK and process for anonymisation. Minor administrative changes to Logos, dates / footer. Addition of Loughborough University to front page
Feb 2016	4	D Delahooke & W Gamble	Risk Assessment form completely revised and sponsor checklists introduced.
Nov 2016	5	D Delahooke	Removal of reference to Research Governance Framework and re-ordered sections in line with UHL.
Nov 2017	6	Michelle Muessel	Reviewed, minor administrative changes, change of address. Addition of risk matrix tool.
July 2018	7	D Delahooke	Correction and streamlining of risk assessment form
Sept 2021	7.1	Cat Taylor	Administrative changes
September 2023	7.2	Cat Taylor	Administrative Changes Minor updates to wording Removal of monitoring and audit criteria