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| **SOP002 Completing an IRAS form for LJMU Sponsored Clinical Research** |
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| **Relevant to:** | All staff and students conducting research |
| **Approved by:**  |  |
| **Responsibility for Document Review:** | *Dave Harriss* |
| **Date introduced:** | *April 2019* |
| **Date(s) modified:** |  |
| **Next Review Date:** |  |
| **RELEVANT DOCUMENTS** |
|  |
| **RELATED POLICIES & DOCUMENTS** |
| *Governance handbook for LJMU sponsored clinical research**LJMU Sponsorship of clinical 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 policy 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](http://www.liverpoolhealthpartners.org.uk/JRO.php).

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/) (v3.2 10th October 2017) states that no research study within the NHS involving individuals, their organs, tissue or data may being until it has a favourable opinion from a research ethics committee (REC). The [NHS REC](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/) is a core function of the [Health Research Authority](https://www.hra.nhs.uk/) (HRA) and review all applications for research taking place within the NHS and consider any adverse risk to participants.

LJMU is not currently in a position to sponsor research defined as a Clinical Trial of Investigational Medicinal Product (CTIMP). When LJMU is able to sponsor a CTIMP, under the EU Clinical Trials Directive 2001/20/EC the research will require a [Clinical Trial Authorisation](http://www.ct-toolkit.ac.uk/routemap/cta-submission/) (CTA) from the Competent Authority in the Member State(s) where research is taking place. The Competent Authority for UK is the [Medicines and Healthcare products Regulatory Agency](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) (MHRA).

[The Medicines for Human Use (Clinical Trials) Regulations 2004](http://www.legislation.gov.uk/uksi/2004/1031/contents/made) (S.I.2004:1031) as amended transpose the EU Clinical Trial Directive into UK Law and require that before a CTIMP can commence a CTA is required from the MHRA and favourable opinion is given by an NHS REC.

LJMU is not currently in a position to sponsor research defined as a Clinical Investigation for a Medical Device (CIMD). When LJMU is able to sponsor a CIMD, the Medical Devices Regulations 2002 requires that that before a CIMD can commence a Notice of No Objection is given from the MHRA and favourable opinion is given by an NHS REC.

Research that falls under the remit of the [Human Tissue Act 2004](https://www.hta.gov.uk/policies/human-tissue-act-2004) or the [Mental Capacity Act 2005](https://www.legislation.gov.uk/ukpga/2005/9/contents) also require ethical review by an appropriate body, normally an NHS REC. LJMU REC can approve studies that fall under the remit of the Human Tissue Act 2004 if the study is conducted under the LJMU Human Tissue Licence.

Approval may be required from additional regulatory bodies depending on the nature of a clinical trial or study. The [Integrated Research Application System](https://www.myresearchproject.org.uk/) (IRAS) provides a single system for applying for the permissions and approvals for health and social care/community care research in the UK. It enables trial information to be recorded once instead of duplicating information in separate application forms.

IRAS captures the information needed for the relevant approvals from the following regulatory/review bodies:

* + [HRA Approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/) (for projects led from England only)
	+ NHS Research Ethics Committees
	+ NHS R&D offices (devolved Nations only)
	+ Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines Division
	+ Medicines and Healthcare products Regulatory Agency (MHRA) – Devices Division
	+ [National Institute for Health Research (NIHR) Clinical Research Network Portfolio](https://www.nihr.ac.uk/research-and-impact/nihr-clinical-research-network-portfolio/)
	+ [Administration of Radioactive Substances Advisory Committee](https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee) (ARSAC)
	+ Confidentiality Advisory Group ([CAG](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/))
	+ Gene Therapy Advisory Committee ([GTAC](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/gene-therapy-advisory-committee/))
	+ National Offender Management Service ([NOMS](https://www.gov.uk/government/organisations/national-offender-management-service))
	+ Social Care Research Ethics Committee ([SCREC](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/social-care-research/))

# Scope of Procedure

The purpose of this standard operating procedure is to outline the process of using IRAS, provide details of where further help can sought and provide advice on answering local questions. For the purpose of this SOP, any reference to clinical 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](https://www2.ljmu.ac.uk/RGSO/93042.htm).

# Procedure

## Who

This SOP is aimed at Chief Investigators (CI), students, trial coordinators and other members of LJMU Staff involved in IRAS application process for LJMU Sponsored research.

Completing the data set is ultimately the responsibility of the CI, however, the Sponsor recognises this is often done with the support of other members of the study team e.g. the student conducting the research, a research nurse or trial coordinator. When signing the form the Chief Investigator is confirming they have full knowledge of the data contained in the form and will abide by the conditions set out in the declaration.

The form also requires the signature of the Sponsor’s representative. If this is LJMU, the study must have approval at least in principle in writing before the Research Governance Manager can sign on behalf of LJMU. This signature confirms that the sponsor will abide by the conditions set out on the declaration.

## When

It is beneficial to start the IRAS process as early as possible when setting up a research project. However, the form should not be submitted until sponsorship have been confirmed with either an Intention to Sponsor or Sponsorship Approval letter. The process must be completed, and approvals received from the relevant governing bodies prior to the study opening for subject recruitment. As the NHS REC have a 30 day period to respond to applications it is advised that this is taken into consideration when planning the study timelines.

# Getting Started

IRAS can be accessed at: <https://www.myresearchproject.org.uk/SignIn.aspx>

New users can create an account by clicking on the ‘Create Account’ tab at the top of the page and setting a user name and password. When setting up a new account is it advised that a regularly accessed email account is used as this is the account that all notifications are sent to.

E-training for the IRAS system can be accessed by the tabs at the top of the page and it is recommended that all users complete training before use of the system.

The answers given in the first section of the form ‘IRAS Project Filter’ (questions 1-10) will determine the data set required for the project. The system will generate only those questions and sections which apply to your study type and are required by the bodies reviewing your study. These questions will automatically appear on all forms and only need to be answered once.

Once the required data set has been generated the navigate feature can be used to access the Integrated Dataset for all project forms which lists all the questions required on 2 or more forms , or to select an individual form and answer all the relevant questions to that form.

When completing the form comprehensive help can be found at <https://www.myresearchproject.org.uk/Help/UsingIRAS.aspx>.

# Application Specific Advice

## IRAS Filter Question 2

Please tick the correct category – based on the information provided in the protocol, participant information sheet and the IRAS form itself. The HRA provides guidance on the different study categories which can be found here: <http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/study-types/>. Where the research is not considered a CTIMP but there is still uncertainty on what category the research fits in to, the ‘other’ option can be ticked as this will open all possible questions within the IRAS form.

## IRAS Filter Question 4. HRA Approval

HRA Approval is the process for the NHS in England that comprises a review by a NHS REC (where required – see the HRA for further information) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA staff. It replaces the need for NHS permission by each participating organisation in England.

You should apply for HRA Approval if:

* + The lead NHS R&D Office for your project is in England; and
	+ Your research is described by any of the IRAS filter question 2 categories (except those for "Research Tissue Bank" and "Research Database").

To apply for HRA Approval you should select the option for "IRAS Form" at project filter question 4.

The IRAS form is used to submit applications for NHS/HSC R&D Permission and NHS REC review (where required) for research led from Northern Ireland, Scotland or Wales.

Applicants must submit a statement of Activities and a Schedule of Events (SOA/SOE) – unless the participating R&D office confirms in writing that they are happy to conduct their review without SOA/SOE. The HRA SOA/SOE templates can be found here <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>.

## IRAS Filter Question 5b. NIHR Clinical Research Network Portfolio

The National Institute for Health Research Clinical Research Network (NIHR CRN) provides infrastructure support for the initiation and delivery of high quality research which benefits patients and the NHS.

The NIHR CRN Portfolio is a database of high-quality clinical research studies that are eligible for support from the NIHR Clinical Research Network in England. The NIHR CRN support for non-commercial studies includes meeting the NHS Support Costs (or equivalent in non-NHS settings) of these studies.

Adoption onto the Portfolio is dependent on meeting the Eligibility Criteria. Studies that are funded by NIHR Non-Commercial Partners are automatically eligible. Those studies that are commercially funded and sponsored and those funded by overseas organisations may be eligible. For further information please see https://[www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-](http://www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-) support/. Studies funded in other ways could be considered for NIHR CRN support via the non-commercial extended review process.

For a study to be considered for NIHR CRN support it must:

1. meet the definition of research as defined by the HRA
2. have appropriate ethical approval (e.g. NHS, Social Care REC, or Ministry of Defence REC); and Health Research Authority (HRA) Approval where required; and
3. have full research funding (i.e. funding to meet all Research Costs in compliance with the [AcoRD guidance](https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/acord/))

Please note, studies will be required to have undergone protocol peer review before they can be considered for NIHR CRN support. Peer review must be independent, expert and proportionate

1. Independent: At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators’ host institution and not involved in the study in any way. Reviewers do not need to be anonymous.
2. Expert: Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service based aspects of the protocol, and/or have the expertise to assess the methodological and statistical aspects of the study.
3. Proportionate: Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review.

For studies which are eligible to be included on the NIHR CRN Portfolio question 5b. “Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio?” needs to be answered as ‘Yes’.

Once the ‘Portfolio Adoption Form’ has been completed click on the ‘E-Submission’ tab. The appropriate CRN needs to be selected from the drop-down list. Select ’North West Coast’ for studies with a CI based in this area. There is further information and guidance available within IRAS.

## IRAS Filter Question 9. Educational projects

Supervisors and students need to give consideration to approval review times; for example in England:

* Studies requiring NHS REC take median 70 calendar days
* Studies requiring HRA assessment only, take median 30 calendar days
* Studies requiring proportionate review take median of 40 calendar days

IRAS Applications can be made without specifically naming students to allow approval to be in place before the start of the academic year. Applications containing different research questions under one specific aim can be made so long as activity is clearly documented and clearly relates to the overall aim.

## IRAS Question A2.1 (Educational Projects)

In addition to the CI role they may have, supervisors must have a clear understanding of research governance requirements for studies they supervise. Click [here](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) to see the UK policy.

Students from courses outside of health and social care should have a co-supervisor with relevant experience, based in a healthcare setting. The role of the co-supervisor is to ensure research is feasible and has minimal burden on the NHS/HSC.

The supervisor role includes ensuring the student understands the research process:

* Research Design
* Application process and regulatory approvals
* Setting up studies in the NHS
* Making students aware of the issues around patient data access, approaching patients and consent.

Supervisors role also includes ensuring studies comply with research governance requirements throughout the study to study close.

## IRAS Question A2.2

Supervisors or course leaders should be the Chief Investigator for student health and social care research, including those at PhD and doctoral level. This is because the CI responsibility includes ensuring the research is scientifically sound, all relevant approvals are in place, satisfying themselves everyone is qualified to fulfil their roles as described in the UK Policy Framework.

Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or doctoral-level study whilst employed by a health or social care provider or LJMU, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

## IRAS Question A3.1 (Chief Investigator)

The Chief Investigator is an individual who is responsible for the conduct of the whole project in the UK. The UK policy states that the named CI should be a researcher who is professionally based in the UK, as they will be able to supervise the research effectively and readily available to communicate with the NHS REC and other review bodies during the application process and where necessary during the conduct of the research.

For educational research, this function should be undertaken by supervisors.

## IRAS Question A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

If the clinical research is sponsored by LJMU, then Dr. Dave Harriss will be your sponsor contact (and signatory):

Dr Dave Harriss

Research Governance Manager

Research Innovation Services

Exchange Station

Liverpool L2 2QP

sponsor@ljmu.ac.uk

0151 2312121

## IRAS Question A5-1. Research Reference numbers

The Sponsor reference number will be communicated to the applicant via the Sponsorship Approval letter – which will be sent to the applicant once the request for sponsorship has been approved – prior to submission of the IRAS form.

## IRAS Question A6-1- Lay Summary

You should be aware that the lay summary provided in this question will be published by the Health Research Authority. It needs to be in non-technical language and be a summary of the project.

## IRAS Question A6-2

This question should detail the ethical (and practical) issues that the project gives rise to and how they are addressed, as well as any elements of the research design that could prompt questions. It’s your chance to show the committee that you have thought through the project, can see what the challenges are and have a plan for dealing with them.

## IRAS Question A11

There have been cases where applications were turned down because of a failure to fill in this question—please complete this question even if you just put ‘not applicable’.

## IRAS Question A26

If you will be interviewing or treating people in their own homes, then the committee is likely to want information about what procedures you have put in place to ensure your own safety (e.g. you could include the home working policy of the lead NHS Trust you are working with).

## IRAS Question A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?

Consider whether the process of identifying potential participants might reveal personal and sensitive information about that individual to others.

If using a third party, such as a gatekeeper, to identify participants, records or samples explain why and provide details of their relationship with the potential participants. (e.g., school authority, coach, treatment provider etc.)

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| IRAS Question A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?   |

If the researcher will need to access an individual’s personal data, explain why they would have legitimate access to the personal data (according to the data protection act).

## IRAS Question A29. How and by whom will potential participants first be approached?

 Consider how to approach participants without revealing private information to others (e.g. an email sent to a group of individuals who have identified themselves as dyslexic to the gatekeeper but not to each other)

Consider time & place – Is it easy for potential participants to say yes or no?

Consider whether you will have legitimate access to contact details according to GDPR or whether you will require a gatekeeper, who has legitimate access to contact details, to contact potential participants on behalf of the investigator.

## IRAS Question A33

Where there are plans to translate documents, please state whether this has been done or will be done by someone who is fluent in the language. The REC are not required to see translated documents but just need to be informed that this approach will be taken.

## IRAS Question A36

Please make sure identifiable data will not be stored on personal or home computers – even if they are password protected. Please use LJMU network drive (e.g. m:drive), LJMU desktops or client managed laptops.

## IRAS Question A37. Please describe the physical security arrangements for storage of personal data during the study?

For special category personal data, please state whether the data will be encrypted.

##  IRAS Question A38. How will you ensure the confidentiality of personal data?

When initially recording data/information consider whether data will be anonymous (to everyone, including the investigator), whether linked-codes/pseudonyms will be used and whether the codes/pseudonyms will be linked to the identity of the participant. Explain how you will ensure that individuals are not identifiable from the codes/pseudonyms.

Consider whether recording devices be password protected and only accessible to the researchers and whether the data/information be deleted from a recording device once transferred to storage.

For questionnaires (used for collecting data and screening participants), explain how the method of submitting/delivering the completed questionnaire to the researcher will ensure confidentiality*.*

Consider whether personal data will be pseudonymised when recorded, stored and disseminated and whether data will be anonymised/de-identified once there is no longer a requirement for it to be identifiable – and when this will be.

## IRAS Question A40. Who will have access to participants' personal data during the study?

For student research, all data must be accessible to the student’s supervisor for data authenticity purposes (including interview audio recordings).

For all studies, all data must be accessible on request to responsible members of Liverpool John Moores University [and the relevant NHS Trust(s)] for monitoring and/or audit of the study to ensure that the study is complying with applicable regulations.

## IRAS Question A42

Usually the Chief Investigator

## IRAS Question A43

Length of data storage needs to always be over 3 years as research data needs to be for 10 years as per LJMU CoP. Any personal data collected that is not fundamental to the research can be destroyed earlier; however consent forms may need to be kept for the whole archiving period.

## IRAS Question A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

The REC will wish to be reassured that research participants are not being paid for taking risks or that payments are set at a level which would unduly influence participants and “cloud there judgement” about whether or not to participate.

Research participants should not be substantially out of pocket because of taking part in a research study and consideration should be given to any expense involved in returning postal questionnaires. If it is not possible to reimburse such expenses this should be explained before the research participant is recruited. A clear statement should be included in the participant information sheet setting out the position on reimbursement.

Payment in cash or kind to participants must only be for costs such as travel expenses, child-care expenses, meals and demonstrable loss of earnings etc. Payment/compensation for time and effort is a considered a wage payment model – and will only be considered by the REC if the tax implications have been considered by the researchers and communicated to the participants.

Consider whether this is a fair reimbursement or compensation or likely to coerce or apply undue pressure to participate. Consider whether the payment/reward is necessary to achieve a representative sample.

Vouchers are preferable as cash could have tax implications. If using a prize draw, consider how and when the winners be notified of results and results will be announced.

## IRAS Question A50

It is recommended for clinical research studies to be registered on a public database but this is not a requirement unless NHIR portfolio adoption is being sought which will require registration (in which case ISRCTN is recommended – at the time of writing the ISRCTN registration is £226 + VAT).

## IRAS Question A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

When disseminating findings, consider whether participants will not be directly attributed to data/information that is disseminated (use of pseudonyms etc.) or whether they will be attributed, but only with explicit consent from the participant.

Following attempts to ensure privacy and confidentiality, if there is the possibility that individuals could be indirectly identified once the study has been DISSEMINATED explain what you will do (including involving the participant in the decision making process) to minimise the potential for indirect identification, and how you will manage the potential for indirect identification. Consider participants with specific characteristics/certain profile or who belong to a specific group might be indirectly identifiable from the things they have said/done that are disseminated by the researcher). Care should be taken that the combination of incidental details e.g. details about occupation, location, age and ethnicity, do not lead to individuals being identifiable. You might want to consult with the participant about how information will be disseminated and what information should not be disseminated.

## IRAS Question A54

Peer review is required for any studies under Policy Framework for Health and Social Care and when wishing for NHIR portfolio adoption. Please refer to the LJMU SOP on peer review of clinical research.

## IRAS Question A64-1

If you are sponsored by LJMU, then Dr. Dave Harriss will be your sponsor contact (and signatory):

Dr Dave Harriss

Research Governance Manager

Research Innovation Services

Exchange Station

Liverpool L2 2QP

sponsor@ljmu.ac.uk

07929999021

## IRAS Question A74

It It should be noted that the sponsor may perform checks as part of their quality programme

## IRAS Question A76. Insurance and Indemnity

Staff – if you require a copy, please Click on the link for LJMUs [public liability](https://teams.ljmu.ac.uk/2/fin/LJMUFIN/Insurance%20Certificates/Employers%20Liability%20and%20Public%20Liability.pdf) and [clinical trials](https://teams.ljmu.ac.uk/2/fin/LJMUFIN/Insurance%20Certificates/Clinical%20Trials%20Cert%202018%20-19.pdf) insurance certificates.

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](https://teams.ljmu.ac.uk/2/fin/LJMUFIN/Insurance%20Certificates/Employers%20Liability%20and%20Public%20Liability.pdf) and [clinical trials](https://teams.ljmu.ac.uk/2/fin/LJMUFIN/Insurance%20Certificates/Clinical%20Trials%20Cert%202018%20-19.pdf) insurance certificates.

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://teams.ljmu.ac.uk/2/fin/LJMUFIN/Insurance%20Information/Research%20Questionnaire%20%28incl%20Human%20Participants%29.pdf) (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.

## IRAS Question A76-1.

Check the second box and use the following text (once edited in accordance with the italic instructions)

“LJMU has arranged Public Liability insurance and/or Clinical Trials insurance (*delete as required*) to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University and the activities here are included within that coverage.

This does not in any way affect an NHS Trust’s responsibility for any clinical negligence on the part of its staff (including the Trust’s responsibility for LJMU employees/students acting in connection with their NHS honorary appointments). (*Delete this 2nd paragraph if not applicable e.g. if your research takes place on University premises and/or involves no clinical intervention by the NHS*).”

## IRAS Question A76-2.

Check the second box if LJMU designed the research and use the following text (once edited in accordance with the italic instructions)

“LJMU holds Professional Indemnity insurance and/or Clinical Trials insurance (*delete as required*) to cover the legal liability of the University as Research Sponsor and/or as the employer of staff/students engaged in the research, for harm to participants arising from the design of the research, where the research protocol was designed by the University.”

## IRAS Question A76-3.

If any of the research participants are NHS patients (or you are using patient tissue or data) then the NHS indemnity scheme will apply. If you check the second box use the following text (once edited in accordance with the italic instructions)

“LJMU’s Public Liability and Professional Indemnity insurance policies and/or Clinical Trials insurance (*delete as required*) provide an indemnity to our employees and students for their potential liability for harm to participants during the conduct of the research and the activities here are included within that coverage.

Again, this does not in any way affect an NHS Trust’s responsibility for any clinical negligence on the part of its staff (including the Trust’s responsibility for LJMU employees/students acting in connection with their NHS honorary appointments). (*Delete this 2nd paragraph if not applicable e.g. if your research takes place on University premises and/or involves no clinical intervention by the NHS*).”

Option a) Use for clinical research within NHS Hospital Trusts add:

“Professor X/Doctor Y/Nurse Z/Student A also holds an honorary appointment with # NHS Hospital Trust giving him/her the protection of the NHS indemnity scheme.”

Option b) Use for clinical research outside an NHS Hospital Trust (including Primary Care) add:

“Professor X/Doctor Y has the protection of medical malpractice indemnity with MDU/MPS (*delete as applicable*).”

Option c) Use where there is a collaborating institution add:

“LJMU’s insurance policies do not provide an indemnity to collaborators or Site Management Organisations (*delete as applicable*). As Research Sponsor we will ensure as far as reasonably practicable at the outset of the study that collaborators/SMOs (*delete as applicable*) hold appropriate legal liability insurance.”

## IRAS Question A77

This asks whether the Sponsor has made arrangements for payment of compensation in the event of harm where no legal liability arises and is most relevant for commercially sponsored trials of medicines and clinical investigations of medical devices.

The University will not normally provide indemnity for non-negligent harm, so the suggested response is that "No provision has been made for indemnity in the event of a claim for non-negligent harm".

## IRAS Question A78

If you answer YES or NOT SURE – please contact Jane Townend in Research Innovation Services and append the supporting documents required.

## Supporting Documentation

Each application form created within IRAS has a related ‘Checklist’ which details supporting documentation for the application.

You must attach your supporting documentation to this checklist before submitting your application.

Statement of Activities/Schedule of Events will need to be submitted for any research involving NHS sites. A Statement of Activities and Schedule of Events needs to be submitted for sites where different activities are to occur (e.g. if some sites will only act as PIC sites and others as the intervention site, 2 sets of Statement of Activities and Schedule of Events will need to be submitted. They will not need to be submitted for each site, just by the activity being performed at the site if different).

Please see here for further information - <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>

## IRAS form electronic signatures

Before getting electronic signatures, you may want to check that your application is complete. You can do this by going in to the form you want to check (by selecting the form from the ‘Project Forms’ menu on the left hand of the page), going to the ‘Submission’ tab, and clicking the ‘Check your form’ button.

In order to obtain an electronic signature on behalf of the Sponsor on the IRAS form please do the following:

* Once the IRAS form is ready to be submitted, open up the form that you want authorised and select the authorisations tab.
* On the row of the table marked “Sponsor's representative” press the ‘request’ button
* A dialogue box will appear requesting an e-mail address—put the following e-mail address in: sponsor@ljmu.ac.uk
* Send all related documents to: sponsor@ljmu.ac.uk

Once LJMU Sponsorship has been approved (refer to SOP001) the Research Governance Manager will electronically sign the IRAS form.

Please note that once the IRAS Form has been signed and authorised by the Sponsor, no more changes can be made to it without invalidating the signature. If you make any further changes you will have to re-submit for authorization.

## Other applications

Upon receipt LJMU Sponsorship Approval LJMU Research Ethics and Governance (REG) will advise if applications to other regulatory bodies mentioned in Section 1 are required and will provide specific advice.

Applications to bodies such as [LJMU Research Ethics Committees](https://www2.ljmu.ac.uk/RGSO/93085.htm) and International Ethics committees are not made via IRAS, and LJMU REG will provide specific advice as and when these applications are required.

# Specific Expertise

Each application form located within IRAS will require input from individuals with particular expertise. These individuals should be identified as early as possible to allow their review and authorisation (where required) before submission.

## Sponsorship

If the study is co-sponsored between LJMU and an NHS Trust it should be determined between the co-sponsors who will be the lead sponsor. The co-sponsor should be added using the “Add Co-Sponsor” button at the bottom of the page and contact details should be obtained from the appropriate NHS R&D department.

## Lead Medical Physics/ Clinical Radiation Experts

Depending on the nature and procedures involved in a study a Lead Medical Physics Expert and/or a Clinical Radiation Expert may need to be involved in advising on the study. This includes any ionising radiation or radioactive medicinal products being administered as required in the protocol even if this is considered standard care.

# Roles and Responsibilities

It is the responsibility of the CI to complete the required application forms within IRAS and although this may be delegated to another member of the study team, the CI retains responsibility for the content of the application. This is evidence by their authorisation on each application form.

The Research Governance Manager will be the authorised signatory on behalf of LJMU as Sponsor. Authorisation requests are to be sent to sponsor@ljmu.ac.uk and only electronic signatures will be provided in line with IRAS guidance.

# Abbreviations

**CI** Chief Investigator

**CIMD** Clinical Investigation of a Medical Device

**CRN** Clinical Research Network

**CTA** Clinical Trial Authorisation

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

**HRA** Health Research Authority

**IRAS** Integrated Research Application System

**MHRA** Medicines and Health care products Agency

**NIHR** National Institute for Health Research

**REC** Research Ethics Committee

# Associated Documents and References

Administration of Radioactive Substances Advisory Committee - <https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee>

Clinical Trials toolkit - <http://www.ct-toolkit.ac.uk/routemap/cta-submission/>

Confidentiality Advisory Group - <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/>

Gene Therapy Advisory Committee - <https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/gene-therapy-advisory-committee/>

Health Research Authority - <https://www.hra.nhs.uk/>

HRA Approval - <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/>

Human Tissue Act 2004 - <https://www.hta.gov.uk/policies/human-tissue-act-2004>

Integrated Research Application System - <https://www.myresearchproject.org.uk/>

Liverpool Health Partners - <http://www.liverpoolhealthpartners.org.uk/JRO.php>

LJMU Research Ethics Committees - <https://www2.ljmu.ac.uk/RGSO/93085.htm>

LJMU Research Ethics and Governance - <https://www2.ljmu.ac.uk/RGSO/93042.htm>

# Monitoring and Audit

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

# Change History

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