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| **Governance Handbook for LJMU Sponsored Clinical Research** |
| **Responsibility for Policy:** | *Robin Leatherbarrow* |
| **Relevant to:** | All staff and students conducting research |
| **Approved by:**  |  |
| **Responsibility for Document Review:** | *Dave Harriss* |
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| **RELEVANT DOCUMENTS** |
| *LJMU Sponsorship of clinical research SOPs (numbers 1-10)*  |
| **RELATED POLICIES & DOCUMENTS** |
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This handbook 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 handbook details the national guidance and legislation as well as internal LJMU Processes. This guide only refers and applies to researchers undertaking, or planning to undertake, research within the NHS, clinical research at an international site. It is not intended to be a substitute for national guidance and legislation or internal LJMU Procedures.

All researchers who wish to undertake research within the NHS must ensure that they have read and are familiar with relevant national guidance and legislation and internal University Procedures. LJMU Research Ethics and Governance (REG) has a suite of clinical research governance SOPs that are available on the [LJMU REG webpages](https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-ethics/university-research-ethics-committee-urec/urec-meeting-dates).

The LJMU REG (located within RIS) should be the first point of contact for all queries relating to clinical research governance or Sponsorship (sponsor@ljmu.ac.uk).

For the purpose of this handbook, 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.

# Governance and Legislation

## Clinical Research

Clinical Research is any research that involves;

* NHS Patients, staff or premises.
* Healthy volunteers participating in Clinical Trials of Investigational Medicinal Products
* Human material

Clinical research can be undertaken using various methodologies such as;

* Clinical trials of investigational medicinal products (CTIMPs)
* Clinical trials of medical devices
* Studies involving the use of human material
* Studies administering questionnaires
* Studies using qualitative methods

Clinical Research is not;

* Clinical audits
* Service evaluations
* Usual practice in public health
* Surveillance work in public health
* Studies involving only animals (even if this may lead to human research)
* Research outside of the NHS (i.e. interviews with University students)

The Health Research Authority (HRA) provide [guidance on defining research](http://www.hra-decisiontools.org.uk/research/). We recommend that [this tool](http://www.hra-decisiontools.org.uk/research/) is consulted at the earliest stages of study design and set up to help determine the required approvals.

## Research Governance

Research Governance may loosely be defined as a range of regulations, principles and standards which exist to achieve and improve research quality across all aspects of health and social care.

Research Governance aims to:

* Safeguard research participants
* Protect researchers
* Enhance ethical and scientific quality
* Minimise risk
* Monitor performance
* Promote good practice

Of these aims, the touchstone of research governance is safeguarding the dignity, rights, safety and wellbeing of all research participants.

## Legislation

There is no ‘one size fits all’ approach and there may be intricacies and complications in even the most ‘low risk’ studies. Investigators must ensure they familiarise themselves fully with the legislation, and ask for advice on any clarifications or concerns they may have.

## Good Clinical Practice (GCP)

The International Conference on Harmonisation have issued guidance for [Good Clinical Practice](https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf) (ICH GCP) which has been incorporated into law in some parts of the EU. The UK has not adopted this as law, and so is not a legal requirement, but UK legislation does make reference to the principles of GCP being adhered to in all clinical research.

The origins of GCP date back to the Nuremburg Trials and the resulting Nuremburg Code in 1947. This was then followed by the Declaration of Helsinki in 1964. ICH GCP guidance (ICH 1996) states that all clinical trials should be conducted in accordance with the ethical principles set out in the [Declaration of Helsinki](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/). These cover general duties that a physician must follow in their routine work, as well as for conducting medical research. In summary;

1. Physicians who carry out medical research must ensure that the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects is protected.
2. The study must be designed and based on the results of scientific literature, relevant sources of information, laboratory and where appropriate animal experimentation, and with a knowledge of the disease history
3. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
4. The design and the methodology of the piece of research must be clearly laid out in a research protocol. The protocol must include, amongst other areas, a statement of ethical considerations. This protocol must then be reviewed and approved by an appropriate research ethics committee [in the UK, for studies involving the NHS, this is HRA REC].
5. The study must be carried out by appropriately qualified and experienced persons.
6. For each piece of research the risks and burdens to participants and to the wider community must be carefully assessed and balanced against the benefits (either immediate or in future years). The research should only be conducted if the benefits outweigh the possible risks or burdens to the participants.
7. Participants must provide voluntary consent to take part and must have the legal capacity to do so. This consent must be given after the participant has been fully informed of the aims and methodologies of the study as well as the potential risks and benefits of participation. If the person does not have legal capacity to consent, this must be provided by a legally appointed representative *[this must be in accordance with the* [*Mental Capacity Act 2005*](http://www.legislation.gov.uk/ukpga/2005/9/contents)*]*.

With the creation of the UK Policy Framework for Health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations 2004 these principles have been placed in UK law and guidance. The overarching message that stems from GCP is that the participant’s safety and wellbeing must be held in the highest regard when conducting clinical research and must come before the desired outcome of the study.

GCP training is not compulsory for investigators undertaking non-CTIMPs, but LJMU may request that investigators to undergo GCP training. [Training is available through the NIHR](https://www.nihr.ac.uk/our-research-community/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/).

## UK Policy Framework for Health and Social Care Research

[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/) sets out principles of good practice in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

It is for organisations and individuals that have responsibilities for health and social care research. This includes funders, sponsors, researchers and their employers, research sites and care providers. The policy framework applies to health and social care research involving patients, service users or their relatives or carers. This includes research involving them indirectly, for example using information that the NHS or social care services have collected about them.

For the purpose of the policy framework, research is defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part of the research, such as screening potential participants for eligibility, obtaining participants’ consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of the policy framework. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with the framework. A decision tool that provides a definitive answer about whether a project counts as research under the policy framework is available at [www.hra-decisiontools.org.uk/research](http://www.hra-decisiontools.org.uk/research).

The policy framework acts as a key text, underpinning the conduct of research in the NHS. LJMU expects all research being undertaken within the NHS to be conducted in line with the policy framework. The policy framework has set out standard responsibilities for all parties involved in the set up and conduct of clinical research. This includes the Chief Investigator (CI); employing organisation; funder; Principle Investigator (PI); organisation providing care; participant; researchers; ethics committees; care professionals and the sponsor. These should be read in detail by each person in the study to ensure they understand their responsibilities. In summary;

The Chief investigator (CI) is the overall lead researcher for a research project and is responsible for;

* satisfying themselves that the research proposal takes into account any relevant systematic reviews, other research evidence and research in progress, that it makes use of patient, service user and public involvement where appropriate and is scientifically sound, ethical, legal and feasible;
* satisfying themselves that the research proposal has been submitted for appropriate independent expert (peer) review and revised in light of that review;
* satisfying themselves that, if expected or required, the proposal has been submitted for review by and obtained approval from a research ethics committee and other relevant bodies (e.g. Health Research Authority (HRA) approval);
* satisfying themselves that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project;
* satisfying themselves that the information given to potential participants is in a suitable format and is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research;
* adhering to the agreed arrangements for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee);
* adhering to the agreed arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished;
* starting the research only once the sponsor has confirmed that everything is ready for it to begin;
* adhering to the agreed procedures and arrangements for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct, the participants’ safety and well-being and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments; and
* adhering to the agreed arrangements for making information about the findings of the research available, including, where appropriate, to participants.

Students should not normally take the role of Chief Investigator any level of study, as this function should be undertaken by supervisors or course leaders.

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 has overall responsibility for the research, including:

* identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications and ensuring that research proposals and protocols:
* take into account systematic reviews of relevant existing research evidence and other relevant research in progress,
* make appropriate use of patient, service user and public involvement and
* are scientifically sound (e.g. through independent expert review), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing;
* satisfying itself that the investigators, research team and research sites are suitable;
* ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;
* ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project; and
* ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants;
* ensuring that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins;
* verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;
* putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;
* ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

## The General Data Protection Regulation (GDPR)

The [General Data Protection Regulation](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/) (GDPR) applies to ‘personal data’ meaning any information relating to an identifiable person who can be directly or indirectly identified in particular by reference to an identifier (e.g. from direct identifiers such as a person’s name, date of birth, identification number, online identifier, picture, audio recording, detailed geographic location etc. AND indirect identifiers such as large household size, specialised profession, unusual health conditions, verbatim textual responses to survey questions).This includes more sensitive categories of personal data (sensitive personal data) such as an individual’s race; ethnic origin; politics; religion; trade union membership; genetics; biometrics (where used for ID purposes); health; sex life; or sexual orientation.

Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or data that has been anonymised - where identifiers/links to identifiers have been removed and an individual cannot be identified even when the data is combined with other data).

GDPR principles:

1. processed lawfully, fairly and in a transparent manner in relation to individuals;
2. collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes;
3. adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
4. accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;
5. kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals; and
6. processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.”
7. the controller shall be responsible for, and be able to demonstrate, compliance with the principles.

In order to maintain confidentiality of participants’ personal data, researchers often code the data/information, link the code to information that can be used to identify the individual and store the link separately and securely from the coded data. This is known as pseudonymisation. [Pseudonymised data](https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf) is still regarded as personal data because the data is identifiable to the researcher[s].

## The Mental Capacity Act 2005

[The Mental Capacity Act](http://www.legislation.gov.uk/ukpga/2005/9/contents) was introduced to protect those who lack the capacity to consent to provide legal protection in all areas of their life, not just healthcare or research. There are 5 underlying principles to the act;

1. A person must be assumed to have capacity unless it is established that he lacks capacity.
2. A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
3. A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
4. An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.
5. Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.

The act applies to all people who lack the capacity to consent, whether this is permanently (learning disabilities, progressive and degenerative diseases) or temporarily (a severe episode of mental illness or following a traumatic injury).

If an investigator plans to undertake research involving participants who lack the capacity to consent extra considerations must be given to consenting and withdrawing procedures, and also to the potential risks and benefits to the participants. [The HRA provide extensive guidance on consenting participants who lack capacity](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/).

Any research involving participants who lack the capacity to consent must be directly linked to the impairing condition or its treatment (for example a new emergency care procedure or research into the quality of life of Alzheimer’s patients would be appropriate pieces of research to undertake, but research into a new vision test may not be appropriate).

## The Human Tissue Act 2004

[The Human Tissue Act (2004](http://www.legislation.gov.uk/ukpga/2004/30/contents)) was introduced to ensure that all human material was removed, processed and stored lawfully. The act is enforced by the [Human Tissue Authority](http://www.hta.gov.uk/).

The act covers all ‘relevant material’ which is any material which consists of or includes human cells. This does not include embryos outside the human body, gametes or hair and nail from the body of a living person.

The act covers 7 sectors including, post-mortem, public display, transplants and research. All investigators must familiarise themselves with the act as a whole, as well as [Code of Practice E Research and Standards](https://www.hta.gov.uk/hta-codes-practice-and-standards-0).

The research Code of Practice states that consent must be gained from participants who provide human materials for the purpose of a research study, and the material can only be used for the purposes consented for. Tissue cannot be stored and used for future research projects unless the participant has explicitly agreed to this. If you wish to remove, store and use material from a deceased person explicit and specific consent must be gained from the deceased person before their death or from a legally nominated representative.

Staff must ensure they are familiar with the [LJMU Human Tissue policies and related documentation](https://www.ljmu.ac.uk/ris/research-ethics-and-governance/human-tissue-governance)

# Sponsorship of LJMU Clinical Research

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.

The UK Policy Framework for Health and Social Care Research requires that all research projects must have a sponsor identified and declared prior to the commencement of the project. All Clinical Research involving the following will require sponsorship under the UK Policy Framework;

* NHS Patients
* NHS Staff (as participants)
* NHS Premises
* NHS Resources

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 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.

## LJMU sponsorship approval process for clinical research

A request for LJMU to act as sponsor can be made in accordance with the LJMU Standard Operating procedures – SOP001 LJMU Sponsorship Application and Approval (Clinical Research). Once the request for sponsorship has been made, the sponsor will review the request in order to decide whether to sponsor the research or to request changes be made before sponsorship can be approved.

The purpose of the sponsor review is to

* Check that the proposed research and protocol are appropriate
* Check that the CI has completed the relevant training
* Assess the quality of the application to anticipate REC queries
* Ensure appropriate information is provided to participants in outward facing documents
* Confirm that the information sheets and consent forms follow HRA REC guidelines
* Ascertain that requisite legislation and guidance is being applied
* Ensure LJMU insurance will cover the participants for harm

# Research Ethics Committee Approval

The Declaration of Helsinki sets out the ethical principles for medical research involving human subjects – including research on identifiable human material and data. It is perhaps the most important document in the history of research ethics.

The Research Ethics Committees (RECs) recognised for reviewing and approving NHS Research in the UK is the Health Research Authority (HRA) NHS REC. The role of the NHS REC is to safeguard the rights, safety, dignity and well-being of research participants by ensuring that research proposals have been designed and will be conducted in accordance with the Declaration of Helsinki. If they are satisfied that this is the case, they will offer a ‘favourable opinion’ for the research (often referred to as ‘REC approval’).

NHS RECs are entirely independent of sponsoring organisations and investigators.

## When do I need it?

As a general rule of thumb, all research taking place within the NHS requires NHS REC approval. The HRA have a useful [decision tool](http://www.hra-decisiontools.org.uk/ethics/) available via their website if you are unsure as to whether your research project requires NHS REC approval.

For researchers undertaking research outside of the NHS (e.g. international only studies or studies recruiting students) Ethical Approval must be obtained from the [University Research Ethics Committee](https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-ethics/university-research-ethics-committee-urec/urec-meeting-dates). In the case of International studies Ethical Approval will also be required from each participating country.

## How do I know if my project is ‘research’?

The term ‘research’ has a specific meaning in the UK Policy Framework for Health and Social Care Research as defined by the HRA and if a proposal does not fall within this definition it will not require review by a NHS REC. If a proposal is not classified as ‘research’ by the HRA, ethical approval may still required from the University REC.

Activities which do not fall within the definition of ‘research’ but may still require ethical approval from the University REC include:

* Audit
* Service Evaluation
* Case Studies or Case Reports
* Consensus Methods
* Patient & Staff Surveys

Applications for NHS REC review may also be made on a voluntary basis for research tissue banks/biobanks and research databases.

The HRA website has useful guidance on [categorising research proposals and on defining research](http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/). We recommend that this tool is consulted at the earliest stages of study design and set up to help determine the required approvals.

If having considered the guidance you are still unsure whether your project is classified as research, please send a 1 page summary protocol to the HRA queries line (HRA.Queries@nhs.net).

## How do I apply?

Applications for NHS REC approval and for other approvals necessary for a project (see below), can be made online via the Integrated Research Application System ([IRAS](https://www.myresearchproject.org.uk/)). This system streamlines the process for seeking relevant approvals by ensuring that, as far as possible, details only need to be entered once for a single project and much of the form then self-populated.

Once you have received confirmation of LJMU sponsorship approval the [Central Booking Service](https://www.hra.nhs.uk/about-us/committees-and-services/central-booking-service/) should be contacted to arrange NHS REC review. It is highly recommended that you arrange a time when you can attend, to answer any queries the NHS REC may have. Students must be accompanied by their supervisor at NHS REC committee meetings.

When the booking process is completed, you will be given the name of the NHS REC, a NHS REC reference number and a submission date. The application should be submitted to the NHS REC the same day of making the booking.

At the meeting of the NHS REC, between 7 and 18 members will be present and will ask questions surrounding any ethical issues arising from your application. You should be prepared to clarify any ethical issues that may be raised.

## How long does it take?

A NHS REC is required to give an ethical opinion on an application within 60 calendar days from receipt of a valid application. Where further information is required to give an opinion, the NHS REC may make a request in writing for further information. The clock will be suspended pending receipt of this information.

# Other Regulatory Approvals

## HRA Approval

[HRA Approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/) is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent NHS REC opinion provided through the UK Health Departments’ Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study. HRA assessment is carried out in parallel with NHS REC review. Further details can be found on the [HRA website](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/).

## MHRA Notification of no Objection for Devices

Studies involving non-CE marked medical devices carried out in the UK may be regulated under the Medical Devices Regulations 200221 and will require approval from the MHRA. As such a Declaration of No Objection is required for clinical investigations (trials) of medical devices. This includes non-CE marked devices, CE- marked devices which have been modified or are being used outside their intended purpose(s), non-CE marked devices developed in-house or ‘off-label’ use. The MHRA will charge for each application as specified below;

|  |  |
| --- | --- |
| **Type of Application** | **Fee payable. The figure in brackets denotes charge for re-application** |
| Class I, IIa, or IIb other than implantable or long- term invasive | £3,820 (£2,920) |
| Class IIb implantable or long-term invasive, Class III, and active implantable | £5,040 (£3,570) |

## Confidentiality Advisory Group (CAG)

[CAG approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/) is required for using identifiable patient data without consent. Applications to CAG must be viewed as a last resort, and all other steps to conduct the research must have been exhausted.

## Administration of Radioactive Substances Advisory Committee (ARSAC) Certificate

An [ARSAC](https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee) certificate is required for any clinician (at each research site) who wishes to use ionising radiation or administer radioactive medicinal products to human subjects. This does not apply to routine X-rays or CT scans.

## Gene Therapy Advisory Committee (GTAC) Approval

[GTAC](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/gene-therapy-advisory-committee/) has UK-wide responsibility for the ethical oversight of proposals to conduct clinical research involving gene or stem cell therapies.

## Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) Approval

If the research involves (or might involve) ionising radiation (diagnostic x-rays, CT scans, DXA scans, radiotherapy, radionuclide imaging), the proposal will need to be [reviewed by a Clinical Radiation Expert and Medical Physics Expert](https://www.gov.uk/government/publications/the-ionising-radiation-medical-exposure-regulations-2000) who will sign-off on any use.

## Human Tissue Authority (HTA) Licence

The storage of human tissue (or ‘relevant material’) for research purposes will require a licence from the HTA in certain circumstances. The Faculty of Science has an [HTA research licence](https://www2.ljmu.ac.uk/RGSO/93204.htm). To undertake research under the licence please contact the LJMU HTA Tissue coordinator

## National Offender Management Service (NOMS)

If research aims to recruit participants who are currently involved with the prison and probation services within the UK then approval from [NOMS](https://www.gov.uk/government/organisations/national-offender-management-service) must be obtained. Applications will be reviewed in line with

NOMS current priorities, resource implications, overlap with current research and ethical considerations.

## Human Fertilisation & Embryology Authority (HFEA)

The [Human Fertilisation and Embryology Authority](https://www.hfea.gov.uk/) is the UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. HFEA can issue research specific licences for research involving embryos. These licenses can last up to three years. If you are planning to undertake any research of this kind please contact LJMU REG in the first instance and visit [http://www.hfea.gov.uk/177.html.](http://www.hfea.gov.uk/177.html)

# Conducting your Research

You will need the following documents in order to begin recruitment to research sponsored by the University;

* LJMU Sponsorship Approval (pre-regulatory approval)
* NHS REC Favourable Opinion (or University REC Approval and/or international site(s) ethical approval as appropriate)
* HRA Approval
* MHRA CTA / MHRA Notice of No Objection (if required)
* Any other required approvals as defined at application stage
* Confirmation of Capacity and Capability from the lead NHS Trust
* Signed contracts / agreements

Once LJMU REG have received these documents you will be issued with a Sponsor Permission to Proceed Notification. This will state that all regulatory and governance requirements have been met, and the study can be set-up and open to recruitment. Further R&D approvals will be required from each NHS site you intend to open.

The CI is responsible for NHS site set-up – for details, please refer to SOP003 Delegation of Roles and Responsibilities for LJMU Sponsored Clinical Research.

It is important that you make contact with LJMU REG in the following circumstances:

* The date the first participant is recruited into the study.
* When an amendment is due to be submitted.
* Any occurrences of Serious Adverse Events (SAE) or Suspected Unexpected Serious Adverse Reactions (SUSAR);
* Where the research has been suspended or terminated by the authorities or trial specific committee;
* Where a research participant dies in the course of a research project;
* Where there are concerns regarding research misconduct, a breach of GCP, protocol or procedure, a breach of any related legislation (such as the Human Tissues Act) or a breach of confidentiality or data protection laws;
* Providing annual or periodic progress or safety reports to a REC or regulatory authority;
* When a project has closed to recruitment including any early terminations or temporary halts;
* When a project has formally completed an End of Study Declaration should also be submitted.

Details of CI roles and responsibilities are provided in SOP003 Delegation of Roles and Responsibilities for LJMU Sponsored Clinical Research. These responsibilities include sponsorship approval, regulatory approvals, REC approvals, contracts/agreements, site set-up, maintaining a study Master File, Delegation at site, amendments, annual reports, safety reports, SOPs, international research, End of research, close out, archiving etc.

You should also contact LJMU REG if you have any queries or concerns or there is any information about your research that you think we should know about.

# Glossary of Terms

**AE** Adverse Event

**AR** Adverse Reaction

**ARSAC** Administration of Radioactive Substances Advisory Committee

**CI** Chief Investigator

**CRF** Case Report Form

**CTA** Clinical Trials Authorisation

**CTIMP** Clinical Trial of Investigational Medicinal Product

**CTU** Clinical Trials Unit

**GCP** Good Clinical Practice

**GTAC** Gene Therapy Advisory Committee

**HTA** Human Tissue Authority

**HRA** Health Research Authority

**ICH GCP** International Conference on Harmonisation Good Clinical Practice

**IMP** Investigational Medicinal Product

**IRMER** Ionising Radiation (Medical Exposure) Regulations 2000

**MHRA** Medicines and Healthcare Products Regulatory Agency

**PI** Principle Investigator

**REC** Research Ethics Committee

**RGF** Research Governance Framework

**SAE** Serious Adverse Event

**SAR** Serious Adverse Reaction

**SSAR** Suspected Serious Adverse Reaction

**SUSAR** Suspected Unexpected Serious Adverse Reaction

**LJMU** Liverpool John Moores University

# Associated Documents and References

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

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

GCP training - https://www.nihr.ac.uk/our-research-community/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/

General Data Protection Regulation - https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/

Good Clinical Practice - <https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf>

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

HFEA - <https://www.hfea.gov.uk/>

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

HRA central Booking Service - <https://www.hra.nhs.uk/about-us/committees-and-services/central-booking-service/>

HRA defining research - <http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/>

HRA guidance on the mental capacity act - <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/>

HTA Codes of Practice and Standards - <https://www.hta.gov.uk/hta-codes-practice-and-standards-0>

Human Tissue Act - <http://www.legislation.gov.uk/ukpga/2004/30/contents>

Human Tissue Authority - <http://www.hta.gov.uk/>

ICO anonymisation - <https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf>

IRAS - <https://www.myresearchproject.org.uk/>

IRMER - <https://www.gov.uk/government/publications/the-ionising-radiation-medical-exposure-regulations-2000>

LJMU Human Tissue Documentation - <https://www.ljmu.ac.uk/ris/research-ethics-and-governance/human-tissue-governance>

LJMU REG website - <https://www.ljmu.ac.uk/ris/research-ethics-and-governance>

Mental Capacity Act - <http://www.legislation.gov.uk/ukpga/2005/9/contents>

NHS REC decision tool - <http://www.hra-decisiontools.org.uk/ethics/>

NOMS - <https://www.gov.uk/government/organisations/national-offender-management-service>

UREC - <https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-ethics/university-research-ethics-committee-urec>

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/>

# Monitoring and Audit

Compliance with this handbook 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 |