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| **SOP001 LJMU Research Sponsorship Application Process** |
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| **Relevant to:** | All staff and students conducting research |
| **Approved by:**  |  |
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| **RELEVANT DOCUMENTS** |
|  |
| **RELATED POLICIES & DOCUMENTS** |
| *Governance handbook for LJMU sponsored research**LJMU Sponsorship of research SOPs (numbers 1-10)* |

This SOP needs to be a useful resource for investigators –please contact sponsor@ljmu.ac.uk with any suggestions for improvements.

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# Introduction

This document significantly replicates the procedures produced by the University of Liverpool, with changes made to encompass LJMU requirements. This is to facilitate research governance procedures in collaboration with the Liverpool Health Partners.

This SOP applies to researchers undertaking, or planning to undertake, healthcare based research undertaken at overseas research sites and health and social care research that is within the responsibility of the HRA or the Devolved Administrations’ Health Departments. This includes:

* research concerned with the protection and promotion of public health;
* research undertaken in or by a UK Health Department, its non- Departmental public bodies or the NHS and social care providers; and
* clinical and non-clinical research, research undertaken by NHS or social care staff using the resources of health and social care providers and any research undertaken within the health and social care

The [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) requires that all research projects must have a sponsor identified and declared prior to the commencement of the project. LJMU also requires that all healthcare based research undertaken at overseas research sites are formally sponsored. If you are unsure as to whether your research requires a Sponsor please contact LJMU REG as soon as possible.

The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. The sponsor is responsible for ensuring that the proposed research respects the dignity, rights, safety and wellbeing of participants. LJMU, as Sponsor, will usually delegate functions related to Sponsor responsibilities to the Chief Investigator while maintaining oversight of all responsibilities. For non-CTIMPs delegated functions to the Chief Investigator will be made via the Sponsorship Approval letter.

This standard operating procedure (SOP) has been produced in accordance with the UK Policy Framework for Health and Social Care Research.

# Scope of Procedure

The purpose of the SOP is to detail the process of the Liverpool John Moores University (LJMU) sponsorship application and approval process. For the purpose of this SOP, any reference to research does not include studies defined as Clinical Trials of an Investigational Medicinal Product (CTIMP). Once established, LJMU sponsorship of a CTIMP will follow procedures for CTIMPs published by the Liverpool Health Partners or by LJMU REG.

# Procedure

## Who

The SOP is applicable to members of LJMU Research Ethics and Governance (REG) who are involved in the sponsorship approval process, to Chief Investigators (CIs) and to research teams applying for LJMU research sponsorship.

## When

The SOP should be referred to when applying for LJMU sponsorship or when completing any steps of the sponsorship approval process.

# Identifying a Research Sponsor

The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research. Any organisation that is a legal entity and which funds, initiates, hosts or employs staff involved in research may act as sponsor. While there is no official rule against individuals acting as sponsors, LJMU will not allow individuals to be the sponsor of a piece of research. The sponsor will usually be:

* The CI’s employing organisation;
* LJMU, for student research projects where the Chief Investigator is a LJMU employee;
* The lead organisation providing health or social care to participants (e.g. NHS Trusts); or
* The primary funder (especially for commercial funders).

LJMU is willing and able to act as a sponsor under the UK Policy Framework for Health and Social Care Research and the Regulations. LJMU will consider accepting sponsorship for the following:

* Research being undertaken by employees of LJMU
* LJMU Student research projects where the Chief Investigator is a LJMU employee
* Healthcare related studies being carried out at international sites by LJMU employees.

# Arrangements for Co-Sponsorship

It may be that the most appropriate Sponsorship arrangement for a study is co-sponsorship with an NHS Trust. This is most likely to be the Lead NHS Trust for the study. Situations where this may occur include;

* + Where co-sponsorship is specifically requested from the Lead NHS Trust
	+ Where the CI is not substantively employed by LJMU

Once this arrangement has been confirmed by LJMU and Co-Sponsor the LJMU REG will begin to draft the Division of Responsibilities which forms an integral part of the Co-Sponsorship Agreement. This will be done in liaison with the NHS Trust and the core study team.

# Development of the research protocol

At the initial planning of the protocol development phase, the CI should refer to and complete the following:

For reference

* + [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)
	+ Governance Handbook for LJMU Sponsored Research
	+ SOP001 LJMU Research Sponsorship Application Process
	+ SOP002 Completing an IRAS Application for LJMU Sponsored Research
	+ SOP003 Roles & Responsibilities for LJMU Sponsored Research
	+ SOP005 Version Control for LJMU Sponsored Research
	+ SOP006 Study Master File for LJMU Sponsored Research

To be completed as required

* + [LJMU Research Ethics Training](https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-ethics/research-ethics-training) (mandatory for students)
	+ FORM008 IRAS Application Checklist for LJMU Sponsored Research
	+ FORM001 Chief Investigator Internal Agreement for LJMU Sponsored Research
	+ TEM001 Research Protocol Template for IRAS Application
	+ TEM002 Peer Review Assessment Form for LJMU Sponsored Research
	+ TEM003 LJMU Participant Information Sheet Template for HRA Approved Research
	+ FORM004 NHS Research Cost form for LJMU Sponsored Research

The CI should develop the protocol using the Template TEM001 Research Protocol Template for IRAS Application and send to all relevant reviewers for peer review as required. The CI should revise the draft protocol in response and send back for peer review as required. This process should be repeated as necessary. In addition, the CI must ensure that

* the research will be covered by LJMU insurance – which may require the CI to make arrangements.
* the research will be adequately costed and funded
* participant facing documents follow LJMU and HRA guidelines

## Scientific Review

Scientific review of a research proposal is important to provide judgement on the value or harm to all parties involved. It can do this by providing detailed knowledge of the subject area, an assessment of the feasibility of the project, an understanding of what is normal care and how research will impact on this and an assessment of the risks from someone with knowledge of the field. Scientific review includes peer review and systematic review of existing research evidence.

LJMU is committed to ensuring that every research proposal must be of the highest standard, and so as part of the sponsorship review process every research protocol must be subjected to review by experts in the relevant fields able to offer independent advice on its quality.

Peer review is a system where a research proposal or protocol is scrutinised by independent experts to promote quality research and prevent poorly designed research from taking place.

LJMU REG will require confirmation of peer review either in the form of a completed proforma or formal reports from funders. LJMU REG will advise if further peer review is required. It is noted that the peer review must be specific to the proposed study and peer review of generic funding applications, or programme grants may not be accepted. If the peer review calls for alterations to be made to the study and its design the Chief Investigator must provide evidence these suggestions have been incorporated, or justifications for the non-inclusion. It should also be noted that where a commercial funder has undertaken peer review further independent peer review may be requested.

Peer review may be commensurate with the minimum requirements dependent on the study type and relative risk. The Chief Investigator is responsible for satisfying themselves that the research proposal has been submitted for appropriate peer review and revised in light of that review. The Sponsor has overall responsibility for ensuring research proposals are scientifically sound and the NHS REC has primary responsibility for reviewing whether the research proposal has been subject to appropriate scientific review and the protocol has been designed to adequately meet its objectives.

The below table which details the minimum requirements for peer review for different study types can be used as a guide by researchers. The Sponsor and the NHS REC may and in certain circumstances request further appropriate independent expert peer review. If research is funded by an external funder (i.e. Medical Research Council, Government department or Charitable Organisation) which has their own peer review system the minimum requirements below may not be appropriate.

Evidence of peer review such as the LJMU peer review assessment form completed by the peer reviewer or grant award letter with confirmation of peer review and statistical review must be submitted to LJMU REG for review by the LJMU Research Governance Manager prior to confirmation of sponsorship approval.

It should also be noted that where a commercial funder has undertaken peer review further independent peer review may be requested.

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| **Level 1 No Peer Review Required** – minimal risk (no patient contact) | **Level 2 Review by project supervisor** (student projects with either no or minor patient/participant involvement) | **Level 3 Review by departmental colleague** (Low-risk projects with minimal patient involvement) | **Level 4 External, independent peer review** |
| Short questionnaire studies for use among hospital staff or GPs. | Human tissue samples [anonymous to investigator] | Human tissue samples [anonymous to investigator] | Clinical trial of an investigational medicinal product |
| Questionnaires asking patients about the quality of hospital services. | Study administering questionnaires | Study administering questionnaires | Clinical trial of a medical device |
| Use of data from medical notes by clinician looking after patient. | Qualitative study | Qualitative study | Performance Evaluation of an in vitro diagnostic device |
|  | Study limited to working with data | Study limited to working with data | Other clinical trial or clinical investigation |
|  |  | Non-intimate examination techniques, e.g. blood pressure measurement. | Research Tissue Bank |
|  |  |  | Human tissue (tissue samples and data) [newly obtained, identifiable or obtained from surplus] |

## Insurance Requirements

Staff – if you require a copy, please click on the link for LJMUs public liability and clinical trials [insurance certificates](https://www.ljmu.ac.uk/staff/finance/departments/insurance).

Students – you will not be able to access LJMUs public liability or clinical trials insurance certificates directly. If you require a copy, please ask your supervisor to click on the link for LJMUs public liability and clinical trials [insurance certificates](https://www.ljmu.ac.uk/staff/finance/departments/insurance).

The LJMUs Public Liability cover automatically operates for all the University’s research that is not considered a clinical trial.

LJMU has clinical trials cover – for insurance purposes, a clinical trial is defined as an investigation conducted on any person for a Medicinal Purpose, which includes:

1. treating or preventing disease or diagnosing disease or
2. ascertaining the existence degree of or extent of a physiological condition or
3. assisting with or altering in any way the process of conception or
4. investigating or participating in methods of contraception or
5. inducing anaesthesia or
6. otherwise preventing or interfering with the normal operation of a physiological function.

For clinical trials limited to the following activities and undertaken in the UK, automatic cover applies to:

* Questionnaires, interviews, psychological activity including CBT
* Venepuncture (withdrawal of blood)
* Muscle biopsy
* Measurements of physiological processes including scanning
* Collections of body secretions by non-invasive methods
* Intake of foods or nutrients or variation of diet (other than administration of drugs).

For clinical trials that involve activities that are not automatically covered, the researcher must email the completed [Clinical Trials insurance questionnaire](https://www.ljmu.ac.uk/staff/finance/departments/insurance) (students – because this is not directly accessible to you, your supervisor will need to access the questionnaire), the trial protocol and any other relevant material to the LJMU Insurance Officer (R.Smith@ljmu.ac.uk) for cover to be arranged. Rachael will seek to obtain a To Whom Letter extending the Clinical Trials cover, as necessary.

For research involving any of the following, an extension to the Clinical Trial cover will be required:

* Investigating or participating in methods of contraception
* Assisting with or altering the process of conception
* The use of drugs
* The use of surgery
* Genetic engineering
* Any research subject under the age of 5 years
* Any research subject who is known to be pregnant at the time of the Clinical Trial
* Where the substance under investigation has been designed and manufactured by LJMU
* Research conducted outside of the UK
* Clinical Trial of an Investigational Medicinal Product (CTIMP)
* Clinical Trial of a Medical Device

The above may require an additional charge, so ensure this extension is sought prior to applications for funding, where possible. This will ensure the funds are available for any additional charge. Please contact the LJMU Insurance Officer in the first instance.

## 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 (SOP007) and Permission to Proceed.

Evidence of costing must be provided. Individual confirmation of available funds must be given by the Investigator and a cost code provided for verification. 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.

A Chief Investigator (CI) intending to conduct a new research study is expected to:

(a) Identify all research study costs and, where appropriate, NHS support and treatment costs in accordance with funder, AcORD, and LJMU guidance;

(b) If the study involves the use of NHS premises, staff or patients then contact the R&D Office of the appropriate Trust, in the first instance.

(c) When seeking external funding refer to the NHS research costs form and consult with appropriate DoH or NIHR guidance;

(d) Consult and check with relevant departments (such as individual Trust’s pharmacies) who will be involved in the study before formal commitment or request for research funding is submitted;

(e) Generate a full project costing and submit for approval (when applying for external funding);

(f) Where external funding is secured, ensure that adequate agreements are in place before starting any new research;

(g) Where study is to be funded from internal sources to confirm with University Finance prior to the start of the study that adequate funds are available to deliver the study. Evidence of this confirmation must be communicated to LJMU REG.

The University expects Chief Investigators to ensure that all costs are identified and adequate funding secured before the start of the study. Final Sponsor confirmation is not released until the funding contract is signed with the Funder.

Where the study is to be internally funded, the Chief Investigator must ensure that adequate funding is ring-fenced for that study and confirmation of this should be secured. Confirmation of internal funding must be communicated to the LJMU REG to enable the Sponsor review process to be completed.

## Expedited Sponsorship Application and review process for Grant Applications

Some Research Grant providers require the applicant to have a Sponsor organisation in place prior to application for funding. In order to allow for these applications to proceed prior to full review by the LJMU Research Governance Manager, the Chief investigator must complete and submit the Study Protocol (Using the TEM001 Research Protocol Template for IRAS Application) to sponsor@ljmu.ac.uk.

A minimum of 5 working days is required for the discussion and review of Expedited applications and so the CI must ensure that LJMU REG is contacted in a timely manner. Therefore, if the request for Expedited Sponsorship Review is received after the 5 working day deadline the LJMU Research Governance manager may be unable to review the application.

If the application is approved an Intention to Sponsor letter will be issued. The Intention to Sponsor letter approves the study in principle and does not constitute final Sponsorship Approval. The Study Protocol, IRAS form and supporting documents will require further reviewed by the LJMU Research Governance Manager once the funding award has been approved.

## Development of Contracts & Agreements

For information, please refer to LJMU Standard Operating Procedure – SOP004 Production and Management of Contracts for LJMU Sponsored Research.

## 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/>)

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.

# Sponsorship approval request

Once the protocol is ready to be submitted for sponsor review, the required information should be included on the [IRAS form](https://www.myresearchproject.org.uk) in preparation for HRA, NHS REC approvals etc. once sponsor approval has been confirmed. The following should be sent to sponsor@ljmu.ac.uk

* + For student research, email confirmation that the student has completed the [LJMU Research Ethics Training](https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-ethics/research-ethics-training)
	+ Email confirmation as applicable from the chief investigator, academic supervisor, lead medical physics expert, lead clinical radiation expert that they have authorized the IRAS form.
	+ FORM008 IRAS Application Checklist for LJMU Sponsored Research
	+ Signed FORM001 CI Internal Agreement for LJMU Sponsored Research
	+ Summary CV for Chief Investigator (CI)
	+ PDF copy of the completed [IRAS form](https://www.myresearchproject.org.uk/help/hlpusingiras.aspx)
	+ Study protocol (based on TEM003 Research protocol Template for IRAS Application)
	+ Validated questionnaires / Non-validated questionnaires / Interview schedules (as applicable)
	+ Participant documentation (information sheets (e.g. TEM003 LJMU Participant Information Sheet Template for HRA Approved Research), consent forms, recruitment material etc. (as applicable)
	+ Evidence of peer review - copy of Independent peer review (TEM002 Peer Review Assessment Form for LJMU Sponsored Research) or grant award letter with confirmation of peer review and statistical review. (If required)
	+ Organisation Information Document (OID) for non-commercially sponsored projects – [template](https://myresearchproject.org.uk/help/help%20documents/Organisation_Information_Document__Non-Commercial_v1-2.docx) and [guidance](https://myresearchproject.org.uk/help/help%20documents/Guidance_Organisation_Information_Document__Non-Commercial_v1-2.pdf) (unless the participating R&D office confirms in writing that they are happy to conduct their review without an OID). Only required if the IRAS form is submitted for HRA approval.
	+ Evidence of Sponsor insurance or indemnity
	+ Confirmation of funding (if applicable/available)
	+ Evidence of costing and confirmation of adequate funding available for the duration of the study
	+ Letter confirming co-sponsorship from the Trust (if applicable/available)
	+ Agreements / contracts that have or will been agreed/negotiated. (If applicable)

Sponsor review cannot begin until all of required information has been sent to sponsor@ljmu.ac.uk

# LJMU Sponsor review

Investigators should allow at least 15 working days for sponsor review. If documents are resubmitted in response to deferral comments, investigators should allow at least 10 working days for the documents to be further reviewed.

Comments on the documentation and any additional questions generated by the Sponsor Risk Assessment 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. Only when all queries, required amendments, and points of clarification have been satisfied will LJMU confirm “LJMU Sponsorship approved in Principle”, thereby giving authorisation to the CI to progress applications to Regulatory Agencies e.g. MHRA, HRA, REC, NHS Trusts etc.

# LJMU Sponsorship Approval in Principle

The LJMU Research Governance Manager will decide whether LJMU can take on the responsibility of Sponsor or Co-Sponsor research. The LJMU Research Governance Manager decision will be one of the following:

* + LJMU Sponsorship approved in principle - Letter issued – proceed to regulatory approvals
	+ Decision deferred. Deferral Decision Letter issued – additional information/clarification required
	+ Sponsorship request rejected - Unfavourable Decision Letter issued

LJMU sponsorship approved in principle is **not** the confirmation to set-up the study or commence recruitment. The LJMU Sponsorship Approved in Principle letter will contain a sponsorship agreement detailing the roles and responsibilities of the CI and will detail the documentation required in order for the Research Governance checks to be completed and for sponsor to provide permission for the study to commence. This includes requirements for

* Regulatory approvals (HRA, NHS REC etc.) (as applicable)
* Sign-off of all contracts and agreements. (if applicable)
* NHS sites capacity and capability (if specified in the HRA approval notification)

Further information is provided in SOP003 Roles and Responsibilities for LJMU Sponsored Research and the Governance Handbook for LJMU Sponsored Research.

LJMU sponsorship can be approved in principle before agreement/contract negotiations have begun. It is a requirement that contracts and agreements must be fully executed before the sponsor provides permission to proceed.

Once all necessary regulatory and organisational Approvals are in place and documentation has been received LJMU REG will provide the CI with the LJMU Sponsor Permission to Proceed notification letter. This letter confirms that all sponsor requirements have been met and that the study may proceed to the next stage to open the study.

# LJMU Sponsor Permission to Proceed

Once the investigator has sent confirmation of regulatory approvals (e.g. HRA, NGHS REC etc.), sign-off of contracts and agreements (if applicable) and NHS sites capacity & Capability to sponsor@ljmu.ac.uk, investigators should allow at least 10 working days for the LJMU Sponsor Permission to Proceed notification to be issued or for further information to be requested.

The Sponsor Permission to Proceed Notification will list the roles and responsibilities of the CI that must be adhered to once the study has opened. This includes:

* Notify LJMU REG of the date of the first participant recruited into the study
* Creation and maintenance of a Study Master file
* Delegation at site
* Study amendments
* Annual reports
* Safety reports
* Standing operating procedures
* International research
* Auditing and oversight provision
* End of study
* Close out
* Dissemination of study findings
* Archiving

Further information is provided in SOP003 Roles and Responsibilities for LJMU Sponsored Research.

# Sponsorship Withdrawal or Refusal

Sponsorship may be withdrawn or refused at the discretion of the Sponsor. The CI will be given 30 days’ notice in writing of the withdrawal of sponsorship, and will be notified within 5 working days of the decision of refusal of sponsorship.

The following reasons for refusal or withdrawal of sponsorship are examples only and not exhaustive.

**Intention to sponsor may be refused if**:

* + - The CI does not have a university contract
		- A multicentre interventional study does not have a dedicated co-ordinator
		- The funding does not cover the costs of the research
		- The statistics and analysis are not robust or suitable for the study design
		- There are considerable ethical or safety considerations

**Full sponsorship may be refused if any of the above conditions are not met and:**

* + - 1 or more unfavourable peer reviews are obtained
		- There is not sufficient funding available for the study
		- There is no sponsor approved risk management
		- No 24/7 contact for interventional studies

**Sponsorship may be withdrawn if any information on the original application changes without prior approval of the sponsorship committee such as but not limited to:**

* + - Change in CI
		- Change in funder or funding arrangements
		- Change in co-sponsor status
		- Change in randomisation strategy

Or there is a failure to comply with University Research Policies and Procedures.

# Oversight of Non-CTIMP studies

Information related to Sponsor Oversight and the CIs delegated roles and responsibilities to facilitated sponsor oversight is provided in SOP008 Oversight of LJMU Sponsored Research.

# Abbreviations

**CI** Chief Investigator

**CTIMP** Clinical Trial of an Investigational Medicinal Product

**CV** Curriculum Vitae

**DH** Department of Health

**LJMU REG** LJMU Research Ethics and Governance

**SOP** Standard Operating Procedure

# Associated Documents and References

To be completed

# Monitoring and Audit

Compliance with this SOP will be audited periodically as part of the LJMU REG audit plan.

# Change History

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| Version No. | Effective date | Significant changes  | Previous version No. |
| 1.0 | See page 1 | This is the first version of this SOP | n/a |