

An Introduction to Newcastle University's Ethics Policy and Procedure

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Key principles



What is research ethics?



Definition: a set of moral principles that guide research from project design through to delivery and publication of results.





The **UKRI framework for research ethics** is based on the following principles:

Benefice and Non-Maleficence

Research should aim to maximise benefit for individuals and society and minimise risk and harm.

Dignity and respect

The rights and dignity of individuals and groups should be respected.

Voluntary participation

Wherever possible, participation should be voluntary and appropriately informed

Independence

Independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.

Accountability

Lines of responsibility and accountability should be clearly defined.

Integrity

Research should be conducted with integrity and transparency





Purpose of ethical approval:



- ✓ Ensures compliance with legal and regulatory frameworks.
- ✓ Improves the quality of research.
- ✓ Provides assurance to research participants, funders and publishers.
- ✓ Protects the **reputation** of the researcher, their supervisor and the University.





University Policy:

Newcastle University Ethics Policy for Research, Teaching and Consultancy https://bit.ly/3NpOOZx

- All researchers are responsible for undertaking research to the highest ethical standards.
- An online ethics form should be submitted for all projects.
- Ethical approval must be in place before work begins on the project.
- Failure to comply is considered a form of research misconduct.





Ethical review process:

STEP 1:

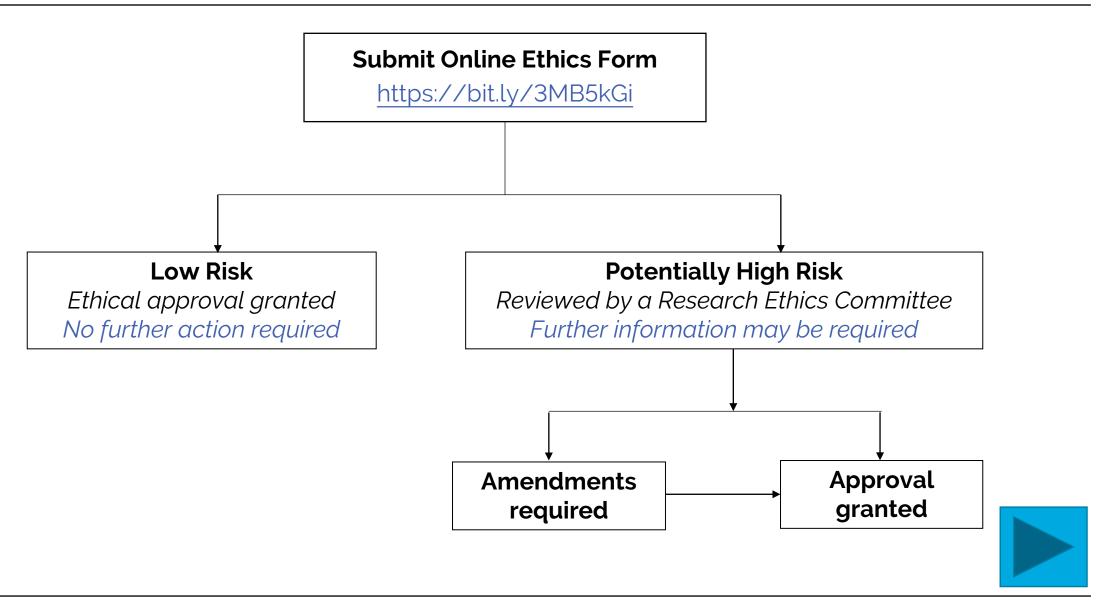
The Principal Investigator completes Newcastle University's **Online Ethics Form**. The form is made up of a series of questions which are designed to assess the level of risk.

STEP 2:

Following submission, the Principal Investigator will receive a notification that either:

- Based on the answers provided, the University is satisfied that the project meets the University's ethical expectations and grants the project ethical approval, <u>OR</u>
- Based on the answers provided, the project requires further review by a Research Ethics Committee before any research can begin.







Potentially high risk activities





Working with Animals

IMPORTANT: all research projects involving animals will be flagged for review by the University's specialist Animal Welfare Ethical Review Board (AWERB).

- Researchers must apply for both a Personal and a Project license in order to carry out regulated procedures on protected animals under the Animals (Scientific Procedures) Act.
- Researchers should always consider the **Replacement**, **Refinement** and **Reduction** of animals (the 3Rs) n the design of their research.
- Care and attention also applies to the **observation of animals** on University premises or in their natural environment.

For further information please refer to the University's Ethics Toolkit: https://bit.ly/39vwVKD







Health and Social Care research

IMPORTANT: the University is unable to approve the following types of research activities. External ethical approval is required from an NHS or Social Care Research Ethics Committee.

- Research involving NHS sites, patients, service users, tissue samples or personal data.
- Clinical trials of new medical devices or investigational medicinal products.
- Health related research involving prisoners.
- Research involving care home staff or residents.
- Research involving adults who lack the capacity to consent.

For further information please refer to the University's Ethics Toolkit: https://bit.ly/3MUUrP1







Working with Human Participants

E.g. qualitative research activities involving interviews, surveys and focus groups.

- Participation should always be voluntary, and participants should have the right to withdraw at any point during the study.
- Information on what the study involves should be provided in advance, so individuals can make an **informed decision** about whether or not they want to take part.
- A process should be put in place for recording consent.
- Sensitive topics should be handled carefully.
- Safeguarding concerns should be reported to the University.

For further information please refer to the University's Ethics Toolkit: https://bit.ly/3zIAOBI







Working with Human Tissue

E.g. samples of blood, bone, organs, skin, saliva, teeth, sweat, urine or faeces.

- Researchers should obtain informed consent for the collection of all samples, unless the samples will be obtained from a registered biobank.
- External approval is required to set up a new biobank.
- To ensure compliance with the Human Tissue Act, the University has developed a number of Standard Operating Procedures regarding the collection, storage and disposal of human tissue samples on campus.

For further information please refer to the University's Ethics Toolkit: https://bit.ly/3MTnaUe







Working with Personal Data

E.g. personal identifiable information such as names, email addresses,

- All researchers should familiarise themselves with the principles of the General Data Protection Regulation (GDPR) by completing the University's e-learning module.
- A **Privacy Notice** should be provided to research participants confirming what information will be collected and how it will be used.
- Personal and sensitive data should be anonymised to protect the confidentiality of research participants.
- Personal data should not be shared with a third party or used for a different purpose without consent.

For further information please refer to the University's Ethics Toolkit: https://bit.ly/3tCcpyP







Environmental impact

- Researchers should consider the impact of fieldwork on the landscape, infrastructure or local community.
- Special permission may be required to conduct fieldwork in areas of cultural or historical significance, or protected areas such as Sites of Special Scientific Interest (SSSI) or Environmentally Sensitive Areas (ESA).



 Researchers should also consider the potential harm caused by gas, noise, particulates, chemicals or ionizing particle emissions.

For further information please refer to the University's Ethics Toolkit: https://bit.ly/3xT8osf





International research

- Researchers conducting overseas fieldwork should consult the Foreign, Commonwealth & Development Office (FCDO) website and complete a Travel Abroad Risk Assessment. Researchers are also responsible for ensuring that they have appropriate insurance.
- Local permissions may be required to carry out research overseas.
- Researchers should also consider how their research could impact
 the people they are studying, whether the research will benefit their
 participants or put them at risk of harm in any way. Particular care
 should be taken when considering the impacts of research involving
 political or cultural sensitive issues.

For further information please refer to the University's Ethics Toolkit: https://bit.ly/3mQa1k9







Support and guidance





Online Ethics Toolkit

Home

Research Impact

Our Strengths

Research Excellence Framework (REF) 2021

Doctoral College

Global Challenges

Centre for Transformative

Neuroscience

Centre for Landscape

Centre for Ageing and Inequalities

Centre for Climate and Environmental Resilience

Centre for Rare Disease

Ethics Toolkit for Principal Investigators

The Ethics Toolkit is designed:

- 1. To assist students and staff when completing their ethical applications
- 2. To provide a repository of useful resources, including example ethics forms, information sheets and consent forms.

The pages below provide detailed information on different topics.



Linked the University's Research Governance webpages: https://bit.ly/3zMMubo





Research Ethics Committees

Faculty Research Ethics Committees:

Faculty Committees manage the ethical review process and provide advice to staff and students in their local areas:

Faculty of Humanities and Social Sciences	Wendy.Davison@ncl.ac.uk
Faculty of Medical Sciences	fmsethics@ncl.ac.uk
Faculty of Science, Agriculture and Engineering	sage.ethics@ncl.ac.uk

School of Psychology:

The School of Psychology Ethical Review Board reviews Undergraduate student applications. Contact: pscyhethics@ncl.ac.uk.

AWERB:

Projects involving animals are reviewed by the specialist Animal Welfare Ethical Review Board. Contact: cbc.awerb@ncl.ac.uk.





Low Risk Projects

If your project is assessed as low risk, you will receive automatic approval on behalf of the University.

Please contact the **Research Policy**, **Intelligence and Ethics** team with any queries relating to low risk projects, or for general advice about the online ethics form or the University's Ethics Policy: res.policy@ncl.ac.uk.





Top tips





- ✓ If external ethical approval has already been granted, further review is not required by the University. However, you will still need to complete the preliminary questions on the online ethics form and provide evidence of this.
- ✓ If you are a student, you should **ask your supervisor for advice** on completing an ethics application if you are a student. Your supervisor should also review your application before you press submit.
- ✓ Use lay language to describe the project, as it may not be reviewed by a subject expert.
- ✓ Provide supporting documentation such as a copy of your protocol, Participant Information Sheets and Consent Forms.
- ✓ Keep a copy of your ethics application for your own records.
- Maintain a record of the ethical approval and project documents for audit purposes. Including evidence of consent, where applicable.
- ✓ Notify the relevant Committee of any changes to the approved protocol.



