

RO33 – York St John University Research Ethics Policy



**York St John University Research Ethics Policy**

**Table of Contents**

[***Introduction 2***](#_Toc79070348)

[***Ethical standards 3***](#_Toc79070349)

[***Responsibilities 3***](#_Toc79070350)

[***Applicability 4***](#_Toc79070351)

[***Researchers’ obligations 4***](#_Toc79070352)

[***Research conduct 5***](#_Toc79070353)

[***Research design 5***](#_Toc79070354)

[***Working with the NHS 5***](#_Toc79070355)

[***Working with external organisations 5***](#_Toc79070356)

[***Risks and benefits 6***](#_Toc79070357)

[***Research participants 6***](#_Toc79070358)

[**Participants’ rights 6**](#_Toc79070359)

[**Treatment of participants 6**](#_Toc79070360)

[**Vulnerable subjects 7**](#_Toc79070361)

[**Informed consent 7**](#_Toc79070362)

[***Complaints 7***](#_Toc79070363)

[***Whistleblowing 8***](#_Toc79070364)

[***Data protection 8***](#_Toc79070365)

[***Confidentiality and disclosure 9***](#_Toc79070366)

[***Freedom of Information and environmental information 9***](#_Toc79070367)

[***Ownership of research 9***](#_Toc79070368)

[***Monitoring of research 9***](#_Toc79070369)

[***Monitoring this policy 9***](#_Toc79070370)

[***Further information 9***](#_Toc79070371)

**Introduction**

This policy sets out the principles underpinning ethical research conduct at York St John University and provides guidance on the application of those principles, including the process for reviewing the ethical conduct of research. It will be reviewed and updated annually by the University Research Ethics & Integrity Sub-committee (UREISC), subject to approval of any substantive changes by the University Research Committee (URC).

Research at York St John University is conducted according to the principles of academic excellence, community, integrity, inclusiveness, and professionalism. All research must be conducted according to appropriate ethical, legal, and professional frameworks, obligations, and standards.

In addition, the following research must be subject to review through the appropriate research ethics committeeand formally approved before it is undertaken:

* Research involving living human participants, their tissue, or their data.
* Research with the potential for adverse environmental impact; and
* Research involving NHS patients, staff, or resources. Including research already approved by the NHS

Research that may raise other significant ethical issues or pose a reputational risk to researchers or the institution should also be referred for advice and / or review. If in any doubt, advice must be sought from the UREISC.

The purpose of ethical review is not to discourage controversial or high-risk research. An ethical approach to research should not imply an impediment to the pursuit of knowledge, rather, the clear recognition of and preparation for any risks inherent in that pursuit.

Researchers will need to consider a wide range of issues, many of which will be specific to the discipline or situation in question. They will also need to ensure that they abide by University policy in areas such as - [Health and Safety](https://www.yorksj.ac.uk/staff/health-and-safety/), [Intellectual Property](https://www.yorksj.ac.uk/media/content-assets/research/documents/RO02_IPPolicy_201903_v2.docx), [Research Data Management Policy](https://www.yorksj.ac.uk/policies-and-documents/library/research-data-management-policy/)

It is always for the individual researcher or supervisor to consider carefully the potential ethical implications of their work, or that of their students. Members of the University are encouraged to reflect carefully upon the broad range of conceptual, as well as practical, issues that may arise. Individuals then have a responsibility to seek appropriate advice from the relevant Research Ethics Committee Chair and / or formal review and approval of the proposed work.

Whilst not an exhaustive list, the following points provide an indication of ethical issues which may require consideration:

* The balance of risk and benefit.
* The physical and psychological health and safety of subject-participants.
* Obtaining informed consent to participate.
* Arrangements for vulnerable subjects.
* Conflicts of interest.
* Confidentiality and data protection.
* Intellectual property issues.
* Funding sources.
* Monitoring and audit.
* Proportionate and reasonable review.

For the avoidance of doubt, all relevant research proposals must be subject to appropriate review.

**Ethical standards**

All research must be conducted to the highest ethical standards. Key principles include appropriate protection and respect for participants (research subjects and researchers); clear lines of accountability for the ethical conduct of research; and an appropriate balance between the value of the research and the rights of the individuals.

**Responsibilities**

All members of the University, whether staff or students, are individually responsible for ensuring that their work is conducted in accordance with the University values and with all policies that form part of the terms and conditions of employment and study. Individual researchers ultimately have responsibility for ensuring that they consider ethical issues and obtain any appropriate ethical approval prior to commencing the research. Work conducted without ethical approval (where this approval is required) may not be covered by the University’s indemnity arrangements. Failure to comply with this policy may lead to the:

* Failure of assessed work
* Suspension of study
* Ending of research projects
* Removal of funding from research sponsors
* Inability to publish.

Failure to secure ethical approval prior to commencing research constitutes research misconduct, please see the University’s [Research Ethics and Integrity pages](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/). This may lead to sanctions under the [Code of Discipline](https://www.yorksj.ac.uk/students/policies-and-documents/behaviour-and-discipline/) or [Staff disciplinary policy & procedure](https://staffroom.yorksj.ac.uk/Content/File/Index/ebd60f5f-b0b1-49a9-8b7b-a75f5f8e7beb?forceApprovalStatus=False&reviewComplete=False) (intranet log in required), and individual may also be legally liable for any adverse outcome.

The Pro Vice Chancellor for Research and Knowledge Transfer is the owner of this policy and is responsible for research ethics throughout the University.

The URC has responsibility for the oversight of research integrity and research ethics matters. Day-to-day responsibility is delegated to the UREISC.

The UREISC is responsible for oversight of the School Research Ethics Committees (SRECs) and is in turn accountable to the URC.

The SRECs are responsible for supporting their school’s research activity by considering best policy and practice with respect to research ethics within their subject areas, by providing review of ethical issues arising from research proposals within their School, by auditing and monitoring compliance and by disseminating best practice. The SRECs are directly accountable to the UREISC.

SRECs must supply UREISC with a report of activity on an annual basis in July. These will inform the HEI annual report which is published in October of every year to comply with the Concordat on Research Ethics and Integrity.

**Applicability**

This policy applies to all staff and students who contribute to research involving the University (including those with joint-clinical, visiting emeritus or honorary contracts, or externally funded projects), whether or not their current place of work or study is within university premises. Third parties (for example staff of other institutions undertaking research with YSJU students) are expected to adhere to the University’s ethical standards of research conduct.

Broadly defined, research includes all investigation undertaken to acquire knowledge and understanding. This would include:

* Work of educational value undertaken to improve the understanding of the research process.
* Scholarship such as contributions to research databases, catalogues, and dictionaries.
* The generation of designs, concepts, artefacts, and performances that lead to new intellectual understanding.
* The experimental use of existing knowledge to develop new materials and processes.

This definition of research would not normally include:

* Routine audit and evaluation, such as the routine evaluation of teaching.
* The development of teaching materials that do not involve original research.
* Routine testing and analysis of materials and processes.

**Researchers’ obligations**

Individual researchers and student supervisors are responsible for ensuring that their projects, or their students’ projects, are designed and conducted to high ethical standards and are appropriately reviewed. More broadly, researchers have an obligation to ensure that research is conducted with:

* Integrity and sensitivity.
* Compliance with the law.
* Reference to appropriate funders and professional bodies’ requirements.
* Regard for participants, particularly those considered to be vulnerable.
* Regard for obtaining informed consent and that any risk to participants or researchers is proportionate and managed.

Details of the current committee chairs can be found on our webpage for [Research Ethics and Integrity](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/).

**Research conduct**

Research must be conducted with integrity. This means that in addition to the satisfactory resolution of issues surrounding consent, confidentiality and data protection, the principles of honesty and openness should be observed in both the conduct of the research and the publication of the results. Researchers, and research student supervisors, must be competent to undertake the research – for example, must have received adequate training in the methodology, techniques and equipment involved.

The University’s Code of Practice can be found on our webpage - [Research Ethics and Integrity](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/)

Artificial Intelligence

**The information in this section should be read in conjunction with the** [**UKRIO ‘AI in research’ webpage**](https://ukrio.org/ukrio-resources/ai-in-research/)

There are additional ethical issues outside scholarship to consider. The data centres and processing needed for large-language models (chatbots for example) use [large amounts of energy](https://dl.acm.org/doi/10.1145/3442188.3445922). Is their use appropriate? The reinforcement learning from human feedback step usually involves [low-paid workers](https://gizmodo.com/chatgpt-openai-ai-contractors-15-dollars-per-hour-1850415474), often from [low-income countries](https://time.com/6247678/openai-chatgpt-kenya-workers/). The training of many large-language models relies on [copyrighted material](https://aicopyright.substack.com/p/the-books-used-to-train-llms), used without permission.

The general consensus is that granting authorship to such tools is not allowed, as agreed by [COPE](https://publicationethics.org/cope-position-statements/ai-author), [WAME](https://wame.org/page3.php?id=106) and the [ICMJE](https://doi.org/10.1093/eurheartj/ehad448) because the tools and their providers cannot take responsibility for the output. Details of the use of large-language models must instead be declared in the Methods and/or Acknowledgements.

Large-language models should not be used by peer reviewers or editors, because:

* This often breaches confidentiality.
* The tools are not validated for the critical appraisal of scholarly content.
* If someone is unable to assess a manuscript, they should decline to review or edit it.

The UK governments five principles are listed below:

1. Safety, security and robustness
2. Appropriate transparency and explainability
3. Fairness
4. Accountability and governance
5. Contestability and redress

**Research design**

In the case of original research, the project design should ensure that the project is necessary for the advancement of knowledge; that it will not duplicate work that has already been undertaken; and that it will address the question which has been posed. In the case of research conducted as part of a taught course, as an educational exercise, the project may duplicate work that has already been undertaken but must be based upon sound pedagogic principles.

**Working with the NHS**

The University’s framework of ethical review is designed to complement that provided by the NHS. If working with the NHS, researchers must provide their completed Integrated Research Application System (IRAS) form as a pdf to the school and university level ethics committees alongside their YSJU ethics application.

Research reviewed by the NHS includes research involving:

* NHS patients, personal data, or tissue.
* Carers of NHS patients.
* Adults lacking the capacity to consent.
* Research classified as a Clinical Trial.
* Human tissue.

The NHS does not require review by an NHS Committee for activities that they consider to be service evaluation, clinical audit, surveillance, or usual practice in public health. Such studies may, however, require University review.

Eight weeks is the standard timescale for the processing of research ethics applications to go through school-level and university-level research ethics committees. The university level takes a minimum of three weeks. Please note that where applications are returned to the researcher requesting that additional information is provided, the standard timescale is likely to be exceeded.

Timescales are available on the [Process for research ethics approval webpage](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/process-for-research-ethics-approval/). Researchers should factor in possible delays due to amendments, into their research plans.

The Research Office will obtain insurance cover documents and will liaise with the insurance provider, on the researcher’s behalf. The Research Office will need sight of the IRAS form, which should be as complete as possible and contain enough information for the insurers to review the project and make a decision. Insurance is always required, when working with the NHS regardless of who the sponsor is. It is the researcher’s responsibility to contact the Research Office to start this process. Further information can be found on the [Working with the NHS](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/working-with-the-nhs/) webpage. Researchers do not have to wait for ethical approval before requesting insurance cover. If the research project requires review by the insurance provider, this can take on average three weeks to receive confirmation.

**Working with external organisations**

The University expects all applications to be considered by the relevant ethics committee, even if there is prior approval from an external organisation. Care should be taken with international research – legislative and cultural imperatives vary widely. Research outside the UK will normally require review within York St John University, as well as being compliant with relevant legal and ethical requirements in the host country.

If staff or students participate in collaborative studies, it is essential that these are conducted to a standard compatible with the University’s requirements. This includes studies undertaken at, or conducted in partnership with, overseas institutions – although it is recognised that careful consideration will be required of local circumstances and of any limitations these might place upon the research protocol, such as difficulties with obtaining written consent. Researchers will be expected to demonstrate that the best possible practice has been adhered to under the circumstances pertaining.

The Research Office will obtain insurance cover documents and will liaise with the insurance provider, on the researcher’s behalf. The Research Office will need sight of the IRAS form, which should be as complete as possible and contain enough information for the insurers to review the project and make a decision. Insurance is always required, when working with any external partners, regardless of who the sponsor is. It is the researcher’s responsibility to contact the Research Office to start this process.

**Risks and benefits**

The expectation is that the likely benefits of research, including the advancement of knowledge, will outweigh the risks involved to subject-participants. Any risks, physical, psychological, financial or of any other type, must be clearly identified; must be manageable; and must be clearly explained to participants before consent to participate is sought.

Researchers will also need to consider the potential for reputational risk, to both individuals and institutions. Advice can be sought, in confidence, from the appropriate SREC, or the UREISC.

**Proportionate review**

The likelihood and severity of the risks posed by projects will, of course, vary, and will be reflected in the process of review and approval.

**Higher risk**

Projects which present higher risks, or more serious or complex ethical issues will require full review by a SREC or, in certain cases, the UREISC.

**Lower risk**

Projects which present lower risks will be reviewed through an expedited procedure proportionate to the nature of the issues arising.

**Research participants**

**Participants’ rights**

The dignity of all research participants must be respected. There is an expectation that participants will have rights to:

* An appropriate and proportionate opportunity to give or refuse informed consent to participate or to withdraw from research projects without inducement or adverse consequence.
* Appropriate confidentiality.
* Security, including appropriate anonymisation and storage of their data or samples.
* Safety and safeguards appropriate to the risks posed by participation in research.
* A clear framework for raising queries, concerns, or complaints.

**Treatment of participants**

All reasonable measures must be taken to protect the health, safety and psychological wellbeing of researchers and all subjects. In particular, the location and environment of the study and any equipment or procedures will be subject to review under national Health and Safety legislation and the University policy on [Health and Safety](https://www.yorksj.ac.uk/staff/health-and-safety/)

Should an adverse incident occur during research, this must be reported to the appropriate person. In most cases, this will be the researcher’s line manager or supervisor. In the case of a critical incident, researchers should be aware of their responsibility to notify the Security Office immediately and complete a report at the first opportunity. More information about critical incidents is available here - [Accidents and Incidents](https://www.yorksj.ac.uk/staff/health-and-safety/accident-or-incident/)

**Vulnerable subjects**

Due consideration must be given to the needs of ‘non-competent’ participants, who may be at risk of feeling pressured into participation or who may not be able to give adequate informed consent to participate. Examples might include children, those with mental disabilities and those only able to give consent through a carer.

Consideration must also be given to the needs of ‘compromised subjects’ who have a dependent relationship with a researcher that may cloud their motives for participating and their perception of their right to withdraw at any time. Examples might include a tutor’s own students, or a clinician’s own patients. Appropriate and proportionate steps must be taken to safeguard the rights and dignity of such participants.

**Informed consent**

The expectation is that researchers will obtain, and record, the informed consent of participants. To achieve this, participants must be given clear information about the study’s aims, the risks and benefits, and the nature of their involvement. Participants must be given sufficient time to reflect upon any information that they are given, and researchers must be satisfied that this information has been understood. A participant’s right to withdraw at any time, without giving a reason, must also be clearly explained and understood. In no circumstances should coercion, disproportionate payment or inducement, or the expectation of any other inappropriate advantage be used to influence consent.

There may be circumstances under which it would not be practicable to obtain participants’ fully informed consent in advance – examples might include projects involving the use of covert observation or projects which depend upon the subject being unaware, at least initially, of the subject under investigation. Under such circumstances, researchers should carefully consider the justification for the methodology employed and be prepared to set out their reasoning. In any case, where it is practicable to do so, it is good practice to obtain participants’ consent to the use of their data (if necessary, retrospectively).

When using observational methodologies, researchers should be aware of whether members of the public who are not direct participants might also be observed, and whether their data might be recorded because of their interaction with a subject. Consideration should be given to whether such interaction takes place within a public or private sphere, and how data collection can be minimised and / or anonymised.

In the case of vulnerable groups, it may be necessary to obtain proxy consent from, for example, a parent or other competent adult. Such participants will, or course, retain the right to refuse participation and to withdraw at any time.

**Complaints**

Complaints from research participants should be dealt with through the [Research Misconduct policy and procedure](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/policies-and-reports/), and this should be stated in the information given to research participants before seeking their consent. Specific wording to be included in consent forms and participant information and a list of independent chairs can be found on the [[Resources and downloads webpage](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/resources-and-downloads/)](https://www.yorksj.ac.uk/policies-and-documents/research/ethics-and-integrity/resources-and-downloads/).

In the first instance, where a researcher does not agree with the outcome of the SREC review, they may request cross-referral from the SREC of a different school committee (with a disciplinary link appropriate to give feedback), by contacting the Research Officer: Compliance. If this does not resolve the issue, or if the issue is with the ethics process, then this would fall under the [Student Complaints Procedure](https://www.yorksj.ac.uk/media/content-assets/university-secretary-office/documents/student-casework/Student-Complaints-Procedure-2324-%281%29.pdf), overseen by [Casework](https://www.yorksj.ac.uk/students/concerns-and-complaints/). On receipt of a complaint, the Research Officer: Compliance may refer the matter to University's Student Casework Team for a decision on whether the Student Complaints Procedure is the appropriate procedure to use, or if instead it would fall under the [Grievance Policy & Procedure](file:///C%3A//Users/k.eldred/Downloads/Grievance%20Policy%20%26%20Procedure%20%28Aug%202023%29.pdf) (staff only) overseen by [Human Resources & Organisational Development](https://staffroom.yorksj.ac.uk/Home/Index/54beb24a-7d20-4bff-82d7-4360730392ea).

**Whistleblowing**

The University has a duty to conduct its affairs in a responsible and transparent way. The [Whistleblowing Policy](https://www.yorksj.ac.uk/policies-and-documents/whistleblowing/) provides a process through which employees, students and Governors of the University can disclosure information which they reasonably believe tends to show one or more of the following:

* A criminal offence has been committed, is being committed or is likely to be committed
* A person has failed, is failing or is likely to fail to comply with any legal obligation to which he is subject
* A miscarriage of justice has occurred, is occurring or is likely to occur
* The health or safety of any individual has been, is being or is likely to be endangered
* The environment has been, is being or is likely to be damaged, or
* Information tending to show any matter falling within statements above are being, or are likely to be deliberately concealed

Anyone wishing to raise a concern under our Whistleblowing policy should contact:

Kathryn Kendon, University Secretary
us@yorksj.ac.uk

**Data protection**

Confidentiality of participants’ data must be assured, including through adequate anonymisation. The storage and use of data must comply with the UK Data Protection Regime which consists of the UK GDPR and Data Protection Act 2018, the Human Rights Act 1998 and the [Research Data Management Policy](https://www.yorksj.ac.uk/policies-and-documents/library/research-data-management-policy/)

The Data Protection Act contains eight basic principles, which state that personal data must:

* be obtained and processed fairly and lawfully and shall not be processed unless specified conditions are met.
* be obtained for a specified and lawful purpose and shall not be processed in any manner incompatible with that purpose.
* be adequate, relevant, and not excessive for those purposes.
* be accurate and kept up to date.
* Not be kept for longer than is necessary for that purpose.
* be processed in accordance with the data subject’s rights.
* be kept safe from unauthorised access, accidental loss or destruction.
* Not be transferred to a country outside the European Economic Area unless that country has equivalent levels of protection for personal data.

**Confidentiality and disclosure**

During their research, it is possible that researchers may uncover information relating to illegal activity; or information about topics that are sensitive or that may carry obligations to consider disclosure to the appropriate authorities (such as potential harm to children or vulnerable adults). The law in this area is complex and it is likely that the question of whether to breach confidentiality in such cases, and to whom to disclose any information, would be best decided upon a case-by-case basis.

Advice upon individual cases is available from the University Secretary. However, there are several general principles which might apply in such cases:

* Researchers should consider whether they can seek the participant’s consent to breach confidentiality.
* There may be a legal obligation to breach confidentiality, for example if a court orders disclosure.
* Under any circumstances, disclosure should be restricted to those who need to know the information concerned and should be relevant and not excessive.

**Freedom of Information and environmental information**

Requests for information made under the Freedom of Information Act 2000 or the Environmental Information Regulations 2004 should be referred to the Information Governance Assistant and the Data Protection Officer, within the University Secretary’s Office from whom advice is also available upon the implications of the Act and Regulations for data confidentiality.

**Ownership of research**

The ownership of research should be clearly documented, and there should be clear lines of responsibility for the conduct of the research. This includes, inter alia, issues of intellectual property; health and safety; and the training and competence of researchers.

**Monitoring of research**

Research should be monitored to ensure compliance with the principles of good practice. Records should be kept for inspection by the appropriate SREC and / or the UREISC, as required.

**Monitoring this policy**

The UREISC is responsible for the monitoring and annual review of this policy. Each school level committee must submit an annual report each summer, which is reviewed at the autumn UREISC. School annual reports form the basis of the institutional report which must be approved by Governing Body and published online every October.

**Further information**

Advice on this policy, research ethics and the Code of Practice for Research Integrity may be sought from ResearchOffice@yorksj.ac.uk

The advice set out above constitutes general guidance upon the type of ethical issues that researchers might encounter, and the expectations of the University and other research stakeholders about how such issues should be managed. It is not intended to be exhaustive, and further advice is available from the SRECs and the UREISC.