

Research Ethics Policy & Procedure

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Introduction

Wrexham University is committed to maintaining the highest standards of ethics, rigour, and integrity in all its research and seeks to protect the dignity, rights, and welfare of all those involved in the research it produces. Research Ethics is a worldwide set of principles that govern how research involving interaction between researchers and humans (including human tissue or data), as well as animals or the environment, is designed, managed, and carried out.

All research conducted under the auspices of the University must be conducted ethically. However, specific projects need to receive research ethics approval from one of the University's Research Ethics Committees before they begin. These projects include.

- Research involving human participants (including where the researcher is the sole participant)
- Research involving human material (including human remains)
- Research involving personal data (including social media data)
- Research involving animals (including animal by-products)
- Research that may impact the environment (including exposure to gas/chemicals that could harm researchers and potential by-standers)

The University's Research Ethics Committee cannot provide retrospective approval of research proposals. If you collect data before you have gained approval, you will not be able to use that data and may be subject to investigation of potential research misconduct.

Scope

This policy provides a framework to ensure that all research is conducted in accordance with fundamental ethical principles. It applies with equal force to projects undertaken by staff and students at the University, regardless of location. This includes collaborative work with third-party organisations, validated and franchised programmes being delivered by partner institutions and research conducted by visiting or honorary staff under the auspices of Wrexham University.

Research should be interpreted broadly to include all investigations carried out under the auspices of the University, regardless of whether they are funded or unfunded. This policy includes, but is not limited to, research projects, pilot studies, audits, service evaluations, and any other activities that involve data collection aimed at generating knowledge, understanding, or assessments that may contribute to academic or public discourse. This includes potential Knowledge Transfer Partnerships (KTPs), Knowledge Transfer Ventures (KTVs), consultancy work, and public engagement activities. Specifically, it covers any project that involves the collection, analysis, or interpretation of data aimed at producing generalisable findings or conclusions.

Principles

The University is committed to ensuring that all its research activities are carried out safely and in a way which respects the rights, dignity, and welfare of all involved.



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The guiding ethical principles of the University are outlined as followed.

- 1. Research should aim to maximise the benefits for individuals and society and minimise the potential risk and harm. All potential risks and harm should be mitigated by robust precautions and all participants involved must be warned before participating.
- 2. Where possible, all participants in research must take part voluntarily, free from any coercion or undue influence, and their rights, dignity, and autonomy should be respected and appropriately protected.
- 3. The confidentiality of the information supplied by research participants and the anonymity of respondents must be respected. Wherever possible, data should be anonymised and there should be full compliance with the principles of the Data Protection Act 2018. Personal data can only be disclosed when permission to disclose is part of the consent procedure.
- 4. Independence of research should be maintained and where conflicts of interest cannot be avoided, they should be made explicit.
- 5. Research should be designed, reviewed, and undertaken to ensure recognised standards of integrity are met, and quality and transparency are assured.
- 6. The research must conform to all relevant statutory requirements, and to the requirements of the institution in which the research is undertaken.

Research Exemptions

Research ethics approval is typically not required for the following scenarios; however these projects should still be considered ethical, upholding the highest standards of integrity and ensure any other governance requirements are in place before research commences.

- Literature/Systematic Reviews
- Documentary Analyses
- Anonymised records and datasets that are publicly available, both within and outside
 the UK. This includes datasets accessible through the Office for National Statistics
 (ONS) or the UK Data Archive, provided that the necessary permissions have been
 obtained and individuals cannot be identified from the information given.
- Research involving established cell lines
- Data collected solely for Wrexham University internal evaluation or business purposes, such as student course assessments or feedback mechanisms. However, this data cannot be used for research purposes, including publication, at a later time.
- Consultations and data gathered from interested parties during the development stages of a research proposal. Like the previous point, this data also cannot be used for research purposes, including publication, later.

Responsibilities

The **University's Research Committee** is responsible for providing policy and guidance on research ethics and research integrity, ensuring an effective and robust process is in place.

The **University's Research Ethics Committees** are responsible for promoting the interest of participants in research through the review of applications seeking research ethics approval and ensuring they are carried out in accordance with the University's research ethics principles, policies, and procedures.





Staff members, including visiting and honorary staff conducting research under the auspices of the University are responsible for considering the ethical implications of their research projects, conducting their research in accordance with the University principles and procedures and obtaining formal research ethics approval from the relevant research ethics committee before research commences.

In the case of research undertaken by undergraduate or postgraduate students, the **Supervisor** is responsible for ensuring that their students have received adequate training in research ethics, are familiar with the policies and procedures of the University, the research being conducted is considered ethical and the correct approvals have been sought before research commences.

Applying for Research Ethics Approval

All applications for research ethics approval must be submitted through the Wrexham Research Ethics System. Applications must be completed to a high standard and should include all relevant documentation before they can be reviewed. Student applications must be signed off by their supervisor prior to submission for approval. Applications will be assigned to either the University Research Ethics Committee or the Faculty Research Ethics Committee, depending on the level of risk involved.

Procedures

The University is committed to providing an independent process of ethical review that is proportionate to the potential risk involved. This process includes a range of procedures for specific application types.

Research that has already received ethical approval

Research that has received prior approval from another recognised research ethics committee will still need to receive ethical approval from the University. The University Research Ethics Committee will usually review and approve these applications by recognising the approval and documentation submitted by the external ethics committee. Researchers must submit their application through the University's online research ethics system. This submission should include all relevant documentation, including the approval letter from the external ethics committee, the complete set of approved application materials which includes Wrexham University involvement.

NHS REC approval

Research requiring the ethical review procedures of the National Health Service are required to submit an application through the Integrated Research Application System (IRAS). Where this is the case, the University will oversee this process and there is no need to get additional ethical approval from one of the University Research Ethics Committees. All projects submitted to the NHS via the Integrated Research Application System have to be sponsored by the University. The University Sponsor is the Head of Research Services, please ensure they are contacted when starting an IRAS application.





Research Involving Animals and Environmental Impact

Please note that Wrexham University does not hold an establishment license required by the Animal Scientific Procedure Act 1986. Any research involving animals or animal by products should refer to the Research Ethics Procedure for work carried out with Animals. Research which includes methods of data collection that may have a negative impact on the environment should refer to the Potential Adverse Environmental Impact Research Ethics Procedure.

Research conducted outside the UK

Any research being conducted outside the UK, including EU and EEA countries, should where possible first secure research ethics approval from a local in-country research ethics committee before applying for Wrexham University Research Ethics approval.

This is because the view of what are ethically acceptable research methodologies depends on the cultural, political, and regulatory environment of the location in which the research is conducted. Ethical considerations of research, how we conceptualise the notions of individual rights in research, and the political and cultural sensitives within research vary across the world. Applicants should refer to the University Research Ethics Approval procedure for Research Conducted outside the UK

After receiving approval

Amendments

Once you have received research ethics approval, your study must be conducted according to the application and documentation that have been approved. Research often evolves rapidly, which may lead to activities that fall outside the original approval. To ensure compliance, any amendments to your application should be submitted for approval before implementing any changes. Conducting research outside the approved scope constitutes a breach of ethical approval and may result in investigations for misconduct.

Reporting Adverse Events

All staff and students should be familiar with the reporting of <u>adverse events procedure</u> before commencing any research. Certain studies involving human participants or personal data carry a risk of adverse events occurring. Legislation and governance frameworks exist to ensure that assessment, monitoring, and reporting of adverse events are clearly defined in order to prevent and mitigate adverse events and promote and protect participant safety. The University defines an adverse event (AE) as an untoward occurrence during a research study that led to or could have led to an unintended or unexpected harm, loss, or damage. The Principal Investigator or Supervisor should inform the University Research Ethics Committee within 10 days of an adverse incident occurring.

Appeals

If an application has been rejected by one of the University's Research Ethics committees or the conditions or modifications requested by the committee are deemed unacceptable by the applicant for justified research reasons, the applicant may appeal the decision of the review. Further details of this process can be found in the <u>Research Ethics Appeal Procedure</u>.





Breach of Policy and Complaints

The University regards any breach of this policy or any breach of the approved terms of a project, as a very serious matter, which may result in research misconduct proceedings. Suspected breaches of this policy should be reported to the University Research Ethics Committee rescadmin@wrexham.ac.uk who under the regulations can withhold, suspend, or withdraw approval of research, whether as part of disciplinary proceedings or otherwise.

Professional Bodies

All staff and students are required to adhere to the University's policies, principles, and procedures when conducting research. Additionally, it is important for staff and students to familiarize themselves with and, when applicable, follow the Code of Conduct, Code of Ethics, and Research Ethics guidelines established by their respective professional bodies.

