Research Ethics Policy and Procedure

Overview

Preamble

'Research ethics' can be described as a set of principles governing the way in which research is designed, managed and conducted.

LIS is committed to ensuring that its research activities are conducted in a way which respects the dignity, rights, and welfare of participants, and which minimises risk to participants, researchers, third parties, the local and global environment, and to LIS itself. In accordance with its policy on research involving human participants and personal data, and research that may pose a risk to biodiversity or the natural environment, LIS requires that all such research be subject to appropriate ethical review.

In addition to academic research undertaken by faculty, research involving human interaction, human data or activities with the potential to affect the natural environment may arise as part of the learning of students at the School, for example in projects and coursework. This document describes the School's Policy and Procedure for ensuring that in preparing and conducting a research project, the dignity, rights, safety, and wellbeing of participants and the natural environment are considered, respected, and safeguarded.

Scope

This Policy and Procedure governs the ethics of research across the School, and applies to all staff, students, and anybody else carrying out research under the auspices of the School, whether their current place of work is within or outside School premises.

Specifically, it applies to:

- A research project involving collection of primary data from human participants
- Secondary data relating to directly identifiable human subjects (whether living or recently deceased), which need to be anonymised by LIS staff or students
- Analysis of data from social media platforms or internet sites
- Research that involves animals, plants, fungi, bacteria, viruses or other living organisms, or the *ex vivo* manipulation of genetic material, cells or tissues that were originally derived from living organisms
- Research with the potential to impact local, national and/or global ecosystems

This Policy and Procedure does not relate to:

- Analysis of academic or newspaper publications
- Creative projects which do not aim to generate new knowledge
- Analysis of policy documents from governmental or international organisations
- Research activities conducted by students for the purposes of prep activities or within a lecture. Collection of primary data during these activities should be from students who are currently attending that module. If it is expected that the data will be used within a publication or to advertise LIS, these research activities will be redefined as a research project.
- Research that is commissioned by an employer as part of a student's work whilst on an immersive internship. Such research is covered by the employer's own research ethics policies and procedures

All investigative activities that fit into the category of a **Research Project** need to receive ethical approval. A research project is defined as an investigative activity that:

- Aims to generate new knowledge that may have practical applications;
- Has the potential to lead to generalised conclusions;
- Relies on the collection of new data or a novel analysis of existing data;
- Data may have been collected from human participants
- Data may have been generated through use of materials
- Generates results which could be published or disseminated.

Legislative and best practice context

This Policy and Procedure have been drawn up with due regard to the reference to the Data Protection Act 2018, the GDPR, and the Mental Capacity Act 2005. It has also drawn on best practice as set out by external organisations such as the Information Commissioner's Office (ICO), UKRI Economic and Social Research Council, UK Research Integrity Office and Universities UK (see Annex 2 for these and other useful resources).

Links to other Policies and Procedures

This Policy and Procedure should be read in conjunction with other School regulations, policies and procedures, including:

• Data Protection Policy

• Data Retention Policy and Detailed Data Retention Schedule

• Safeguarding Policy and Procedure (including Prevent)

• Code of Ethical Conduct

• Academic Freedom Policy

Principles

The School's Research Ethics Policy and Procedure has been adopted in support of the School's wider commitment to academic freedom and excellence. It seeks to ensure sound ethical standards in research without creating a disproportionate and onerous procedure that will impede the conduct of academic research. It seeks to facilitate ethical research and promote a culture where students and staff continuously reflect on the ethical implications of their research.

Where a member of staff is teaching a module that comprises a piece of work that may include a research project, they must make students aware of the required ethical standards and this Policy and Procedure. They should also provide advice and guidance on the ethical implications of any proposed research project. This research project may be undertaken independently by a student or group of students, or in close collaboration with a staff member. All student applications must be countersigned by an appropriate member of staff (see 'Procedures' below).

Informed Consent

Where information is to be collected from human participants, prior informed consent must be obtained from those subjects for any use of their information. Consent should be:

- **Freely given,** without pressure or manipulation; not under the influence of drugs or alcohol
- **Reversible** – participants are aware that they have the right to withdraw from the research at any time, without giving a reason, and to request removal of their data from the study
- **Informed –** participants are given enough detail about the research to make an informed decision, including whether their data will be anonymised, how their data will be stored and for how long, who has permission to view or use their data, how the research findings will be disseminated, and (if applicable) what will happen to any images or video footage.

Where the research exposes its participants to a risk of harm, the researcher has an ethical duty to consider these risks, even where the participants have consented to participate in the research; this is particularly important in dealing with vulnerable groups.

Research that does not entail the direct participation of living human persons may nonetheless indirectly but significantly affect living persons. Researchers may be assessing information about identifiable individuals, the publication or analysis of which may have ethical or legal implications. For example, collection and use of archive, historical or legal materials may raise ethical issues for the families of deceased people. Researchers must consider these implications in considering the ethics of their research proposal. Secondary use of datasets must be given careful consideration by the researcher and the Research Ethics Panel, especially where reliance is being placed on a presumed consent by subjects to the use of their information, or where there is a potential risk of disclosure of sensitive information.

For the purposes of Research Ethics Panel submissions, 'Informed Consent documentation' is defined as a copy of the information sheet that will be supplied to participants in advance of the research, when seeking consent, as well as the consent form that the researchers intend to use. The participant information sheet should include the name and contact details of the researcher and their supervisor, as well as information on what to do in the event of a complaint or concern about the research and details of how to withdraw consent. The researcher is obligated to archive documentary evidence of informed consent. Collection of primary data should not commence prior to the researcher receiving ethical clearance.

Legal and data protection requirements

Any student or staff member conducting research must ensure compliance with the Data Protection Act 2018 and the General Data Protection Regulations (GDPR), as well as the School's Data Protection Policy, Data Retention Policy, and Detailed Data Retention Schedule. It is the researcher's responsibility to ensure that arrangements are in place to maintain the integrity and security of research data. Advice on data protection requirements can be obtained from the School's Data Protection Officer, the Registrar.

Training in Research Ethics

Staff: All staff undertaking research are required, in the course of their career, to have undertaken appropriate training or to have had significant relevant experience before embarking on an evaluation of the ethical implications of their research. Staff members who do not feel that they have sufficient training or experience to evaluate the ethics of their research must seek advice from a senior member of the Teaching and Learning Department.

Students: All students will undergo training in ethical research as part of the programme, and this Policy and Procedure will be incorporated into the training. Students will be required to prepare and submit an ethics checklist prior to commencing a research project. The rationale for this requirement is as follows:

- To protect the rights and dignity of research participants as well as students acting as researchers
- If any of our students wish to go on to graduate studies at other institutions to pursue academic research, they will benefit from an understanding of research and ethics.
- These principles of research (see below) are relevant beyond the scope of 'pure research'.
- Understanding ethical research offers an opportunity for students to develop critical thinking about existing research (and historic, unethical research), as well as methods and study design.

Training should include learning about core principles and concerns in ethical research such as:

- Protection of participants; maximising benefits, avoiding or mitigating any possible harm
- Consent: freely given, reversible, informed, and obtained *before* the study (in writing wherever possible)
- Confidentiality: maintain anonymity of the participants where desired, consider long-term repercussions of writing about the lives of others
- Right to withdrawal: ensure freedom to withdraw at any point during the study, with no negative impact on participants
- Deception: avoid where possible, but if unavoidable, ensure all participants are fully debriefed after the study and have a clear understanding of the actual aim of the study
- Systems perspective: avoiding or mitigating any possible harm to non-human participants and ecosystems; minimising any risks from hazardous chemicals, ionising radiation, genetically modified organisms, pathogenic or potentially pathogenic organisms, etc.

As applicable, the training can also include an exploration of some key issues to consider when thinking about ethics and research:

- Ethical research design: building students' capacity to think through the aim of their study, the target population, the necessary methods and the limits in terms of the principles outlined above, including the issue of the researcher's personal health and safety.
- Participants: what kind of information is required from participants? Avoid unnecessary questions and undue intrusion into participants' personal space, consider participants' familiarity with techniques, etc.
- What kind of informed consent will be taken? What will participants be told in advance? Consider participants' ability to give free and informed consent and, where applicable, relations with gatekeepers, e.g., institutions or parents.
- Are there power imbalances? Avoid economic or academic exploitation, offer fair return for assistance where appropriate, etc.
- How will data be stored and shared with colleagues, sponsors, funders, employers, etc.? Are there any (apparent) conflicts of interest, including financial or other personal considerations that may hinder (or have the appearance of hindering) the researcher's ability to make a professional judgement in conducting or reporting research? Note that a supervisor's conflict of interest is inherited by the students.

- Research space/protection for the researcher: clarify roles and expectations before signing contracts; know about the planned use and dissemination of data and findings; ensure the rights and interests of the participants are protected.

Ethical Review Procedures

Staff members and students are obligated to submit their research project for ethical clearance if investigative activities are being conducted under the auspices of the School, it is not part of the work conducted on an immersive internship with an employer and it involves investigative activities outside of those performed during lectures or prep. Regarding investigative activities associated with prep or lectures- these activities can only involve students attending that particular module and could be later redefined as a research project if a student or staff member later seeks clearance for the purposes of publications or advertisements.

There are currently three stages of review; the first involving self-assessment. During this stage of the ethical review procedure, **undergraduate and masters level students** are obligated to send an ethics checklist to their module leader or academic tutor. If their counter signatory is satisfied that there are no significant ethical issues, then these students can commence research.

The study may need to undergo Stage 2, internal panel review, if their counter signatory deems the study as raising significant ethical concerns. Members of LIS staff and PhD students are obligated to submit an ethics checklist for internal panel review prior to conducting a research project unless their study has already received ethical clearance from another academic institution.

Finally, a study may undergo Stage 3, external panel review, if the research project requires the approval from a governmental body. Such research projects may use data from the NHS, involve prisoners or people on probation or focus on the issues related to the UK Armed forces.

At each stage of the ethical review process, it is possible that a research project may not receive clearance. These research projects may not be deemed viable due to concerns over feasibility of research activities, ownership and responsibility of primary or secondary data, ethics and/or lack of safeguarding.

Stage 1: Self-Assessment with Countersignature

All BASc and MASc students are required to submit an ethics checklist on their research project for Stage 1 of the ethical clearance process if they involve any of the following:

- primary research with human participants (for example, interviews, surveys, focus groups or experiments)
- secondary data relating to directly identifiable human subjects
- the use of animals, plants, fungi, bacteria, viruses or other living organisms
- the *ex vivo* manipulation of genetic material, cells or tissues that were originally derived from living organisms
- any potential risk to local, national and/or global ecosystems;

The student in question must complete the Research Ethics Review Checklist, in which they will provide details on their research methods, ethical implication of their research and risk of harm to human and non-human participants and wider ecosystems. If they are conducting analysis of secondary qualitative or quantitative data, then they may need to provide details on whether the data has been anonymised or not. In

research projects involving collection of primary data, they will need to provide details how the participants will be samples, steps they will take to ensure their confidentiality and anonymity and how they will ensure the security of personal data. These research projects will require the applicant to attach informed consent documentation.

If, on completion of the Checklist, a **staff member** determines that there are no significant ethical issues raised by their research, or that adequate safeguards will be put in place, they must mark this on the form in the designated section and submit it for countersignature to the **Director of Teaching and Learning or their nominee**.

If, on completion of the Checklist, a **student** determines that there are no significant ethical issues raised by their research, or that adequate safeguards will be put in place, they must mark this on the form in the designated section and submit it for countersignature to an appropriate staff member. This would normally be the student's **academic tutor** in the case of Level 4 modules, and the **module leader** (or their deputy if necessary) for Level 5 and above.

Countersignature

If the designated counter-signatory is satisfied *either* that the research raises no significant ethical issues *or* that the safeguards are adequate and have been explained in sufficient detail, they should countersign the form and (if applicable) forward a copy to the Director of Teaching and Learning.

If the counter-signatory requires more information about the proposed safeguards before reaching a decision, they may, at their discretion, ask the student to revise the Ethics Checklist and resubmit it to them by a specified date. This may be done only once and if the second attempt is unsuccessful, the application should be immediately referred to Stage 2 (Internal Panel Review).

Stage 2: Internal Panel Review

Automatic referral

Academic status

All research projects submitted by staff members or PhD students will automatically go for internal panel review. In cases where either the BASc or MASc student or the individual reviewing the checklist determines that there are significant ethical issues raised by the research that are not satisfactorily mitigated by the proposed safeguards, they must mark this on the form and refer the research proposal for an Ethical Review by the Research Ethics Panel.

Concerns raised in Stage 1

Staff members reviewing a BASc or MASc students' research project for a stage 1 application must **always** refer it to stage 2 if they have concerns about procedures associated with consent of human participants, the rights and dignity of the researcher and/or the respondents, the protection of data, the feasibility research and the handling of materials.

In regards to the consent of human participants, stage 1 applications may automatically be referred to stage 2 if the research project involves one or more of the following:

- Research involving deception of participants, or that is intentionally conducted without their full and informed consent at the time the study is carried out or when the data are gathered
- Research where informed consent will be obtained orally but not in writing

- Groups where permission of a gatekeeper is normally required for initial access to members (where involvement of the gatekeeper might raise questions as to whether the participants' taking part is fully voluntary);

In terms of the rights and dignity of the researcher and/or the respondents, stage 1 applications may automatically be referred to stage 2 if the research project involves one or more of the following:

- Vulnerable groups, i.e., individuals in a dependent relationship who may be coerced or pressured into taking part, e.g. children or people with learning difficulties;
- Historically marginalised groups;
- Sensitive topics, as defined by Dickson-Swift, V. et al, Undertaking Sensitive Research in Health and Social Sciences;
- Potential to cause undue psychological stress, anxiety or humiliation, or to pose an elevated health and safety risk, to human participants and/or researchers.
- Incentives to participate (financial or otherwise)

Regarding protection of data and confidentiality, stage 1 applications may automatically be referred to stage 2 if the research project involves one or more of the following:

- May lead to the publication of confidential information
- Use of un-anonymised secondary qualitative or quantitative data
- Use of user data from internet sites and/or social media platforms
- Commercially sensitive information or possible conflicts of interest

In regards to feasibility of research, stage 1 applications may automatically be referred to stage 2 if the research project involves one or more of the following:

- Research which may require an external panel review (see also Stage 3 below). In the UK, research projects involving recruitment through NHS, Prisons or Probation Trusts and/or the Ministry of Defence may require an external panel review from their respective panels. If the study is being conducted in an international setting, then it is possible that authorities within these countries may require review of the research by their own ethics panel.
- Additional ethics training needs which are not within the scope of the module, e.g. training on obtaining consent from children
- Responsibilities which are too onerous for the requirements of the module, e.g. ownership of anonymised data containing personal information

In terms of handling of materials, stage 1 applications may automatically be referred to stage 2 if the research project involves one or more of the following:

- Any *ex vivo* manipulation of genetic material, cells or tissues that were originally derived from living organisms
- Research that has the potential to cause distress or suffering to any animal, damage to vegetation, or serious harm to local or global ecosystems, e.g., through the release or possible release of hazardous or potentially hazardous substances, ionising radiation, or pathogenic or potentially pathogenic organisms.

Application process

Applicants must submit the ethics checklist with any relevant additional documentation attached. They must also fill in the stage 2 form. All forms and attached documents will be considered by the Research Ethics Panel.

Research Ethics Panel

The Research Ethics Panel is a Panel of the Academic Council and is comprised of a minimum of three and a maximum of five faculty members, of whom at least two should be senior faculty members or co-opted external experts. The membership of the Panel should include at least one person with experience in assessing risks to human participants, and at least one with experience in assessing risks to the natural environment. The Panel is chaired by the Director of Teaching and Learning or their nominee.

The Panel will be convened to review the ethics of research proposals as they arise, and always within two weeks of the submission of a proposal for review, unless otherwise specified. Module leaders may, for example, require all students taking a particular module to submit their proposals by a specified deadline so that the Panel can review them all on the same day. The Director of Teaching and Learning may also, at their discretion, instigate specific dates for the Panel to be convened and corresponding deadlines for the submission of proposals.

In convening Panel meetings, the Director of Teaching and Learning or their nominee should ensure that members are provided with the proposals in advance and given adequate time to read them and note any concerns before the meeting.

The Research Ethics Panel will ensure that adequate consideration has been given to the ethical aspects of a research project, reducing the potential for harm and upset to participants and researchers and damage to local or global ecosystems.

The Ethics Panel will assess whether the research proposed can be ethical, i.e., whether:

- it is justified—whether it is likely to add to the existing knowledge base;
- it is of sufficient standard, including whether researchers are qualified to undertake it;
- participation is voluntary;
- incentives to encourage participation are appropriate or ethical;
- appropriately recorded consent is assured;
- adequate support and protection are in place for participants and researchers;
- the sensitivities of the research (e.g., cultural sensitivities, and/or inequities and power dynamics involving historically marginalised groups) have been appropriately managed;
- there is an appropriate policy and practice concerning confidentiality, anonymity, or acknowledgment of research participants;
- any risks of the research to the participants and/or researchers (in terms of dignity, rights, safety or wellbeing) are outweighed by the potential benefits;
- any risks of harm to living organisms or damage to local or global ecosystems have been appropriately assessed and mitigated;
- the research complies with all statutory and other guidance;

- collection and management of data comply with data protection regulation and the School's Data Protection Policy, Data Retention Policy and Detailed Data Retention Schedule;
- there are any conflicts of interest;
- feasibility of the research activities within short module timelines
- there are any issues of commercial confidentiality.

The Research Ethics Panel will make a decision by majority; where there is a split vote, the Chair shall have the final say. The Research Ethics Panel will give written response to the researcher as quickly as possible, and in all cases within five working days of meeting to consider the research proposal. The Panel decision may be either

(i) Approve unconditionally;
(ii) Approve with conditions;
(iii) Require additional information or clarification;
(iv) Require revision; or
(v) Reject. The decision to reject a proposal outright, rather than calling for it to be revised and resubmitted, should be taken only as a last resort if the Panel considers that the research is unjustifiable or the risks are so great that they cannot be adequately mitigated.

Once a research project has gained approval from the Research Ethics Panel, it must be conducted as proposed; any significant change to the research methodology, approach or purpose must be reassessed by the Research Ethics Panel.

Where the student or staff member disagrees with the decision of the Research Ethics Panel, they may refer the matter in writing to a nominated independent member of the Academic Council (i.e., a member who is not on the Research Ethics Panel) within ten working days. The decision of the independent member of the Academic Council will be final and will be given in writing within fifteen working days of receiving the appeal.

Stage 3: External Review

Studies may be required to undergo an external ethical review for the following reasons:

a. The research is being sponsored or conducted in collaboration with an external organisation with its own regulatory conditions
b. The study is sampling from populations overseen or protected by that particular organisation
c. Proposed research will be conducted within that particular organisations settings
d. Data collection is being conducted in a foreign setting which may contain its own rules and regulations

In England, it is required to seek ethical clearance for the Health Research Authority if the researcher is recruiting patients and/or relatives or carers through the NHS, collecting data from NHS settings, analysing patient records or collecting primary data from participants (aged 16 and over) who are unable to give informed consent due to a learning disability or mental health problem. It is possible for researchers to establish if they need approval for research from the Health Research Authority through using the HRA decision tool. There are also online sources providing guidance on applying for ethical clearance from the Health Research Authority.

Meanwhile, research involving prisoners, youth offenders, probation services and staff working within prison settings may require an application to His Majesty's Prison and Probation Service. Information on applying for external ethical clearance for such research is available through the HMPPS website. Finally, research which is either conducted on the UK Armed Forces Staff or is funded by the Ministry of Defence may require an external review by MoDREC.

LIS strongly discourages students from proposing any research activity that is likely to require an external review, unless there is a compelling reason to do so as part of their capstone project *and* there is a suitably qualified and experienced member of faculty available to serve as the lead applicant.

Failure to comply

Where a student fails to comply with this Policy and Procedure, they will be subject to the provisions of the Academic Misconduct Policy and Procedure. If they fail to ensure that they have gained ethical clearance prior to the commencement of research, they may risk their research project being excluded from consideration of their summative assignments.

Where a staff member fails to comply with this Policy and Procedure, they will be subject to the School's Employee Disciplinary Procedure, which can be found in the Staff Handbook.

Audit

The Research Ethics Panel will periodically conduct a selective audit of current staff research projects. Where it considers that a study is being conducted in a way that is not consistent with the conditions of the project's original approval, the Panel may withdraw its approval.

The Director of Teaching and Learning or their nominee will audit a sample of student Research Ethics Review Checklists on an annual basis to determine whether the determinations of low or appropriately mitigated risk are appropriate.

Monitoring and Review

This Policy and Procedure is subject to oversight by the Research Ethics Panel, which is accountable to the Academic Council. This Policy and Procedure will be reviewed annually any appropriate amendments authorised by the Academic Council or its delegated sub committee..

Version Control

Name of policy/procedure:	**Research Ethics Policy and Procedure**
Document owner:	**Hannah Kohler, Director of Admissions and Student Support**
Date Originally Created:	**02/2019**
Related documents: (eg associated forms, underpinning processes, related policies or overarching policies)	**Research Ethics Panel: Membership and Terms of Reference** **Code of Ethical Conduct** **Data Protection Policy** **Data Retention Policy** **Detailed Data Retention Schedule** **Academic Council: Membership and Terms of Reference** **Academic Misconduct Policy and Procedure** **Staff Handbook (includes Disciplinary Procedure)** **Safeguarding Policy and Procedure (including Prevent)** **General Academic Regulations**

Version Control			
Version	**Author**	**Date**	**Brief summary of changes**
1	Hannah Kohler (Director of Admissions and Student Support)	20/02/2019	Original draft
2	Hannah Kohler (Director of Admissions and Student Support)	08/07/2019	Addition of information on research relating to internships
3	Prof. Chris Maguire (Registrar)	10/07/2019	Inclusion of provision for faculty research, included checklist step and annexed checklist, included resources, further detail on Panel procedure and membership
4	Prof. Carl Gombrich (Director of Teaching and Learning)	04/11/2019	Minor wording changes
5	Academic Council	18/12/2019	Requires review given overall update on general academic regulations in light of decision to pursue NDAPs
6	Dr Ash Brockwell (Faculty member)	02/03/2020	Subheadings to differentiate stage 1 and stage 2; addition of a clause on provision of additional information by students at stage 1 if requested by module tutors; addition of references to researchers'

			safety; further detail on Informed Consent documentation.
7	Dr. Priya Lall (Faculty member)	02/03/2020	Additional stipulations in relation to secondary analysis of established datasets; additions to Research Ethics Panel referral criteria
8	Academic Council	16/03/2020	Approved
9	Regulatory Working Group	11/08/2021	Revised version approved
10	Chair's action of Policy and Regulatory Committee	09/02/2023	Revised version approved