



**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-1002 UoL**

Version 5, January 2018

**Initial Documentation Review Process for Research Sponsored by
University of Leicester**

OFFICE BASE

Research Governance Office
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Effective Date: April 2018

1. Introduction

This Standard Operating Procedure (SOP) describes the process that the University of Leicester (UoL) Research Governance Office will follow when conducting initial research documentation reviews prior to confirmation that the UoL will act as the Sponsoring Organisation.

The review will ensure that:

- documentation has been reviewed to ensure that the UoL is able to deliver the study with or without external support
- an appropriate Peer /Scientific Review has been conducted
- a study has adequate funding

The outcome is that UoL as a Sponsor has ensured that there are robust study documentation & management processes in place.

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. Document Management

It is expected that as a minimum, study documentation will consist of the following:

- a) Completed UoL Sponsor Application Form ([Appendix 1](#))
- b) Protocol – it is recommended that the HRA protocol templates are utilised as appropriate to the study. The researchers own template may be used but it is recommended that it is checked against the HRA examples to ensure it captures all the relevant elements. Please see [SOP S-1027](#) for further information.
- c) Full Data Set from the [Integrated Research Application System](#) (IRAS)
- d) [Participant documentation](#) which may include Informed Consent Forms (ICF), Participant Information Sheets/Leaflets (PIS), Letters of Invitation, Letter to GP etc
- e) Study recruitment aids i.e. Posters, Advertisement text etc
- f) Evidence of [Peer Review](#) as relevant to nature of study
- g) Evidence of costing and confirmation of adequate funding available for the duration of the study
- h) Investigator Brochure or Summary of Product Characteristics (where relevant)
- i) Signed and dated copy of the Chief Investigator CV & copy of relevant training Certificate

3.1 Completed Sponsor Application Form

The UoL Sponsor Application Form ([Appendix 1](#)) must be completed and submitted as part of the required documents when requesting that the UoL act as Sponsor for a research study. The form asks for information that will be used by the UoL to inform the Sponsor Risk Assessment.

3.2 Protocol

The UoL expect that the Protocol include every aspect of the proposed study. It should be regarded as the 'manual'. A Protocol template is available from the [College Research Governance web pages](#). With effect from 1st January 2017 where a protocol template has been published on the HRA website, there is an expectation that this will be used to develop a study Protocol instead. The researchers own template may be used but it is essential that it is checked against these examples to ensure that they capture all the relevant elements.

3.3 Full Dataset IRAS

The Integrated Research Application System requires information about the study and should be completed once a final protocol as been agreed by the Chief Investigator (CI) and study collaborators as appropriate. The information in the IRAS forms must be consistent with the Protocol and all other study documentation. The Full Data Set must be submitted for the Sponsor review, as this includes all parts of the form. Please note that every question must be answered as appropriate to the study, and references such as 'see above' must be avoided as when the form splits for submission to the various regulatory agencies some information may be lost.

Please be aware that some questions ask for information about the study in language which can be understood by a 'lay' person. In addition, it is recommended that you do not simply copy and paste the protocol into the IRAS form.

Guidance on specific questions can be found within the IRAS form and it is recommended that researchers take the time to read the FAQs and Question Specific Advice available within IRAS.

3.4 Participant Information Documentation

It is imperative that participants are fully informed about their involvement within the study. Revisions to participant documentation are the most frequent request of Research Ethics Committees. A template for PIS & ICF is available on the HRA website (<http://www.hra-decisiontools.org.uk/consent/>) Both the UoL and the HRA strongly recommend that researchers use these examples.

It is particularly important that participants give express permission for each aspect of the research. This may include storage of their data or tissues outside of the NHS organisation that provides their care. Permission must also be sought to allow the Sponsor to access their medical notes and research data as part of the monitoring and audit process. Wording for these aspects is suggested on the templates. It is expected from 1st January 2017 that this wording is incorporated into all consents forms to be used in research sponsored by UoL.

All participant documentation must be reviewed by the Sponsor as part of the Sponsor Risk Assessment ([SOP S-1003 UoL](#)) and Green Light Process [SOP S-1025 UoL](#)).

3.5 Study recruitment aids

Any literature, or scripts that are proposed to increase awareness of a research study must be reviewed as part of the Sponsor review process. This will also be required for submission to the Ethics Committee. Generic posters and general awareness, informing that specific departments conduct research, do not necessarily require individual approval, but when referring to a specific study or a number of studies formal approval is required. This includes when adding information on websites and utilizing social media as a method of recruitment.

It is recommended that advice is sought from the Press Office at the UoL. They may be able to assist you with design, wording or signpost you appropriately. They will also be able to advise on the appropriate use of Social media to raise awareness of your study.

3.6 Peer Review

All research protocols require appropriate Peer Review (also referred to as “scientific quality review”, “independent scientific review” or “independent review”).

It is one of the responsibilities of a “Research Sponsor” to ensure that:

An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money.

Peer Review is the assessment of a research protocol by “reviewers” who are experts in the relevant field of study or discipline. Reviewers are able to offer independent advice on the scientific validity of the study.

The Peer Review process ensures the methodology employed in a research study will produce robust and credible results. It is expected that the reviewer is independent from the research team and that they should not have had any input into the design, supervision, collaboration, recruitment, conduct and subsequent analysis of the research study.

It is the responsibility of UoL to ensure that an appropriate Peer Review has been undertaken. In certain instances it may be necessary for UoL to arrange Peer Review when it has not already occurred as part of a competitive funding process.

NIHR Portfolio studies that have been peer reviewed as part of the funding application process will not require a further review. However, it is important to recognise that this only applies where individual funding applications are similar to the final individual study protocol. Where multiple studies are being generated from a Programme Award, or where student research is being submitted to the NIHR for adoption, the NIHR Peer Review guidelines must be followed.

Where the proposed research has not been subject to rigorous external review, or in the case of a student project not being submitted to the NIHR for adoption, or review by an academic supervisor, the Chief Investigator may arrange for an appropriately qualified person to conduct the Peer Review on behalf of the UoL Research Governance Office. A copy of the Peer Review form is attached as [Appendix 2](#). The form must be completed and submitted along with the other documents required for sponsor review.

Where the UoL Research Governance Office is arranging the peer review, the College Peer Review process will be followed.

The aim is to conduct the internal peer review process as quickly as possible, after the identification of the need for such review, to ensure that all studies reach the ethics and regulatory system without undue delay.

If a researcher does not accept the comments within a Peer Review, it can be escalated to their Head of Department and the UoL Research Sponsorship and Management Group for further discussion on a case by case basis.

Peer review must be undertaken before confirmation of Sponsorship is agreed and before submission to the main REC/HRA and MHRA if required.

Details of the peer review must be documented for the Trial Master File & Sponsor file.

3.7 Evidence of costing & funding

Every research study must provide evidence of adequate funding provision for the duration of the study. Where a study is long term, an undertaking to ensure that adequate funds will be identified during the course of the research is expected. In cases where adequate funding is not forthcoming for future years, it will be expected that the University department will underwrite the study to ensure completion. In these cases a discussion to agree provision of funding in subsequent years will form part of the Sponsor Risk Assessment ([SOP S-1003 UoL](#)) and Green Light Process ([SOP S-1025 UoL](#)).

Evidence of costing must be provided. In most cases this should be through the Lucre system. In some cases, the Lucre costing will not be available, and individual confirmation of available funds must be given by the Investigator and a cost code provided for verification, in accordance with the Sponsor Finance Process [SOP S-1040 UoL](#). Where whole or part of the study is funded by the investigator's department, written confirmation of funds in a named account for the duration of the study must be given.

3.8 Investigator Brochure (IB) / Summary of Product Characteristics (SPC)

All Protocols of research using Investigational Medicinal Products & / or Non CE Marked Devices (if applicable) must be accompanied by either an Investigator Brochure (IB) or a Summary of Product Characteristics (SPC). Details of when these are required and an IB Template can be found in [SOP S-1023 UoL](#). Copies of the IB / SPC will be forwarded to Pharmacy / Medical Physics for review.

3.9 Chief Investigator CV and appropriate training Certificate

A signed and dated copy of an up-to-date summary CV from the Chief Investigator and valid relevant training Certificate must be provided.

4. Initial Sponsor Documentation Review

On receipt of a valid application, the Research Governance Manager or their delegate will commence a documentation review using the Sponsor Risk Assessment Form and/or relevant Sponsor Review Checklist and Sponsor Green Light Process as documented in [SOP S-1003 UoL](#).

An application will be deemed as 'valid' only when all documentation for the study has been received. An email will be sent to the CI or Point of Contact for the study to confirm that the application is valid.

The Initial Sponsor documentation review may take up to 14 calendar days.

During peak times or where numerous studies requiring risk assessment have been submitted, it may take longer to conduct the sponsor review and every effort will be made to conduct the initial review within 21 days.

Where appropriate and in accordance with [SOP S-1003 UoL](#), a meeting to discuss the initial documentation review will be arranged with the CI and relevant members of the study team.

Comments on the documentation and any additional questions generated by the Sponsor Risk Assessment Form and/or Sponsor Review Checklist will be sent to the CI, and where relevant the study team, for comment and document revision as appropriate.

A response to each question, revised documentation and any points of clarification will be required before a further review is conducted by the Research Governance Office. Only when all queries, required amendments, and points of clarification have been satisfied will the UoL confirm Sponsorship “in Principle” thereby giving authorisation to the CI to progress applications to Regulatory Agencies e.g. MHRA, HRA, REC, NHS Trusts etc.

Sponsorship will remain ‘in principle’ only until all relevant external permissions have been received. The Sponsorship will be confirmed when the study team receive confirmation of the Sponsor Green Light.

It should be noted that only the Research Governance Manager, and on their authority, the Research Governance Officer at the UoL has the authority to sign the IRAS form on behalf of the Sponsor.

5. Responsibilities

| Number | Responsibility | Undertaken by | Activity |
|--------|--------------------|---|---|
| 1 | Sponsor | Research Governance Manager or their Delegate | Confirm study documentation is valid and commence initial documentation review in accordance with SOP S-1003 UoL |
| 2 | Sponsor | Research Governance Manager or their Delegate | Communicate findings of the initial documentation review with the CI/Research Team |
| 3 | Chief Investigator | Chief Investigator or their Delegate | Respond to communication of findings from the initial documentation review. Amend documentation as required and return to Research Governance Office. |
| 4 | Sponsor | Research Governance Manager or their Delegate | Conduct re-review of documentation and points of clarification. Confirming in principle Sponsor decision when appropriate |

6. Monitoring and Audit Criteria

| Key Performance Indicator | Method of Assessment | Frequency | Lead |
|---|---|---|---|
| All research sponsored by UoL has appropriate Peer Review | Included in the monitoring / audit programme. | Random audits / monitoring conducted on risk-based assessment of research activity. | Research Governance Manager or their Delegate |

7. Further information

- 7.1 [Sponsor Application Form – Appendix 1](#)
- 7.2 [Peer Review Form – Appendix 2](#)
- 7.3 [Protocol Template](#)
- 7.4 [PIS /ICF Template](#)
- 7.5 [Research Governance Framework](#)

8. Development and approval Record for this document

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

| | |
|-------------------------------|--|
| Author / Lead Officer: | Wendy Gamble |
| Job Title: | Research Governance Manager |
| Reviewed by: | UoL Research Management and Operations Group (RSMOG) |
| Approved by: | Professor Nigel Brunskill  |
| Date Approved | 16/04/2018 |

9. Review Record

| Date | Issue Number | Reviewed By | Description Of Changes (If Any) |
|------------|--------------|------------------|--|
| Oct 2013 | 2 | Wendy Gamble | Supersedes S-1002 UoL Sponsor review process SOP. Document revised and renamed following review of sponsor processes. |
| April 2015 | 3 | UoL RSMOG | SOP reviewed and revised. Changes to Logos. Additions to section 3, added sections 3.8 and 3.9. Addition to 3.5 to include use of social media. Addition to 3.6 to clarify need for peer review for student projects applying for adoption onto NIHR portfolio. Minor administrative changes to appendix references and dates / footer. Addition of Loughborough University to front page. |
| Oct 2016 | 4 | Diane Delahooke | Update logos, reference to the HRA templates and Sponsor review checklist added. Text added in 3.7 to confirm funds available to studies funded in whole or part by dept. |
| Jan 2018 | 5 | Michelle Muessel | Reviewed, updated address and added device information. |

10. Distribution Record

| Date | Name | Department | Received |
|------|------|------------|----------|
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