

**Sponsor Risk Assessment & Management for
Sponsored Research in UHL
Research & Innovation SOP S-1003**

University Hospitals of Leicester 
NHS Trust

Trust Ref C9/2012

1. Introduction

This Standard Operating Procedure (SOP) describes the process that University Hospitals of Leicester NHS Trust Research and Innovation (UHL R&I) will follow when completing a Sponsor review for research. In addition, it describes when a Risk Assessment is required and also when it is not.

The outcome will be that UHL R&I have completed a comprehensive review of each research application, have identified appropriate actions to mitigate any identified risks, which enables UHL to provide an 'in principle' decision to sponsor the Study and for the Sponsor Green Light Process to begin.

2. Scope

This SOP applies to all staff and any external individual who approach UHL to request that the organisation acts as sponsor for research activity.

3. Sponsor Review and Risk Assessment

A formal process of risk assessment is not required for every study. A Risk Assessment Decisions Flow Chart (Appendix 4) is provided to show when a risk assessment may be needed.

In order for a Sponsor review to take place, a complete application should be provided to the R&I Office. The required documents and formats are detailed in SOP S-1002 UHL.

It should be noted that an incomplete application will delay the commencement of a Risk Assessment or Sponsor Review.

3.1

A Risk Assessment will use the UHL Risk Analysis Matrix Tool (Appendix 1) which can also be found in the Policy for Risk Assessment. The tool helps to assess the potential risks associated with a specific research application. It is expected that the Risk Assessment will be completed by the Head of Research Operations, or their delegate, in communication with the Chief Investigator, research team members and service managers as appropriate. N.B. with effect from October 2017 the Risk Assessment is completed within attributes / workflows in EDGE. The previous Risk Assessment Form Appendix 2 is appended to this SOP indicating the locations of relevant information within the EDGE system and should be used as a reference guide.

The assessment is dependent on an understanding of risks associated with the study and the capabilities of UHL 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.

The assessment also depends on circumstances at the time, for example, if key resources or staff are available or unavailable when the study is expected to be delivered. It is therefore a 'live' document and should be reviewed on a regular basis.

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 but 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 efficient delivery of the research to time and target.

In addition, the comprehensive Risk Assessment will assist with the HRA requirements for Assess, Arrange & Confirm, and will provide additional information for feasibility.

Where research requires a Risk Assessment, the process will be started by the Head of Research Operations 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.

3.1.1

The Risk Assessment considers the following topic areas of risk from the perspective of a research Sponsor and is provided as a guide. The list is not exhaustive:

- CTIMP
- Device
- Participants' rights and safety
- Facilities, equipment and resources
- Study design and reliability of results
- Documentation, governance and compliance
- Finance
- Available staff

Each topic area has a set of specific questions. The answers will be subject to a Risk score. 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 trial risk based monitoring guidelines table which can be found at Appendix 2 to SOP S-1007 UHL.

The Risk Assessment will be repeated as risk mitigation is completed and will be revisited during the life cycle of the trial if any material changes are made to the study documentation, staffing or operational circumstances. The Risk Assessment completion, review and revision record will be completed within EDGE.

3.2 Management of Risk

Following completion of the Risk Assessment and initial meeting to discuss mitigation of risks, a research study with any specific area with a remaining risk total of 6 or more will be referred to the R&I Management Group for review and further discussion and confirmation of sponsorship.

Research studies with a remaining risk assessment of 12 or more will be referred to both the R&I Management Group and the R&I Executive Committee in addition to Clinical Management Group meetings, as appropriate, for discussion and confirmation of mitigation decisions, further discussion and confirmation of sponsorship.

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

The Risk Assessment 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. Confirmation that this has happened will be recorded on EDGE using SPONSOR 26 or 27 Workflows (as appropriate).

3.3 Sponsor Review

A sponsor review is required for studies whether a Risk Assessment is required or not. A sponsor review will be carried out using attributes / workflows within EDGE. Previously, the sponsor review documentation would have been completed. This is now appended as reference documents to aid location of relevant information within the EDGE database – Appendix 5 – Sponsor review for Risk Assessed Studies Checklist EDGE locations and Appendix 6 – Sponsor review for NON Risk Assessed Studies Checklist EDGE locations.

3.4 Multi Centre studies

The multi centre checklist (appendix 7) will be completed for every study to inform the delegation of responsibilities where UHL is the sponsor of a multi-center study. (EG: CTU)

A collation of the Sponsor review will be system generated through EDGE into either EXCEL or Word and sent to the Chief Investigator using email. The document will detail all comments, questions, points of clarification and changes required prior to confirmation of sponsorship. Full response to all queries must be received prior to confirmation being provided and authorisation to submit given.

4. Responsibilities

Complete Study Risk Assessment Form

	Responsibility	Undertaken by	Activity
1	UHL R&I Office	Head of Research Operations or their Delegate	Commence completion of Risk Assessment within EDGE
2	UHL R&I Office	Head of Research Operations or their Delegate	Refer studies with specific area risks $\neq$ >6 to R&I Management Group and $\neq$ > 12 to the R&I executive Committee/CMG Committees as appropriate
3	UHL R&I Office & Chief Investigator	Head of Research Operations or their Delegate & Chief Investigator	Develop proportionate risk mitigation actions as appropriate.

5. Legal Liability Statement

Guidelines or procedures issued and approved by UHL are considered to represent best practice. Staff may only exceptionally depart from any relevant UHL guidelines or procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional, it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

6. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

7. Guideline Standards and Procedure

Additional flowchart provided in SOP S-1003: Appendix 4.

8. Education and Training

None

9. Monitoring Compliance

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate Risk Assessment	Included in the monitoring / audit programme.	Random audits / monitoring conducted according to Risk profile of research activity.	Head of Research Operations

10. Supporting Documents and Key References

SOP S-1003 Appendices 1, 2, 4, 5, 6 & 7

SOP S-1002

SOP S-1007

11. Key Words

Research, Innovation, EDGE, Sponsor, Green Light, Risk Assessment, Multi centre

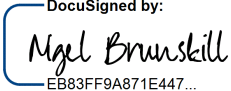
12. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	Executive Lead Medical director
Details of Changes made during review: Review and update	

13.

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Author / Lead Officer:	Carolyn Maloney		Job Title: Head of Research Operations
Reviewed by:	UHL R&I Governance Meeting		
Approved by:	Professor Nigel Brunskill 		Date Approved: 07-10-2021
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Date	Issue Number	Reviewed By	Description Of Changes (If Any)
December 2013	V3	R&D Management Group.	Revised content to reflect changes to Risk Assessment Process.
March 2015	V4	R&I Management Group	Revisions to Logo. Amended sections for the Risk Assessment Tool.
November 2016	V5	CM, LW, JJ	Adding Assess, Arrange, Confirm assurance for HRA as part of Risk Assessment process.
March 2017	V6	CM	Update to Logo
December 2017	V7	CM	Revision to process incorporating EDGE. Removal of Appendices 2, 5 & 6.
September 2018	V8	CCL	Updated R&I logo
March 2020	V9	CM/LW	Revision of wording
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