LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1002 LU

Initial Documentation Review Process for NHS Research Sponsored by Loughborough University

Effective Date: October 2015

1.0 Introduction

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

The review will ensure:

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

The outcome is that LU as a Sponsor has ensured that there is robust study documentation and management process in place.

2.0 Scope

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

3.0 Document Management

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

a) Completed LU Sponsor Application Form (Appendix A)

b) Protocol – See SOP-1027 LU. A protocol template can be found on the Ethics Approvals (Human Participants) Sub-Committee website.

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

3.1 Completed Sponsor Application Form

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

3.2 Protocol

LU expects that the Protocol include every aspect of the proposed study. It should be regarded as the 'manual'. A Protocol template is available from the Ethics Approvals (Human Participants) Sub-Committee web pages, and it is recommended that this document is used to develop a study Protocol. As a minimum it should be used as a reference tool, in order to ensure that all aspects of a protocol have been considered.

3.3 Full Data Set IRAS

The Integrated Research Application System requires information about the study and should be completed once a final protocol has 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 is the most frequent request of

Research Ethics Committees. A template for PIS & ICF is available on the HRA web pages (http://www.hra-decisiontools.org.uk/consent/examples.html) and it is recommended that researchers use these.

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.

All Participant documentation must be reviewed by the Sponsor as part of the Sponsor Risk Assessment and Approval Process.

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 NHS Research Ethics Committee (REC). 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 adding information on websites and utilizing social media as a method of recruitment.

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” as defined in the Research Governance Framework (RGF) Version 2 (2005) 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 LU to ensure that an appropriate Peer Review has been undertaken. The Research Office will arrange for Peer Review to take place.

A copy of the Peer Review form is attached as Appendix B. The form must be completed by the Reviewer and submitted to the Research Governance Officer.

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 initially to their Dean of School and then, if unresolved, to the Ethics Approvals (Human Participants) Sub-Committee and/or Loughborough University Ethics Committee 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 if required.

Details of the peer review must be documented for the 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 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 School 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 and Approval Process.

Evidence of costing must be provided. In most cases this should be through the Agresso system and RX2.

4.0 Initial Sponsor Documentation Review

On receipt of a valid application, the Research Governance Officer will commence a documentation review using the Sponsor Risk Assessment Form and Sponsor Approval Process as documented in SOP-1003 LU.

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. Where appropriate and in accordance with SOP-1003 LU, 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 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 Officer. Only when all queries, required amendments, and points of clarification have been satisfied will LU confirm Sponsorship “in Principle” thereby giving authorisation to the CI to progress applications to Regulatory Agencies e.g. 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 approval.

It should be noted that only the Director of the Research Office at LU has the authority to sign the IRAS form on behalf of the Sponsor.

5.0 Responsibilities

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

6.0 Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by LU has appropriate Peer Review	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Officer or their Delegate

7.0 Further information

7.1 Sponsor Application Form – Appendix A
7.2 Peer Review Form – Appendix B
7.3 Protocol Template
7.4 PIS /ICF Template
7.5 Research Governance Framework
7.6 Peer Review Process

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Jackie Green	**Job Title:** Research Governance Officer
Approved by:	Ethics Committee	**Date Approved: 23/10/15**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

APPENDIX A

Research Sponsorship Application for Projects Requiring Approval by NHS Ethics Committee and Involving Research on Human Subjects, their tissues, organs or data, by Staff and/or Students of Loughborough University

The project must not commence until insurance, ethics approval and sponsorship are obtained

PART A - PLEASE COMPLETE ALL QUESTIONS

1. Title of Study:

Start date: (dd/MM/yyyy) End date: (dd/MM/yyyy)

2. **Researcher's Details**

Title: Mr/Mrs/Miss/Ms/Professor/Dr Name

School:

Department:

Address:

Tel: Email

3. Are student researchers involved with this project? Yes ☐ No ☐

4. Is the study based solely on questionnaires, or other research **not** involving invasive techniques or medicinal products? Yes ☐ No ☐

Please estimate numbers of volunteers participating in the study:

	Adults	Minors *
Patients		
Healthy human volunteers		

* Minors under 18 years of age

5. Is this a Multi Centre Trial? Yes ☐ No ☐

If yes and the trial is to be sponsored by LU or managed by LU, please estimate numbers of volunteers participating in the study overall:

	Adults	Minors
Patients		
Healthy human volunteers		

6. Does the study involve invasive techniques? Yes ☐ No ☐

7. Does the study involve the use of a medicinal product or the testing of a medical device? Yes ☐ No ☐

IF AN INVESTIGATIVE MEDICINAL PRODUCT IS INVOLVED

Please indicate which phase category the study falls into Phase 1, 2, 3, 4

8. Who is the Funder?

Will any part of this study take place outside the UK? Yes ☐ No ☐

If Yes, in which country(ies)?

PART B - PLEASE COMPLETE QUESTIONS AS APPLICABLE

9.

For Student projects Student status: UG/PGT/PGR

Supervisor's Details

Title: Mr/Mrs/Miss/Ms/Professor/Dr Name:

School

Department

Address:

Tel: Email

10.

For multi site studies

How many sites are involved?

Is University the lead site?

Are any sites outside the UK?

Are contracts/site agreements in place?

11.

For studies involving the NHS Patients, staff or resources

Is the study approved by an NHS Trust R+D office? Yes ☐ No ☐ Pending ☐

Is the study approved by an NHS ethics committee? Yes ☐ No ☐ Pending ☐

12.

For studies using tissue samples

Are the tissue samples accessed via a licensed tissue bank? Yes ☐ No ☐

Are you seeking ethical approval for your study? Yes ☐ No ☐

13.

For all studies, will the Applicant be responsible for:

Reporting amendments to the protocol Yes ☐ No ☐

Reporting adverse events and significant developments Yes ☐ No ☐

If No, who will be responsible?

Please send this form with all other supporting documents to:

Research Governance Officer
Research Office
Loughborough University
Loughborough
Leics LE11 3TU

e-mail researchpolicy@lboro.ac.uk

APPENDIX B

SPONSOR PEER REVIEW FORM FOR NHS IRAS APPLICATIONS

Thank you for agreeing to undertake a peer review of this project, please ensure ALL sections are completed.

Chief Investigator: **Project Title:**

1. Does the project have a clear hypothesis or study objective?

☐ YES – satisfactory ☐ NO – requires improvement (please comment below)

2. Does the background information adequately justify the study?

☐ YES – satisfactory ☐ NO –please comment below

3. Is the proposed sample size sufficient to answer the research question?

☐ YES ☐ NO – please explain below

4. Is the methodology appropriate for the project?

☐ YES ☐ NO – please suggest improvements below

5. Is the clinical/biological significance clearly explained?

☐ YES ☐ NO –please comment below

6. Given the current proposal, is the study feasible and achievable (able to answer the research question)

☐ Very likely
☐ Probably – please explain concerns below
☐ Not likely – please offer advice below

7. If there are any other comments you wish to make about the study please use the space below.

8. Declaration

I declare that I have not been involved in the design of this study, am not part of the study team, have read and reviewed the study proposal/protocol and that I have no conflict of interest in acting as a referee.

Signature: ……. Date: …….

Print Name: ……..

Post held: ……..

Contact Address: …….

……

Contact details:

Telephone: ……..……..

Email: ……

Please return this review to the Secretary of the Ethics Approvals (Human Participants) Sub-Committee.