UNIVERSITY OF LEICESTER, UNIVERSITY OF LOUGHBOROUGH & UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1003 UoL

Version 5, November 2016

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

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Effective Date: April 2017
1. Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office within University of Leicester (UoL) when completing a Sponsor review and, where required, a Sponsor risk assessment and corresponding mitigation plan, prior to completing the Sponsor Green Light Process.

The outcome is that the Research Governance Office has completed a comprehensive review of a research application and has identified appropriate actions to mitigate any identified risks, which enables the UoL to provide an “in principle” decision to sponsor the Study.

2. Scope

This SOP applies to all staff, and any external individual who approach the UoL to request that the organisation act as Sponsor for research activity.

3. Sponsor Review and Risk Assessment

The Risk Assessment decision flow chart (Appendix 4) should be consulted to identify the type of review and/or risk assessment required for this study.

Sponsor application documentation required to commence a Sponsor Review and Risk Assessment, and to begin the Sponsor process are listed on the Sponsor Green Light Review Process Flowchart which is available via the UoL Research Governance Pages on the College of Medicine, Biological Sciences and Psychology website.

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

3.1 Risk Assessment

The Risk Assessment Form, (Appendix 1) helps to assess the potential risks associated with a specific research application. It is expected that the Risk Assessment Form be completed by the Research Governance Manager, or their delegate, in communication with the Chief Investigator, research team members and service managers as appropriate.

The 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 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 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 Form will assist with the HRA requirements for Assess, Arrange & Confirm, and will provide a great deal of information required in place of a feasibility for a Single Centre study at UHL.

In cases of research requiring a Risk Assessment the process will be started by the Research Governance Manager 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.

3.2 Risk Assessment Form (Appendix 1)

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

- CTIMP
- Device
- Participants rights and safety
- Facilities, Equipment and Resources
- Study Design and Reliability of Results
- Documentation, Governance and Compliance

Each area has a set of specific questions. The answers will be subject to a likelihood (Low, Medium and High) 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 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 trial 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.

3.2 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 Research Governance Manager 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.

4. 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 likelihood 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.

5. Indemnity

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

6. Responsibilities

Complete Study Risk Assessment Form:

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<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
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<tr>
<td>1 Sponsor</td>
<td>Research Governance Manager or their Delegate</td>
<td>Commence completion of Risk Assessment Form</td>
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<tr>
<td>2 Sponsor</td>
<td>Research Governance Manager or their Delegate</td>
<td>Refer studies with specific identified high risk to both RSMOG and the RSC.</td>
</tr>
<tr>
<td>3 Sponsor &amp; Chief Investigator</td>
<td>Research Governance Manager or their Delegate &amp; Chief Investigator</td>
<td>Develop proportionate risk mitigation actions as appropriate.</td>
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7. Monitoring and Audit Criteria

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<th>Key Performance Indicator</th>
<th>Method of Assessment</th>
<th>Frequency</th>
<th>Lead</th>
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<tr>
<td>All research sponsored by UoL has appropriate Risk Assessment</td>
<td>Included in the monitoring / audit programme.</td>
<td>Random audits / monitoring conducted on 10% of research activity.</td>
<td>Research Governance Manager or their Delegate</td>
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This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

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