London South Bank University Code of Practice for Research Ethics and Integrity

University Ethics and Integrity Committee

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Section 1: Overview

1.1. Introduction

London South Bank University is committed to maintaining the highest standards of research governance aligned with our EPIIC values of Excellence, Professionalism, Integrity, Inclusivity and Creativity. This Code of Practice serves as a guide for anyone conducting research at or with LSBU, outlining procedures and practices that support the University's commitment to research excellence.

Research Integrity refers to all factors that contribute to good research practice including the research environment. The UK Concordat to support Research Integrity sets out five core areas: **Honesty** in methods, data collection, findings, attribution, and interpretation; **Rigour** in the selection and use of appropriate methods, accurate interpretation and communication; **Transparency** in conflicts of interest, methods used, and accessibility of findings (including null results); **Care** and respect for all research stakeholders including their cultural and environmental contexts; **Accountability** to ensure all stakeholders foster a responsible research culture and environment and address breaches of this Code of Practice.

The principles used for formal research ethics review are the "Belmont Principles" described below:

Autonomy – every individual has the right to think independently and act freely to decide to participate, continue or withdraw from a research study without hindrance. This includes researchers ensuring that participants are fully informed prior to their giving consent to participate and respecting their decisions. **Beneficence** – research must have value to individuals, groups, communities or to add to the knowledge base. It is unethical to conduct research that cannot be demonstrated to be of benefit or have a purpose. This principle can be extended to include natural ecosystems **Non-Maleficence** – participants and researchers should always be protected. Associated risks and how these will be minimised must be considered and articulated. **Distributive justice** – all research is conducted fairly and with respect for the human rights of all involved; benefits and burdens are shared equitably.

It is the duty of every researcher, staff, student, supervisor, line manager, to ensure compliance with all legal obligations in relation to each research project being undertaken. This includes compliance with:

- Human Rights Act 1998
- Data Protection Regulations including the <u>UK General Data Protection Regulations (UK GDPR)</u> and the Data Protection Act (2018)
- Mental Capacity Act 2005
- Health and Safety at Work etc. Act 1974 and related Regulations
- Freedom of Information Act 2000

Further reading:

<u>UK Concordat to support Research Integrity</u> <u>UKRIO Research Ethics support and review in research organisations</u>

1.2. Scope

This policy encompasses the scientific and scholarly research undertaken by staff and students at London South Bank University, regardless of the funding source. It applies to all aspects of the research process, including designing studies, securing funding, collaborating with external organisations, obtaining ethics approval, conducting research, and reporting or disseminating findings (see also section 3 for potential exemptions). This code of practice must be adhered to by all groups below henceforth referred to as *researchers*:

- All staff including academic, research, visiting, professional staff;
- All students including postgraduate research students, students on taught programs, visiting students registered elsewhere, as well as their supervisors;
- All those wishing to conduct research with members of our university community, including patient and public researchers, visiting, honorary or Emeritus staff, contractors and consultants.

We acknowledge that there are a range of professional associations, groups and funders with differing ethical traditions, requirements and guidance. The University expects researchers to acknowledge and follow the appropriate ethical guidelines from their professional or regulatory body, or disciplinary association.

Importantly, where different applicable guidelines exist, the most stringent guidelines should be followed.

1.3. Structure of LSBU Research Ethics and Integrity

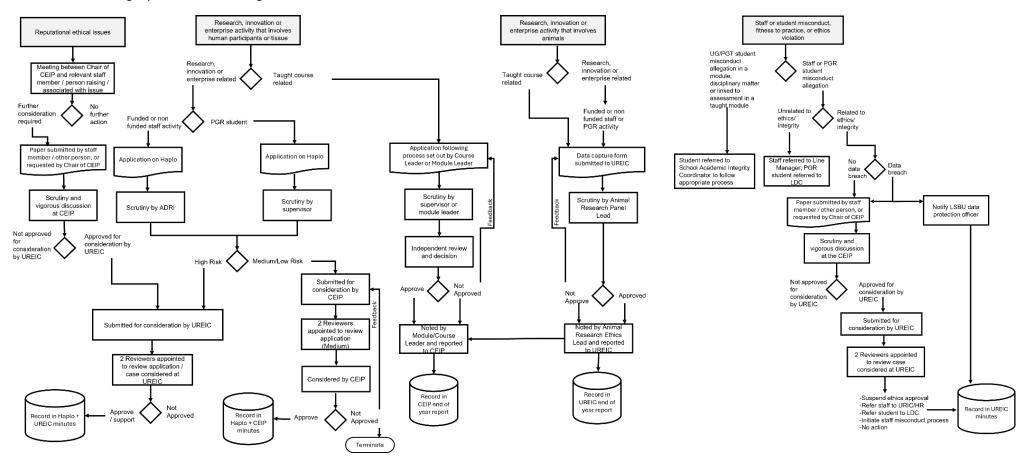
The University Ethics and Integrity Committee (UEIC) comprises a Chair and deputy Chair, the Chair of each College Ethics and Integrity Panel (CEIP), a postgraduate research student representative and an independent member who is not an employee of LSBU. The UEIC reports to the University Research and Innovation Committee.

Each College Ethics and Integrity Panel (CEIP) comprises a Chair and deputy Chair, at least one panel member representing each School in the College, a panel member from a different college, a postgraduate research student representative and an independent member who is not a student or researcher at LSBU. The CEIPs report to UEIC.

The majority of day-to-day decision-making around ethics applications is conducted by the CEIPs. However, the UEIC considers applications that are deemed to be of high risk (as identified during the application process) as well as reputational ethical issues referred from to UEIC. The UEIC conducts reviews of the work of the CEIPs to identify and share good practices; periodically updates the code of practice to keep in line with developments in the field; and manages any other ethics and integrity issues that arise in research and enterprise at the university. It also reviews and ratifies approvals granted by universities where LSBU researchers are collaborators, or where such universities wish to recruit from LSBU staff or students.

Each taught degree teaching team identifies an ethics representative who processes the ethics applications from students on taught courses, who keeps an audit trail of reviews and decisions for each student. The ethics representative reports annually to the respective CEIP. See also the Ethics and Integrity Process Flow Diagram.

Ethics and Integrity Process Flow Diagram:



Ethics applications should always be reviewed by two staff members who are independent of the research project. One member will serve as the reviewer, providing a detailed assessment of the application, while the other will act as the decision maker, ensuring an impartial and well-informed judgment. Applications reviewed in this manner must then be presented to the respective CEIP for discussion and minuting.

For ethics applications involving students on taught degrees, it is acceptable for the supervisor (who is not independent of the research project) to serve as the reviewer. However, an independent staff member must act as the decision maker and may request an additional independent review if deemed necessary.

The processing of all ethics applications must be documented and auditable. Records should include the research team's identification, study title, research proposal, ethics application (including all participant-facing documents), submission dates, communication logs, feedback provided to the applicant, and the final decision. Students on taught degrees conducting research for their dissertation should identify themselves to participants as *student-researchers* to clarify their status.

Further reading:

LSBU Terms of Reference for UEIC LSBU Terms of Reference for CEIP

1.4. Auditing and Maintaining Records

The University Ethics and Integrity Committee audits its processes to identify areas for improvement and ensure the highest standards of research ethics and integrity are maintained. Therefore, all researchers, College Ethics and Integrity Panels (CEIPs) and ethics representatives on taught degrees must maintain an auditable trail of decisions for all research governed by this Code of Practice.

Regular audits take place on the CEIP processes (previously School Ethics Panels). These are typically audited by the Chairs of a different CEIP and the UEIC and involve the applications submitted to the Research Manager software (currently Haplo).

In addition, every year the CEIP audits the ethics applications processed as part of taught degrees (e.g., final year Dissertation or Research Project). These ethics applications and their processing must therefore be recorded by the ethics representative for the taught course and it should be available for auditing (e.g., in the University's virtual learning environment).

UEIC processes undergo periodic external audits, with the most recent conducted in 2024. Additionally, UEIC publishes an annual report detailing all ethics and integrity activities carried out at the university during the preceding academic year.

1.5. Insurance

Insurers accept that research is part of the normal activities of a university. Consequently, the University's liability insurances will in general cover incidents arising from the proper conduct of research. However, policy terms, conditions and exclusions apply and sometimes the research will need to be referred to the insurer to guarantee cover or extend cover.

Research that needs to be referred to the insurers to guarantee cover. Please do this in advance of submitting an ethics application:

- Children (Under the age of 18) (excluding pure questionnaire / interview based).
- Vulnerable adults* (excluding pure questionnaire / interview based).

- Pregnant women (excluding pure questionnaire / interview based).
- Dangerous environments*.
- Any project which would be classed as invasive i.e. any samples taken (excluding straight forward blood taking)
- Significant overseas stays over 12 months.
- Invasive Medical Device/Product Products that the University have manufactured to use in research. Invasive would be anything that is implantable and/or penetrates the body.
- US Exposure US Exposure Referral required when research conducted within the US. If the University is collaborating with a US entity but the University's operations remain in the UK it doesn't need to be referred, unless the research involves any of the above.
- If the University have manufactured a product which is being exported to the US, for example an invasive device a referral will be required.
- Clinical Trials.

Research that is not covered by LSBU's insurance policy. If researchers wish to pursue these topics, please contact the insurers in advance of submitting an ethics application. (Research based on questionnaires or interviews about the topics below are covered by insurance.)

- Blood products (blood, blood components, blood preparation) and products of human or animal origin (products consisting of, or manufactured from e.g. body fluids, organs, tissues, cells etc...) for the medical-pharmaceutical purpose/application/use.
- Contraceptives.
- Pregnant or breastfeeding women, fertilization.
- Projects with over 10 years duration.
- Immunomodulators and vaccines.
- Lifestyle producs (e.g., Viagra, weight loss products, cosmetic surgery, anti-adiposis, performance-enhancing means/remedy (so-called nootropics), vaping/e-cigarettes, use of nicotine).
- Tissue and cell technology.
- Transplant, xenogenic pharmaceutical products, xenogenic transplantation.
- Antisense therapy.

Requests for clarification or additional specialist cover should be directed to the Corporate Procurement Unit in the first instance. Please do this in advance of making an ethics application.

Researchers are reminded that insurance cover is not a substitute for carrying out appropriate <u>risk</u> <u>assessments</u> or for getting all necessary ethical approvals in place before commencing fieldwork.

1.6. Academic misconduct and Disciplinary procedure

The University reserves its position on dealing with breaches of this Code or failure to comply with it. For staff, failure to comply with the code may lead to disciplinary action (see LSBU Disciplinary Policy & Procedure). For students, failure to comply with the code may constitute Academic Misconduct

(see <u>LSBU Student Academic Misconduct Procedure</u>). In all cases, data collected may not be allowed to be used and in extreme circumstances civil or criminal liability may arise.

The LSBU Procedure for the Investigation of Misconduct in Research will be applied to address any identified breaches of this code, in alignment with the UKRIO Procedure for the Investigation of Misconduct in Research and LSBU procedures.

Carrying out research without the necessary ethical approval constitutes misconduct for staff and students, is likely to prejudice insurance cover and may also prejudice funding or other commitments from third parties. Retrospective ethical approval for investigations is not normally granted. Participation as a researcher in a clinical trial without having secured ethical approval may expose the University to unnecessary liability and is a criminal offence under the Medicines for Human Use (Clinical Trials) Regulations 2006. Research with species protected by the Animals in Scientific Procedures Act 1968 and its amendments (which includes all vertebrates, and cephalopods) is not permitted at LSBU. Other animal research is discussed in the relevant section below.

Further reading:

LSBU Student Academic Misconduct Procedure
LSBU Disciplinary Policy and Procedure
LSBU Procedure for the Investigation of Misconduct in Research
UKRIO Procedure for the investigation of Misconduct in Research

Section 2: Integrity

2.1. Open Science (FAIR principles)

Open science has come to mean the practices and strategies that increase transparency in research including the sharing of research outputs publicly and freely. Research publications and other outputs and their associated data created by LSBU researchers should be made available open access wherever possible. There are exceptional circumstances where research outputs may not made publicly available and this should be clarified on the ethics application form. LSBU's Open research policy requires all academics to deposit accepted research outputs into the LSBU Research and Innovation portal within three months of acceptance.

Moreover, the principles of open science emphasise that outputs should be: **Findable** (making research outputs discoverable by the wider academic community and the public); **Accessible** (using unique identifiers, metadata and a clear use of language and access protocols); **Interoperable** (applying standards to encode and exchange data and metadata); **Reusable** (enabling the repurposing of research outputs to maximise their research potential).

To strengthen rigour, all researchers at LSBU should consider pre-registering their research with an Open Science registry such as the Open Science Framework (OSF), UKRN Open Research Platform, Prospero, or others, depending on the nature of their research. Trials can also be registered on the ISRCTN or ClincalTrials.gov. Pre-registration helps ensure transparency, accountability, and reproducibility by specifying the study design, hypotheses, and analysis plans before data collection begins. Researchers can also record their findings ahead of publication by publishing pre-prints of their manuscript at the same time and the manuscript is submitted to publication. Pre-prints allow for immediate dissemination and open peer feedback but unreviewed work may lead to inaccuracies or misinterpretations so the researcher may invite peer review but should exert caution when disseminating the results.

To strengthen author rights at LSBU to reuse their work and share it widely immediately on publication, we use a Rights Retention Strategy. To this effect, authors should insert the following in the funding or acknowledgements section of the submission and covering letter/email: "This work was funded by [Funder] [grant number]. For the purpose of open access, the author has applied a Creative Commons Attribution (CC BY) licence to any Author Accepted Manuscript version arising." If you are unfunded insert the following in the Acknowledgments section of your submission manuscript and covering email: "For the purpose of open access, the author has applied a Creative Commons Attribution (CC BY) licence to any Author Accepted Manuscript version arising". For more information consult the LSBU library research support.

Further reading:

LSBU Open Research

UKRIO Open Research

2.2. Data Management

It is important for all researchers to consider how their research data will be (or has been) created, managed and used to conform to legislative, regulatory, ethical, and other requirements at the local, national, and international level (see also 4.3).

Every research project that involves the collection and/or use of research data should have a data management plan (DMP). This is a structured document describing how data will be created,

managed and used during the life of a research project and beyond, with plans for data sharing and preservation. For postgraduate research students, a data management plan is a requirement at the RES2 stage and for externally funded research this is a requirement at the award stage before the data collection starts.

When applying for ethics approval, researchers must show in their applications that they have considered each type of data their research will collect, use and store, particularly:

- Type of data (e.g. experimental measurements, models, records and images)
- Methods and timeframe for data storage (i.e., specifying when each data set will be made (pseudo)anonymous and when it will be made public)
- Methods for data sharing (i.e., planned mechanisms for making data available, including through deposition in existing public databases or on request, including access mechanisms where appropriate)
- Secondary use (i.e., further intended or foreseeable research uses for each dataset and how it will be shared)
- Proprietary data (i.e., any restrictions on data sharing due to the need to protect proprietary or patentable data)

For research involving human participants, researchers must clearly describe in their ethics application how they intend to collect, use, store, and share data. They should also specify how they will protect the data against loss, corruption, unauthorized access, or modification, ensuring compliance with Data Protection Regulations. This information must be communicated to participants through the information sheet, and consent for the intended use of the data must be obtained via the consent form prior to initiating any data collection (see Templates for these documents). Where possible data collected for research should be anonymised at the earliest opportunity.

Projects using previously collected datasets (e.g., sensitive or commercially restricted) also require proper data management to ensure that they are managed in accordance with commercial agreements and legislation.

Further reading:

LSBU Research Data Management Policy

Contact for data management plan: researchdata@lsbu.ac.uk

Contact for data protection officer: dpa@lsbu.ac.uik

2.3. Artificial Intelligence

The development and use of AI presents important opportunities for research as well as risks. At the moment, AI does not reflect societal values such as fairness, ethics, and data protection and therefore its use and/or development must proceed in a responsible manner. Anyone looking to use AI in their research should be abreast with its limitations (e.g., biases, fabrication, intellectual property infringement) to appreciate and mitigate the risks of its use in their research practice.

Care must be taken to ensure data handling by AI complies with data protection regulations and ethical frameworks (anonymity and consent). Care should also be taken not to breach IP agreements held with third parties (by sharing data which then becomes part of training sets). The potential use of AI software for data analysis in a research project must be disclosed in the ethics application so the software can be checked for regulatory abidance (e.g., in the transcription of speech into text). The use of AI in content creation should be declared in resulting outputs to ensure transparency.

Care must be taken to use AI critically given its limitations with accuracy and transparency (e.g., AI software is known to fabricate results and often fails to attribute ideas to its authors). While AI can support researchers' and students' ability to communicate in written non-native languages it is paramount that research teams use critical reasoning during its use.

Researchers should also be mindful of the significant energy and water required to run AI models and their environmental impact, and therefore use them responsibly.

Further reading

<u>UKRI Transforming our world with AI: UKRI's role in embracing the opportunity</u> Sense about science, responsible handover of AI framework and guidance

2.4. Safeguarding good scientific practice

Research groups and leaders should create environments that are conductive to honesty and good scientific practices in research, for instance critically discussing methodologies and findings. It is unacceptable for line managers, supervisors or external partners such as commercial companies to pressure researchers into producing research results as this may act as pressure to fabricate results.

Researchers are responsible for maintaining professional standards, documenting methods and results, questioning findings, and honestly attributing others' contributions.

Primary data (i.e., information collected directly by the researcher) should be retained at the University for reproducibility and verification (see also 2.2). Storage methods should ensure data availability for at least five years after research completion. Some research areas require data availability for ten years and best practice is to keep anonymous data indefinitely to safeguard against fabrication. Data collected by students may need to be retained and stored by their supervisor at the University. Other datasets should also be retained and stored at the University whether or not they can be made publicly available. Laboratory notebooks are crucial for recording data, procedures, and materials used. Any errors in notebooks should be crossed out and initialled, not erased. All laboratory material and reagents, such as cell lines, antibodies, inhibitors, plasmids belong to the University (not the researcher). Therefore, the researcher must label all materials and reagents clearly and show their storage location to their Director of Studies, Supervisor or Line Manager before they leave.

Further reading:

BBSRC: Safeguarding Good Scientific Practice
MRC: Principles and guidelines for good research practice
UK Concordat to Support Research Integrity
LSBU Safeguarding Good Scientific Practice

2.5. Authorship recognition and fair attribution

Ensuring individuals are recognised for their contributions to research articles is essential to maintain high standards of integrity. Authorship and byline order should be agreed verbally at the start of each research project with the first and last authors clearly identified.

On occasion, research teams may want to invite other individuals to contribute to a project that is already in the data collection, analysis or writing up stage. This would ideally be done with agreement of the entire research team. When inviting new individuals to join an existing project, it must be made clear from the outset whether their contribution will lead to co-authorship and what are the expectations for the contribution.

Technicians, students, research assistants and other colleagues should be recognised as authors provided they make a significant contribution to a research project. In cases where contributors have made a smaller contribution to the research project, the research team should consider including an acknowledgment in the relevant section of the output. The CREDIT TECHNOLOGY provides a useful guide on how to identify what constitutes a fair attribution to research.

The Director of Studies or Principal Investigator would normally lead the discussion on authorship and byline order at the start of the project and lead any later discussion regarding the proposed integration of other co-authors in the byline.

Further reading:

LSBU Technician Commitment Action Plan

2.6. Trusted Research and Export Control

International research collaborations are welcome and encouraged, but they must also follow the guidance published by the UK government on Trusted Research and Export Controls. This guidance aims to protect staff and their research from misuse, and from the exploitation or theft of personal information, sensitive research and intellectual property by organisations which operate in nations that hold different ethical and democratic standards from the UK. The scope of Trusted Research and UK Export Control framework is particularly focused on strategic goods, software, technology, data and knowledge that could be used or modified for military or dual-use. The LSBU policy asks staff to disclose all international collaborations and exercise caution in choosing collaborators, sharing data and publishing research.

LSBU staff and students working with international collaborators must submit a Global Research and Innovation Disclosure form (on Connect, find Trusted Research page) following the LSBU's guidance on Safe and Secure Partnerships (Export controls, National security and sanctions policy), and adhere to the UK Government Trusted Research guidance for academic staff.

Additional reading:

NPSA: Trusted Research guidance for academics
GOV.UK: Export controls applying to academic research
LSBU Trusted Research guidance

Section 3: Ethics - potential exemptions

All University activities must adhere to principles of ethics and integrity. However, certain activities may be exempt from requiring formal ethics approval.

3.1. Online personal data and social media/internet research

Typically, the use of online personal data and social media is *not* exempt from LSBU ethics oversight. The data for these studies could include posts made in online forums, videos posted to social media channels or blogs/vlogs freely available online. Although posts may be made under a pseudonym it can not be assumed that the posts are anonymous because they may be linked to an account,

several posts combined may identify the person and the person's identity may be known within their social network even if they are unknown to the researcher. Case by case consideration of individual studies is needed as ethical guidance here is based on the principles outlined below, the benefits of the research project and the risks to the individuals who provided the data. Researchers should contact the <u>data protection officer</u> for advice on the specifics prior to submitting ethics approval.

Identifiable and potentially identifiable online personal data, whether held on computer, on a publicly available website, on social media or in hard copy, closed-circuit television (CCTV), audio or video recordings, or email, are subject to data protection regulations. This would normally mean informed consent is required from the individual who can be identified to use their words/image/online content for research purposes.

It cannot be assumed that by sharing their data shared on public social media a data subject is intending for or has given consent for that data to be used for other purposes. In addition, the exemptions that can allow data to be used for research do not apply if the data is 'likely to cause substantial damage or substantial distress to a data subject' (DPA 2018). It is therefore best practice to obtain consent from individual users when processing identifiable personal data. For children under the age of 13 consent is required from the parent or guardian (see also Consent).

Personal data should be recognised here as different from expert information from journalists, politicians, academics, and other public figures, who are named in their social media accounts. When acting as experts in their field, their work (e.g. forum posts or blogs), should be given full recognition, and cited as any other publication. This, however, only applies when the public figure is discussing their area of expertise, not their private life or personally sensitive information.

If data taken from publicly available online sources are anonymous (e.g. web forum posts, some YouTube channels), a "low risk" ethics application is advised. This is to ensure that the principle of "fair processing" is being met and to allow the researcher to demonstrate that they are only taking data from anonymous, online sources which have an age limit of 13 to register. The researcher may be asked to demonstrate that the website used to harvest data requires contributors and content creators to be aware of the 'fair use' principle (https://www.gov.uk/guidance/exceptions-to-copyright#non-commercial-research-and-private-study- accessed June 2024). This allows copyrighted material to be reused for non-commercial research and educational purposes.

If you have any questions or are unsure about how data protection regulations apply to your research please contact the Data Protection Team for advice DPA@lsbu.ac.uk

3.2. Use of secondary data

The Economic and Social Research Council (ESRC), Medical Research Council (MRC) and NHS (National Health Service) all have guidelines on the use of secondary data, and we advise all researchers considering the use of such data to consult these alongside with the guidelines below (which draw on these sources, in particular ESRC guidance).

Secondary data includes: a) Archival data. The use of archives is governed by the Code of Ethics for Archivists – <u>ARA in the UK</u>; b) Publicly available and secure datasets which exist already. In particular, anonymised records and data sets that exist in the public domain do not require ethical review, although see section 3.1 for the use of online content taken from social media. Specific examples include Office for National Statistics or the UK Data Archive data where the source contains data where appropriate permissions have already been obtained and where it is not possible to identify

individuals from the information provided.; and c) potentially also material available from media and other sources (e.g., newspaper articles etc; see 3.1).

Published biographies, newspaper accounts of an individual's activities and published minutes of a meeting would not be considered 'personal data' or sensitive personal data requiring ethics review, nor would other data which are explicitly publicity driven such as a biography or a press release.

The use of secure (e.g., not in public domain) data which is not and cannot be anonymous or NHS data should be submitted for ethics review, and evidence that adequate permissions to use the data are in place should be provided. In the case of historical archives, there will usually be separate ethical approval processes at each archive which researchers need to follow.

When data has been collected by a third party, but it is not clear (or reasonable to assume) that those providing the data understood it may be used for research purposes, an ethics application should be submitted for review.

Research using anonymized LSBU student data may be conducted because, as part of their enrolment, students are required to read and accept the Student Privacy Notice. This notice explicitly states that student data may be used for various purposes, including research.

In addition, the use of NHS data with patient identifiable information obtained without explicit consent needs NHS approval.

Any research which involves the subject of terrorism should be submitted to the University Ethics and Integrity Committee for consideration, and follow procedures laid down in the LSBU Prevent policy. In addition to the usual considerations, the applicant should carefully assess the risks to the research team and develop appropriate mitigation strategies.

3.3. Getting ethical approval from external agencies including the NHS

3.3.1. Health Research Authority (HRA)

Health Research Authority (HRA) Approval is for all project-based research that involves NHS organisations in England. This includes recruiting staff or patients via GPs or pharmacies as well as recruiting NHS-funded residents in private care homes. HRA brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC).

Do I need NHS REC approval? – Applicants are advised to use the <u>online tool</u> to establish whether they are required to apply for REC approval (and therefore should apply for LSBU approval via the dedicated route).

Research support – A vast array of information and support is available from the HRA <u>online</u>. services. If your research project involves accessing confidential patient information without consent in England and Wales, you will need to additionally apply to the <u>Confidentiality Advisory Group</u> (CAG).

If your project is eligible for HRA Approval there are five main steps that should be completed in this order:

- On the NHS Integrated Research Application System (IRAS), complete a draft research application form but <u>do not submit</u> the application at this stage;
- On the LSBU HAPLO system prepare and submit your ethics proposal and study documents for internal ethics review (using the NHS-related research option on HAPLO);
- Contact the LSBU member of the Finance team responsible for providing LSBU approved insurance (currently the Category Manager, or your procurement officer) to inform them of your intended submission and the LSBU NHS research sponsor (<u>Karen Sanders</u>);
- Book your application in through the <u>Central Booking Service</u> only after you have received approval from the ethics panel at LSBU
- E-submit your applications in IRAS having included the feedback from the LSBU ethics panel.

3.3.2. Approval from other Universities

Usually, LSBU will accept ethical approvals from other universities as ratifications. However, chair's action approval should be sought via Haplo using the route for Amendments to applications that received approval outside the system and including the original approval letter and supporting documents.

3.4. Teaching activities and academic audit

Classroom activities that involve learning or practising research or other techniques are exempt from applying for ethical approval if the data obtained are used only for learning and teaching purposes or for the evaluation of a course, programme, or service. Student dissertations do not fall into this exception and should receive ethics approval before data collection.

Routine academic audit that is expected of all course and module leaders is also exempt. Audit or service evaluation differs from research in that the main purpose of data collection is to monitor and improve a particular service delivery (rather than with the intention of using data to understand a situation more generally or develop a concept).

Where teaching and learning activities are used as the subject matter of research (e.g., data are collected from students or from the Virtual Learning Environment for the purpose of research publication), then a full ethics application should be submitted and approved before the start of data collection.

One special case of teaching activities that <u>does</u> require ethics approval is where students collect data for their research dissertations (typically at levels 6, 7 and 8). Different taught degrees will place different emphasis on the learning outcomes regarding ethics and therefore the requirements for the students may differ between taught degrees but in all cases, data collection involving human participants must undergo ethics scrutiny and be recorded in an auditable way. However, in all cases, the research project must gain ethics approval before data collection starts.

3.5. Research impact

Activities that concern the evaluation of research impact do not usually require ethics approval. They do however involve important ethical considerations (as do other academic activities) particularly when collecting data from vulnerable populations or on sensitive topics.

Research is defined as the generation of new knowledge or understanding through a structured process of inquiry, which is then effectively disseminated. Impact activities typically do not fit this definition. Instead, impact is usually considered a form of service evaluation, with research acting as the 'service.'

Impact activities that do not require ethics approval involve collecting data solely for evaluating research impact. These data are shared within the research team and used in broader research assessment exercises (e.g., REF 2029).

Research impact activities that do require ethics approval may involve data that will be shared with a broader audience (e.g., website or conference). Impact evaluation can be included in the original ethics application or be submitted as an amendment to the original application.

3.6. Patient and Public Involvement and Engagement

Many projects engage in Patient and Public Involvement and Engagement (PPIE) work prior to the start of data collection. Such work could involve inviting stakeholders in the research (i.e., public or patients) to review research materials and provide feedback, attend research planning meetings or provide their opinions on the relevance and suitability of the project for the people who may participate or who may benefit from the research in some way. Ethical approval is not normally required as no personal data are collected, no recordings are made and any notes taken during the meetings are only shared with named members of the research team. PPIE work is not designed to contribute to knowledge per se, but to improve the quality and potential impact of research, prior to the project starting. Researchers may normally recruit and form a PPIE group before their research gains ethics approval (e.g., while writing the grant which will fund the study). However, where PPIE itself is being used for research purposes (e.g., investigating the engagement of different PPIE groups) then an ethics application is required. Also, PPIE conducted with vulnerable groups or on sensitive topics or where personal data needs to be stored after the session takes place would also need ethics approval.

3.7. Animal Research

All research involving non-protected (under the Animals in scientific procedures act (1986) and its amendments) live animals should be submitted for ethics review by LSBU's Non-Protected Animal Ethics Panel following the Guidance for research and teaching activities with living animals (available from the HAPLO system under Guides).

Protected animals include all living vertebrates, other than humans, and any living cephalopod. Such research is not currently permitted at LSBU.

Further reading:

LSBU Guidance for research and teaching activities with living animals (available from the HAPLO system under Guides)

Animals in scientific procedures act (1986)

Section 4: Ethics - routine study issues

4.1. Vulnerable Individuals and Disclosure and Barring Service (DBS)

Certain groups are potentially vulnerable and extra care and steps must be taken for their safeguard when securing their participation in research. Children are one such group and there are other groups. Vulnerability can take different forms and may arise due to age, disability, marginalisation, abusive relationships, or personal or professional relationships where participants may feel coerced to participate. The Safeguarding Vulnerable Groups Act 2006 also lists several factors which may signal vulnerability as an adult, including:

- is in residential accommodation,
- is in sheltered housing,
- receives domiciliary care,
- receives any form of health care,
- is detained in lawful custody,
- by virtue of an order of a court, is under supervision per <u>Criminal Justice Act 2003 sections</u> regarding community sentences;
- receives a welfare service of a prescribed description,
- receives any service or participates in any activity provided specifically for persons who has
 particular needs because of his age, has any form of disability or has a prescribed physical or
 mental problem. (<u>Dyslexia</u>, <u>dyscalculia</u> and <u>dyspraxia</u> are excluded disabilities),
- has payments made to him/her or to an accepted representative in pursuance of arrangements under <u>Health and Social Care Act 2012</u>, and/or
- requires assistance in the conduct of own affairs

In cases involving potentially vulnerable groups including children special care must be taken to ensure: a) active consent, rather than solely the consent of a gatekeeper; b) information is given about possible negative effects or lack of benefits from their involvement with the research where these may be expected; c) the researchers in contact with the participants have obtained a disclosure from the Disclosure and Barring Service (DBS) prior to commencing the data collection. Regarding DBS, the level of disclosure is likely to be an Enhanced Disclosure because of the position of trust in which the researcher is likely to be. Further advice may be obtained from the DBS.

Researchers will also consult and abide by subject-specific codes of conduct (e.g. British Psychological Society, British Sociological Association) for additional guidance on consent from vulnerable individuals. Where the research involves participants covered by the Mental Capacity Act 2005 it may be appropriate to obtain permission from the person with authority or legal responsibility for the participant. However, all such arrangements are governed by the Mental Capacity Act 2005. Social care research carried out in England that involves adults lacking capacity is required to be reviewed by a 'Recognised Appropriate Body' under the Mental Capacity Act. The

only committee recognised by the Secretary of State for this purpose at the time of writing is the NHS Research Ethics Committee (see also 3.3.1).

4.2. Participant Recruitment, Selection and Rewards

Applications for ethical approval should include full details of the recruitment and selection of participants and any questionnaires to be used in the selection process should accompany the application. If the questionnaire is drawn from a battery of pre-validated tests, it is helpful to indicate the source in the ethics application.

LSBU staff or students may form part of a research sample. Students in close contact with staff or student researchers should not normally be recruited, to avoid the risk of (actual or perceived) coercion from someone in a position of influence on their study or careers. In such cases, anonymising whether participants have taken part or not (or withdrawn after consent) is a potential mitigation strategy.

Global (whole organisation) recruitment emails are prohibited by the University's Email policy. However, university staff lists can be accessed with the agreement of the College Ethics Lead and permission from the individual responsible for staff/student email list use. When recruiting outside of the university, email policies of the organisations with potential participants must be followed.

Principles of Equity, Diversity, and Inclusion, are crucial in research ethics as they aim to create a fair, inclusive, and diverse environment in research practices, ensuring that all individuals, regardless of their background, have equal opportunities to participate in and benefit from research. Particular thought should be given to recruitment efforts that ensure samples are representative of the entire population under study.

Coercion (perceived or actual) should not be used to persuade people to participate in a research study. Careful study advertising, separation of information about participation and gatekeepers or those with power or influence over participants should be considered as ways of mitigating coercion (see also 4.3 and 4.4.).

Any payment made to participants should be *proportionate* to the study and the risk of undue influence on participation decisions should be considered. Such payment can be in the form of cash or vouchers and the researcher must be able to explain the payment choice. Participants should not need to spend/engage in activity to redeem an incentive (i.e., buy X to get 10% off) and commercially funded research should not reward participants with vouchers solely redeemable with the funder or with their own products (because this may be interpreted as the research team condoning the product). Note that vouchers should only be purchased from providers with ethical business practices and/or with values that align with LSBU. Academic rewards in the form of course credit (such as the Division of Psychology Research Participation Scheme) can be given for students where the process has been agreed within the School and is overseen. All proposed payments to participants including course credit must be approved by the CEIP. It is not appropriate for student-researchers to financially reward participants themselves as this creates an unfair advantage in relation to other student-researchers unable to do so.

A note on sample sizes: Studies should be powered amply to detect differences between conditions or relationships between variables with a reasonable level of sensitivity (i.e., at power =>.80) for quantitative studies. Evidence of power analysis should be provided. For qualitative studies, it should be reasonable to expect sufficient data is collected to produce good insights. Underpowered samples are unlikely to produce *beneficence*.

4.3. Anonymity, Confidentiality and Data Protection

It is important for all researchers to consider how their research data is handled (see also 2.2).

Data are considered *confidential* when access is restricted to a designated group of individuals and not disclosed to others outside this group (e.g., the research team). Personal identifying information collected in the course of research should be kept confidential.

Anonymity and confidentiality are cornerstones of both good data management and research ethics. *Anonymity* is achieved when <u>no-one</u>, <u>including the research team</u>, can identify the individuals associated with the data. Care must be taken to ensure that different data fields cannot be combined to identify a participant(). Data are considered *pseudo-anonymous* when a key file, such as a spreadsheet, links participant codes used in a separate datafile with personal identifiable information. Names, emails, physical addresses, phone numbers are all examples of personal identifiable information which renders data non-anonymous. Note that some online surveys record internet protocol or IP addresses and these are also considered personal identifying information therefore researchers must use compliant software (see also 4.11).

As a guiding principle, data should be collected anonymously or made anonymous as soon as practicable. Non-anonymous data and key files should be stored using a double-lock system (i.e., two locks secure the data such as using a password-protected file in a password-protected server, or in a locked filing cabinet in a locked office). Where data cannot be made anonymous it should be used only for the purposes that participants have opted in for and be held only for as long as necessary to achieve the purposes stated in the ethics application form.

Regardless of whether data is anonymous or not, it should be made clear to participants how data will be stored, for how long and in what form. It should also be made clear what are the scope and limits of confidentiality. This is usually outlined in the Participant Information Sheet, and participants consent to such processes in the Consent Form. If anonymous data is to be archived (e.g., in a data repository), the process and access rights should be made clear to participants.

All data, especially personal data collected, stored, used, archived or destroyed in the conduct of research with human participants must comply with Data Protection Regulations and the Common Law duty of confidentiality. Research data that has been fully anonymised is not subject to these legal requirements.

Researchers should be familiar with and abide by data protection regulations and employ the practices outlined above but should also be aware that someexemptions apply to specific areas of the regulations, if data is being processed for historical, statistical and scientific research purposes. These exemptions may be available as long as the he data is not processed to support measures or decisions with respect to particular individuals, and the data is not processed in such a way that substantial damage or distress is, or is likely to be, caused to data participants.

These key exemptions for researchers are an allowance for data that was not originally collected for research to be used for research purposes without breaching the transparency principle of the regulations. Also, the exemption allows data that is being used for research to be kept for longer than necessary for the original purpose for which it was collected, for example indefinitely in an archive or published work. However, the transparency principle still applies and so if data is being collected directly from the participant they should be informed about how it will be used, stored and retained.

Research data is exempt from some individual rights provisions, such as the subject access, if it is processed in compliance with above conditions and the results of the research/any statistics are not made available in a form that identifies any individual participant.

Further reading:

LSBU compulsory staff and PGR training on GDPR
Information Commissioner's Office training video
LinkedIn Learning Getting started on GDPR compliance

4.3.1. Additional Guidance for Health and Social Care Research

- Research Ethics Committee (REC) approval and the legal gateway for processing confidential
 patient information on the advice of the Confidentiality Advisory Group (CAG) will continue,
 as will the other common law provisions. A summary of the key changes for all data
 processing (not just research) is available from the Information Governance Alliance.
- Researchers should comply with the <u>UK Policy Framework for Health and Social Care</u>
 Research
- Researchers may need an NHS research passport (https://www.hra.nhs.uk/planning-andimproving-research/best-practice/research-passport/)
- The Health Research Authority (HRA) has published detailed guidance about operational
 arrangements that researchers and organisations may need to put in place. This operational
 guidance was produced for researchers and study coordinators on the implications of the
 GDPR for the delivery of research in the UK GDPR guidance (see also note below)
- Please see up to date guidance available from the <u>HRA website</u>

NOTE: From 1 April 2025, for any new research applications submitted via IRAS the researcher(s) will be expected to either:

- use the new <u>GDPR transparency wording template</u>. This template is designed to help you in your communications to research participants (it was <u>developed alongside Expert Citizens</u>).
 This is something that the sponsor will check before submission to the IRAS.
- o demonstrate how your own bespoke wording meets the four principles for meaningful involvement of patients and the public in health and social care research. If you decide to use your own bespoke GDPR wording it should follow the four principles: 1) Involve the right people; 2) Involve enough people; 3) Involve those people enough; 4) Describe how it helped.

4.4. Obtaining consent

Researchers have an obligation to protect participants from any possible harm and to preserve their rights. This includes providing potential participants with enough and appropriate information about the research project for them to make an informed decision whether to consent to participate. Consent should be obtained in writing. Where this is not possible, and the researcher should clearly outline why this is the case, consent can be obtained orally. In such circumstances, usual practice is that it should be tape-recorded or witnessed by at least one other observer. There should always be auditable evidence of consent. Consent forms must be retained for at least five years from data collection and should preferably be electronic. Any paper forms should be scanned and securely stored, with paper copies destroyed

4.4.1. Coercion

Research participants can be compensated for their time and involvement. However, the value of the compensation should not be such it unduly influences their decision to participate, or to take risks that they otherwise would not (all proposed payments to participants, including non-monetary payments, must be approved by the relevant ethics panel). This can be seen as coercion by inducement. In a similar way, participants who are students, employees, or residing in an organization such as a residential care home, prison, detention facility, or psychiatric ward under section can be seen as having their consent influenced by fear of penalties or expectation of benefits (see also <u>4.1</u>).

In such circumstances the researcher should be particularly careful when getting consent as there could be factors impacting on the individual's ability to freely and voluntarily give this. Incentives should not benefit the end-user of the research (i.e., a study commissioned by an online retailer should not be incentivised by vouchers redeemable solely at that retailer).

LSBU staff or students may be invited to volunteer to take part in research, taking into consideration the sensitive issue of coercion. The University recognises that it is normally reasonable for students to be recruited to take part in research but that they should not normally be recruited by (or for research done by) their current module lecturers, particularly if marking cannot be anonymised. Teaching exercises where one of the primary objectives is to enable students to make their own observations does not fall into this category.

4.4.2. Information Sheet and Informed Consent

Before participating in any research, prospective participants must be provided with clear and comprehensive information about the project they are considering participating. This should include an overview of key aspects of the research and its methodology that reasonably influence their decision to participate. Researchers should use the appropriate template to deliver participant information and collect informed consent (respectively information sheet and consent form).

This information should be provided to the potential participant in the research information sheet, which should accompany the request for consent.

Voluntary consent must be obtained from participants before data collection begins. There are certain circumstances where this may not be possible or appropriate (see <u>4.9. Deception</u> and <u>4.10 Observational Research</u>) in which case there are additional considerations that the researcher must address.

Participants have the right to withdraw up to the point agreed in the information sheet, without having to give a reason. This period should be as long as practicably possible. Participants should be made aware that at the point where the data has been anonymised or the findings have been published the right to withdraw cannot realistically be exercised. If a researcher suspects at any point that a participant may have doubts about continuing their consent to participate, they should proactively and explicitly address this with the participant. Participants wishing to withdraw must always be given the opportunity to do so, and, if desired, have access to a private discussion to share their reasons for withdrawal.

There may be circumstances where the potential participant does not/cannot be considered to fully appreciate the implications of participation. For, example:

• Pre-competent children. In which case the researcher has a legal duty to obtain consent from the parent or legal guardian. Children in such circumstances should *also* give consent

or give a form of age-appropriate assent to take part. GDPR puts the default age at which a person is no longer considered a pre-competent child at age 16, but parental consent is recommended for higher risk studies or sensitive topics with this age group. GDPR allows to adjust this limit to as low as age 13 and research on 13-15 year olds would typically be required to ask for some form of parental consent.

• An adult without the capacity to consent. In which case, consent cannot, in law, be given on their behalf – other than in certain clinical situations.

Upon completion of the participants' involvement, researchers should normally provide a debriefing explaining the full purpose of the study. If this is not appropriate, the reasons why must be explained in the application for ethical approval.

Consent forms contain personal data and must be securely stored using a double-lock system to ensure participant confidentiality. These forms should be retained for a minimum of five years following data collection, though digital scanning is permissible to facilitate secure storage. Details regarding storage duration, disposal arrangements, and related procedures should be clearly outlined in the participant information sheet.

4.5. Debriefing

After participant data has been gathered, and especially in cases where any deception or withholding of information has occurred, participants should be provided with an appropriate verbal and written debriefing. The debriefing should include a statement or clarification of the research aims and objectives, an explanation of how the data will be used and reference to supporting organisations if there is any likelihood of distress associated with participating in the research. In some circumstances where the research aims and objectives were clearly communicated in the participant information sheet, a verbal debriefing may suffice.

In some cases, a distress protocol should be in prepared to ensure the safety and well-being of participants, especially in studies that involve sensitive topics, potentially traumatic materials, or vulnerable populations. Such protocol refers to a predefined plan established to respond to situations where a research participant becomes distressed or experiences discomfort, either emotional or psychological, during the course of a study.

Research involving patients/ NHS and categorised as high risk may require a suitably qualified healthcare professional to be responsible for an investigation or to be in attendance when certain procedures are carried out or require that facilities for emergency medical care should be at hand.

Participants may need to be (medically) screened before taking part in research. Where appropriate, participants should be asked about their previous medical history and asked to give permission for the researcher to contact their doctor and to authorise the doctor to release any relevant details of their medical history. Sufficient time should be allowed to permit participants to consult their doctor before they agree to participate in the research.

Participants should be strongly advised to report any unusual or unexpected signs and symptoms after the research study to the researcher and to their own doctor as soon as possible.

Any adverse event or untoward event affecting a participant during or after a research study should be communicated as soon as possible to the CEIP. For staff and postgraduate research students this should also be logged on Haplo within the approved application. For students on taught degrees this should also be reported to their supervisor. Swift reporting is crucial since there is an obligation that

LSBU inform its insurers and following on this – with the individual's consent – to inform the participant's doctor.

Applications for ethics approval should state and justify their stance on giving feedback to participants about any medical conditions revealed through screening and/or participation in the research (see also 4.7. Safeguarding and Adverse Events).

4.7. Safeguarding and Adverse Events

Everyone involved in research ethics should be aware of, and comply with, LSBU's Safeguarding Policy as well as ensure the research is risk-assessed. Special care should be taken where the research involves sensitive topics or vulnerable populations (see also <u>4.1.</u>).

Alongside the responsibilities of safeguarding, researchers at LSBU have a responsibility to report adverse events associated with research.

An adverse event is a negative physical or psychological outcome which may be linked to participation in a research study. Typically, an event would be considered adverse if it were of a level of severity that would lead one to seek medical or professional help (e.g., to a GP or Accident and Emergency department or seeking mental health professional support).

Projects where adverse events are likely should have a clear process for identifying and handling the events, for example who events are reported to, who is responsible for reporting them to the CEIP/UEIC and other panels (such as steering or safety panels) and providing contact information external to the project for participants to report events if appropriate. Reporting processes should be clear to participants and all members of the research team. Note, if the trial is a Clinical Trial of an Investigational Medicinal Product (CTIMP), a medically qualified person must assess the adverse event for seriousness and relatedness.

Researchers must be aware that adverse events should be reported on Haplo by finding the relevant project and selecting the 'report adverse event' option. Additionally, adverse events should be reported directly to the CEIP or UEIC as appropriate who will examine the reported adverse effects and advise on revisions to the project and may require project activity to be suspended while these are enacted. The CEIP/UEIC reserves the right to withdraw ethical approval temporarily or permanently following an adverse event. Failure to report adverse events can be considered non-compliance with this code of practice.

Further reading:

LSBU Safeguarding Policy

4.8. Public and Patient Involvement and Ethical Oversight

Public and Patient Involvement (PPI) includes NHS patients and members of the public who are consulted about a plan of research prior to, during, or after the research has been undertaken.

PPI potentially includes activities such as:

- members of the public or NHS patients acting as research partners (the application may require ethics approval, but the involvement of the PPI members in the research project team would not);
- as part of the process of identifying research priorities;
- part of project governance groups such as project advisory or steering group;
- Developing, consulting, and/or commenting on study materials such as patient information

sheets or advertising materials;

• assisting with the interpretation and dissemination of findings.

Formal ethics approval is not usually required for the involvement of patients or members of the public in research even if recruited via the NHS because they are not participating as research participants but instead providing specialist advice and sharing experience. As such, ethical approval is not required for activities like helping to design protocols, creating questionnaires or information sheets, joining advisory groups, or serving as co-applicants, even when recruitment occurs via the NHS.

However, ethical approval should be sought when members of the public or NHS patients are participants in the research itself or members of the public or NHS patients are researchers or collect data as part of the research process.

Further reading:

UKRIO Co-production: participant and stakeholder involvement in research

4.9. Deception

Although the idea of deceiving research participants may be seen as inappropriate, there are many instances where clearly indicating the purpose of the research to participants in advance of data collection would influence participants' responses and behaviour. As deception contradicts the principle of informed consent, its use in research should be carefully considered and only used when it is absolutely necessary to the running of the study and there is no deception-free alternative.

Deception can refer to the deliberate withholding of information as well as deliberately giving misinformation. Researchers should seek to supply as full information as possible to research participants. However, in some cases an essential element of the research design would be compromised by full disclosure to participants at the outset, which justify the withholding of information or misinformation. The reasons for this should be clearly stated in the ethics application. Deception should only take place where it is essential to meet the research aims, where the research objective has strong scientific merit and when there is an appropriate risk management and harm alleviation strategy. Where any deception or withholding of information has occurred, participants must be debriefed as soon as possible following data collection. In some cases, additional retrospective consent (after the deception has been revealed) may help to ensure that the research is, and is seen to be, properly ethically managed. In these cases, following debriefing, participants' consent to use of their data, publication or other dissemination should be sought. Researchers should be prepared for refusals and subsequent withdrawal of participant data. Deception should never be used if physical pain or emotional distress are likely to occur.

4.10. Observational Research

Wherever possible, participant information sheets should disclose as much information about a research study as is possible. However, in some cases, full disclosure is not possible. A situation where full disclosure (and even consent) is not possible is in some forms of observational research.

Observational research involves researchers recording the behaviour of participants in either a field or laboratory-based setting. When consent for a study involving an observational element can be reasonably obtained (for instance, when people are taking part in the lab-based study which involves some unobtrusive observation) then it should be. In other cases, the assumption should be that the observation is essentially a form of deception and should be treated as such.

In field studies, observational research is likely to be covert and participants may not consent or be debriefed as part of the research process. In such cases, researchers should follow the British Psychological Society's guidance on observational studies:

'Studies based on observation in [public] natural settings must respect the privacy and psychological wellbeing of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in public situations where those observed would expect to be observed by strangers. Additionally, particular account should be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.' British Psychology Society Code of Human Research Ethics (2014, pg. 25). Wherever possible, and when the balance of benefit to the participant is in favour of it, participants should be debriefed, and consent to use the data should be sought.

4.11. Use of Online Software for Research

This guidance concerns the use of online tools for questionnaires, interviews, and interview transcription.

In the use of **online tools for research**, researchers must ensure that General Data Protection Regulation and the Data Protection Act (2018) are followed. In practice, this means researchers must declare and use the online tools that have been vetted by LSBU's data officer. These are currently: MTeams, NVivo, Qualtrics, Online Surveys. Alternatively, researchers must declare other online tools they plan to use in their ethics application so their Terms and Conditions can be reviewed for approval by the LSBU data officer. Particular attention should be given to new artificial intelligence tools or language models (e.g., ChatGPT, Whisper AI, Otter) which offer free transcription services which may not be GDPR-compliant (see also <u>2.3</u> and <u>4.3</u>).

Contact for data protection officer: dpa@lsbu.ac.uik

4.12 Working with Other Organisations

Researchers often work with other organisation in a variety of roles including funding, recruitment, dissemination, co-researchers, public engagement. Some organisations may have their own ethical guidelines and LSBU researchers must be aware of those guidelines and keep in mind the rule that the most stringent ethics guidelines should be followed. Collaborations with organisations outside the UK must be declared as per the trusted research and export control policy (see 2.6).

Researchers must also ensure that they are aware of and meet any specific, general, contractual or ethical requirement of any UK Government Department, Local Authority, Research Council or research funder in relation to the proposed research. Typical risks that require mitigation in working with other organisations refer to Coercion see 4.4.1)

4.13 Environmental Sustainability

Researchers should recognise the interconnectedness of all living beings and environments. LSBU supports the 'Concordat for the Environmental Sustainability of Research and Innovation Practice'. Researchers should responsibly consider sustainability, climate change, biodiversity and the global community more broadly in their research purposes; funders; infrastructure; procurement; travel; and collaborations. If research is being done directly with animals, researchers should refer to the additional Code of Practice for Research with Animals.

Section 5: Further reading

5.1. Map of Ethics and Integrity Areas of Responsibility

Below is a summary map outlining the areas of expertise and responsibility related to ethics and integrity at LSBU:

	Routine ethics applications		
Individuals	Students on taught programs' research with human participants	Staff and PGR students' research with human participants	
Routine processing	Taught degree staff with CEIP oversight	CEIP with UEIC oversight	
Recording of audit trail	VLE or locally. Course/ module leader reports annually to CEIP	HAPLO. CEIP and UEIC report annually	
	Ethics and integrity issues		
Adverse events	Student reports to supervisor and CEIP records	Researcher records on HAPLO and CEIP reports	
Data protection	Data protection officer; CEIP records		
Academic or Research misconduct	Student academic misconduct procedure	Disciplinary policy and procedure	
Insurance	Procurement Services Operations Officer		
Risk assessment	Technician	Staff self-declares	
Trusted research	Not applicable		
Participants' prizes and awards	Not allowed unless linked to staff research	GovLegal	
Contracts and grants	Not applicable	REI department	
Impact, innovation, enterprise, service evaluation	Same processes as normal ethics application; see Code of Practice for exceptions		
Non-protected animals excluding cephalopods	Animal research panel, UEIC	Animal research panel, UEIC	

5.2. Internal Documents and Contacts

UEIC Terms of Reference

CEIP Terms of Reference

LSBU Disciplinary Policy and Procedure

LSBU Procedure for the Investigation of Misconduct in Research

LSBU Student Academic Misconduct Procedure

LSBU Safeguarding Good Scientific Practice

LSBU Trusted Research guidance

Contact for

Data management plan: researchdata@lsbu.ac.uk

Data protection officer: dpa@lsbu.ac.uik

LSBU ethics: ethics@lsbu.ac.uk

5.3. External Documents

Freedom of Information Act 2000

Health and Safety at Work etc. Act 1974 and related Regulations

Human Rights Act 1998

Human Tissue Authority Act 2004

Human Tissue Act flowchart

Mental Capacity Act 2005

UK Concordat to support Research Integrity

UK General Data Protection Regulation (UK GDPR)

UKRIO Research Ethics support and review in research organisations

<u>UKRIO Procedure for the investigation of Misconduct in Research</u>