

RESEARCH ETHICS POLICY

1. INTRODUCTION

This Research Ethics policy outlines Keele University standards and expectations relating to the ethical conduct of research involving human participants (and their data), animals, the use and exchange of genetic resources (Nagoya protocol), and researching using artificial intelligence / automated systems.

1.1 Purpose

The purpose of this policy is to explain the University's stance in relation to the ethical conduct of research and research related activity.

1.2 Scope

This Research Ethics policy applies to any person(s) who conducts research on behalf of the university, including but not limited to an employee (including academic, technical, and professional services staff); an independent contractor or consultant; a student; a visiting or emeritus member of staff; or a member of staff on a joint clinical or honorary contract.

2. POLICY

Keele University is committed to conducting high quality research underpinned by appropriate ethical standards for the benefit of society and in the public's interest.

The University recognises the benefits of a positive culture of ethical reflection, debate, and mutual learning particularly against the continuing emergence of new situations and research methodology which require creative approaches to ethics issues.

The Policy does not replace the need for researchers to critically and responsibly consider their own activities and issues that arise during their research but does provide a framework to illustrate how to proceed.

Good research ethics applies to all researchers (see annex A for definition) who conduct research for Keele University – regardless of whether the research is funded or unfunded, who it is funded by and where the research is conducted including research related consultancy.

Student research must always be overseen by an identified academic, who takes responsibility for ensuring that the University's Research Ethics Policy, [Code of Good Research Practice](#) and any other relevant legislation, policies and procedures are followed.

2.1 Ethical Principles

Research conducted by the University covers a wide range of disciplines, requiring an equally diverse set of ethical review processes united by a common set of principles.

Ethical principles for research with human participants and personal data

The principle of **respect**:

- Acknowledges the dignity and autonomy (when possible) of individuals and requires that people with diminished autonomy be provided with special protection.

- Ensures that certain participant populations including (but not limited to) children, prisoners, the mentally disabled and people with severe illnesses are appropriately protected.
- Requires that participants (and third parties – which may include family members, carers, or the wider community) are fully informed about the purpose and intended possible uses of the research, what their participation involves and details of any risks (unless the ethics committee explicitly approves otherwise because, for example, the research involves the deception of participants in the research project).
- Ensures that participants freely and voluntarily provide their consent to participate in such research and can choose to withdraw without adverse consequences (or, for those with diminished autonomy, consent is sought from an appropriate representative).
- Requires researchers to observe the confidentiality of information provided by participants and, where appropriate, respect their anonymity.

The principle of **beneficence**:

- Requires that any risk of adverse effect on people, either directly or indirectly because of participation in the research project, is outweighed by the benefits.

The principle of **non-maleficence**:

- Makes it necessary to examine carefully (through risk assessment) the design of the study and its risks and benefits including, in some cases, identifying alternative ways of obtaining the benefits sought from the research.

The principle of **justice**:

- Requires that we treat participants fairly. Participants should be carefully and equitably chosen to ensure that certain individuals or classes of individuals – such as prisoners, elderly people, or financially impoverished people – are not systematically selected or excluded, unless there are academically or ethically valid reasons for doing so.
- Requires that unless there is careful justification for an exception, research should also not involve persons from groups that are unlikely to benefit from subsequent applications of the research.

Each of these principles carries strong moral force, and difficult ethical dilemmas arise when they conflict. A careful and thoughtful application of the principles will not always achieve clear resolution of ethical problems. However, it is important to understand and apply the principles, because doing so helps to ensure that people who agree to be research participants will be treated in a respectful and ethical manner.

The University will call to account any member of staff involved in upheld allegations of research misconduct and breach of compliance with this policy in accordance with the Research Misconduct Policy.

2.2 Ethical principles for animal research

Replacement, Reduction and Refinement (3R's¹) of animals will be sought wherever possible.

Researchers are required to show a respect for all life.

- **Replacement** refers to technologies or approaches which directly replace or avoid the use of animals in experiments where they would otherwise have been used.
- **Full replacement** avoids the use of any research animals. It includes the use of human volunteers, tissues and cells, mathematical and computer models, and established cell lines.
- **Partial replacement** includes the use of some animals that, based on current scientific thinking, are not considered capable of experiencing suffering. This includes invertebrates² such as *Drosophila*,

¹ National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs)

² Note cephalopods such as octopuses and squid are protected in the UK by the *Animals (Scientific Procedures) Act 1986*.

nematode worms and social amoebae, and immature forms of vertebrates³. Partial replacement also includes the use of primary cells (and tissues) taken from animals killed solely for this purpose (i.e. not having been used in a scientific procedure that causes suffering).

- **Reduction** refers to methods that minimise the number of animals used per experiment or study consistent with the scientific aims. It is essential for reduction that studies with animals are appropriately designed and analysed to ensure robust and reproducible findings.

Reduction also includes methods which allow the information gathered per animal in an experiment to be maximised to reduce the use of additional animals. Examples of this include the use of some imaging modalities which allow longitudinal measurements in the same animal to be taken (rather than for example culling cohorts of animals at specific time points), or micro sampling of blood, where small volumes enable repeat sampling in the same animal. In these scenarios, it is important to ensure that reducing the number of animals used is balanced against any additional suffering that might be caused by their repeated use.

Sharing data and resources (e.g. animals, tissues, and equipment) between research groups and organisations can also contribute to reduction.

- **Refinement** refers to methods that minimise the pain, suffering, distress, or lasting harm that may be experienced by research animals, and which improve their welfare. Refinement applies to all aspects of animal use, from their housing and husbandry to the scientific procedures performed on them.

Examples of refinement include ensuring the animals are provided with housing that allows the expression of species-specific behaviours, using appropriate anaesthesia and analgesia to minimise pain, and training animals to cooperate with procedures to minimise any distress.

Evidence suggests that pain and suffering can alter an animal's behaviour, physiology, and immunology. Such changes can lead to variation in experimental results that impairs both the reliability and repeatability of studies.

Researchers working with animals must adhere to any applicable legislation (e.g. ASPA / Home Office requirements) and must ensure appropriate husbandry of animals in accordance with species specific welfare standards.

2.3 Ethical Principles for artificial intelligence (AI) and automated systems

AI can be defined as the use of digital technology to create systems capable of performing tasks commonly thought to require intelligence. AI is constantly evolving, but generally it:

- involves machines using statistics to find patterns in large amounts of data
- is the ability to perform repetitive tasks with data without the need for constant human guidance⁴

Researchers using AI for research purposes should comply with the overarching principles of the UK Data Ethics Framework⁵: transparency, accountability, and fairness.

- **Transparency** means that your actions, processes, and data are made open to inspection by publishing information about the project in a complete, open, understandable, easily accessible, and free format.

³ Under the UK's *Animals (Scientific Procedures) Act 1986* embryonic and foetal forms of mammals, birds and reptiles are protected during the last third of their gestation or incubation period, fish and amphibians once they can feed independently and cephalopods at the point they hatch. Embryonic and foetal forms are protected from an earlier stage of development if they are going to live beyond the stage described above and the procedure is likely to cause them pain, suffering, distress, or lasting harm after they have developed to that stage.

⁴ Source: GDS, OAI (2019) 'A guide to using artificial intelligence in the public sector'

⁵ Data Ethics Framework: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/923108/Data_Ethics_Framework_2020.pdf

- **Accountability** means that there are effective governance and oversight mechanisms for any project.
- **Fairness** — It is crucial to eliminate your project’s potential to have unintended discriminatory effects on individuals and social groups. You should aim to mitigate biases which may influence your model’s outcome and ensure that the project and its outcomes respect the dignity of individuals, are just, non- discriminatory, and consistent with the public interest, including human rights and democratic values.

When working with AI/ automated systems researchers have a responsibility to ensure that any potential harms (e.g. bias and discrimination; denial of individual autonomy; recourse and rights; non-transparent, unexplainable, or unjustifiable outcomes; invasion of privacy, isolation, and disintegration of social connection; unreliable unsafe or poor-quality outcomes) must be mitigated against as far as practicable.

2.4 Responsibilities

Researchers have an ethical obligation to refrain from tampering with data. Thus, research data and data analyses should not be fabricated, altered nor discarded. In addition, researchers have a responsibility to exercise reasonable care in processing data to ensure no errors affect the results.

Researchers are required to declare any conflicts of interest and should be aware of the potential influence of personal or commercial interests on their work and take all practical measures to ensure that information is presented without distortion.

Nothing that is said in this policy will absolve the responsibility of the researcher to act in accordance with the best interests of the participants, and researchers should undertake research legally and in accordance with any relevant frameworks / professional codes of conduct.

Appropriate risk assessment for any research activity must be undertaken in line with the University’s health & safety policy and processes.

When accessing specialist research facilities at the Keele University, researchers will be required to adhere to any specific building/equipment Standard Operating Procedures (SOPs) and risk assessments.

2.5 University staff and students as participants in research

The Keele University extends to its staff and students the same protection as to all other participants.

Staff and students may be invited to participate in research carried out in the University, but their participation must be entirely voluntary, they may withdraw and their participation or decision not to participate will not affect their employment or academic assessment in any way.

It is normally acceptable for students to be invited to take part in teaching exercises, one of the main aims of which is to train them to make their own observations.

2.6 Training and mentoring

The University will encourage ethical research conduct among staff and students through the provision of training to equip them with the skills to recognise potential risks and by raising awareness of the University’s policy and procedures and the responsibilities of researchers in helping the University meet its obligations under the relevant legislation.

2.7 Research requiring research ethics committee review

Review by a research ethics committee is required where research involves humans, their data⁶ or biomaterial⁷; animals; risk of damage to the environment; risk of damage to any artefacts of cultural

⁶ Includes primary data originating from human subjects (e.g. anonymous questionnaires or identifiable interview data); and the use of secondary data, which originated from or is about human subjects, which was initially provided for other purposes (e.g. other research projects or organisational datasets).

⁷ Anything that originates from a human subject including cells; tissues; organs; bodily fluids (e.g. blood, plasma, spinal fluid); secretions and excretions (e.g. breath, urine); outgrowths (e.g. hair, nail, teeth).

significance; politically or socially sensitive topics with impact on the welfare and interests of local, national or international communities; potential reputational risk to the researchers or University or where a source of funding has the potential to compromise the University's position as a publicly funded charitable body.

Projects including high / substantive risk activity as defined in the [Central Research Ethics Committee Criteria] will be reviewed by the Central Research Ethics Committee (CREC). All other activity may be reviewed by Faculty Research Ethics Committees (FREC) / Student Project Ethics Committee (SPEC).

2.8 University Ethics Oversight Committee and Research Ethics Committees (RECs)

The University has appointed RECs to review research activity conducted by the University, its staff, students and on its premises, facilities, or property. These RECs are appropriately constituted to provide a competent, timely, proportionate, and authoritative review of research. This review is independent of the research team, based on their members' judgement and not subject to managerial direction.

Review is divided between Centralised RECs and Faculty RECs / Student Project Ethics Committee (SPEC) according to the level or risk. The REC structure is provided in annex B.

The Ethics Oversight Committee has overall accountability for the functioning of the RECs in accordance with this document. The Ethics Oversight Committee is responsible for ensuring there are effective mechanisms to make staff and students aware of relevant policies, standard operating procedures, associated documents and processes.

The Ethics Oversight Committee will support and oversee audits, investigations and monitoring activity for research activity that falls within its remit and may involve members of staff with named roles from other areas where research is cross disciplinary.

The Ethics Oversight Committee will consider and advise on non-research ethical issues referred to it by Council, any committee of Council; the Vice-Chancellor; Pro Vice-Chancellors; Faculty Deans; Heads of School; Directorates; Directors of centres or research units and the ethics committees.

2.9 Research Committee and Senate

The University's [Research Committee](#) is one of the Senate committees, and is responsible for all matters concerning the management of, and support for, Keele University research.

Senate is the academic governing body of Keele University. Its responsibility is to direct academic policy in relation to teaching and research, and to assure itself that the University's academic standards are properly observed.

2.10 Remit of REC Review

The University is committed to providing a competent, rigorous, and externally moderated process of ethical review that is proportionate to the potential risk and, where a high risk is identified, assesses that risk against the benefits.

RECs shall review all aspects of research proposals for their ethical integrity. This will involve considerations of the design, management, conduct and proposed outputs of the research.

RECs shall not assess the scholarly or scientific standards of proposals. Where the REC requires understanding of peer review to make a judgment about ethical issues the RECs may request evidence of peer review or seek further advice / information.

Ethical review of research shall fall into one of three categories:

- Research requiring 'light touch' review (where the actual or potential risk of harm to participants (or others affected by the proposed research) is minimal).
- Research requiring full review (where research involves more than minimal risk).

- Research requiring expedited review (in exceptional circumstances an expedited review may be appropriate where a research project requires review but has a short lead time and is commissioned in response to a demand of pressing importance).

2.11 Retrospective review

University RECs **may not** give retrospective opinions on research activity.

2.12 Ethical review undertaken by other another UK HEI, NHS / Social Care Ethics Committee

University research ethics review shall not seek to duplicate ethical review from another UK HEI, NHS / Social Care Ethics Committee.

A Keele-based REC may wish to consider additional ethical issues that are specific to the University. The reviewing REC must maintain oversight of external ethical approval and that work is carried out in accordance with it.

2.13 External request for ethical review or requests to conduct research at Keele.

Where the University is approached by external bodies (organisations or individuals) who wish to request an ethical review or, conduct research involving the University's staff, students, facilities and/or data, or any other thing owned or controlled by the University, we shall facilitate such requests, provided does not act to the detriment of the University or its staff and acts to the public good or to the advancement of knowledge.

2.14 Research conducted overseas

Research activity conducted by the University overseas should meet, as a minimum, the ethics standard required by the University. Researchers are expected to seek appropriate ethics approval from a properly constituted and independent ethics committee in all states involved in the research. These local ethics approvals must be presented to the appropriate University REC for consideration and approval.

The reviewing REC must maintain oversight of external ethical approval and that work is carried out in accordance with it.

2.15 Non-research related ethical review

The University has a general duty to act ethically in all its activities including but not limited to teaching, fundraising, partnerships, investments, and procurement where separate policies and codes apply. Due regard to all ethics policies/codes must be taken where activity is also conducted for non-research purposes and this research ethics policy should be read in conjunction with those broader ethical policies/codes.

2.16 Ongoing ethical review

RECs may require annual reports about the progress of the research they have reviewed. These reports must explain any developments adversely impacting on participants' dignity, rights, safety or well-being and any aspect relating to research ethics, including but not limited to recruitment rate, urgent safety measures and deviations/breaches of protocol. A REC should reconsider its favourable opinion considering pertinent information that comes to its attention. If the REC, given that information during its initial review, would not have reached a favourable opinion, it must notify the Ethics Oversight Committee and should notify the researcher that its opinion is no longer favourable.

Where a research design is emergent the REC may agree procedures for reporting to the REC or sub-committee to enable ongoing ethics review. Triggering events or situations which might provide grounds for further review or discontinuation of the research should be agreed with the researchers before the REC's initial decision is granted.

2.17 Safeguarding

One of the aims of robust ethical review is to safeguard the health and wellbeing of individuals and groups

of individuals with whom research is being conducted. Any unanticipated or serious harms must be reported to the reviewing REC, including a description of the event and any immediate remedial actions taken.

The REC may, at the discretion of the Chair after consultation with no fewer than two members of the Committee, one of whom must be a lay member, re-review the proposal considering any safety events and may request modifications to prevent any future concerns.

2.18 Monitoring

RECs adhere to the principle of openness, transparency, and accountability. The Ethics Oversight Committee will maintain a schedule of audit of REC procedures, ensuring robustness and assuring the University of the independence and rigor of the review. The monitoring carried out must respect the independence of the University's RECs and are not intended to make a judgement on the accuracy or correctness of REC decisions.

Monitoring may take the form of desk-based review of a sample of reviews. Any monitoring reports may be made available to Research Councils UK funders should they wish to see them.

The Ethics Oversight Committee may direct audit and monitoring of individual research projects and request access to study documentation, records, and activities.

2.19 Suspension and withdrawal of favourable ethical opinion

Where the reviewing REC considers that a study is being conducted in a way which breaches the conditions of the ethical opinion or otherwise fails to protect the rights, dignity, and wellbeing of participants it will arrange a meeting with all researchers involved in the research with a view to resolving the matter.

Where the issue is not resolved the REC may suspend or withdraw its favourable ethical opinion on the grounds of:

- a) Scientific validity of the study, for example in the light of new research findings, which may affect consequent research ethics issues
- b) Risks to the safety or physical or mental integrity of participants
- c) The competence or conduct of the researchers
- d) The feasibility of the study
- e) The adequacy of the locations or facilities
- f) Legal non-compliance

Before suspending or withdrawing its opinion the REC will consider whether to consult with the applicant's Faculty to give them an opportunity to address concerns within a specified timeframe. Where RECs feel that risks to participants warrant it, they may immediately suspend approval.

Withdrawal of favourable opinion must only be done following a quorate meeting of a full committee and must be notified to the Applicant and Ethics Oversight Committee.

2.20 Status and sanctions

The University regards any breach of this policy as suspected misconduct and will be handled in accordance with the [Research Misconduct Procedure](#).

In appropriate circumstances, EOC has the power under the policies and procedures to withhold, suspend or withdraw a favourable opinion of research, whether as part of disciplinary proceedings or otherwise.

2.21 Appeals and complaints

Appeals against decisions made by Faculty RECs or Central REC may be addressed to the Senior Research Governance Manager who will liaise with the Chair of EOC.

The Chair of EOC will decide whether to allow the appeal.

If the appeal is allowed, EOC will consider the substantive and procedural soundness of the REC's decision

and may ask the REC to reconsider its decision or may substitute its own decision.

The Ethics Oversight Committee will not hear appeals against decisions of RECs external to Keele University.

REC members shall treat applicants with courtesy and professionalism. If an applicant feels they have been treated unfairly or discourtesy, they may raise a complaint with the Chair of the REC in the first instance. Applicants may also contact the secretary of the Ethics Oversight Committee with their complaint who will initiate the appeal and complaints procedure.

Disputes, appeals and complaints must be dealt with in a confidential manner by those involved in investigation and resolution of the issue.

2.22 Reporting to external bodies

Where breaches of ethical approval are identified, the Ethics Oversight Committee will ensure that any resultant suspension or discontinuation is notified to external bodies as required, e.g. suspensions or withdrawal of favourable ethical opinion on any UKRI funded research will be reported in accordance with funder terms and conditions by the Ethics Oversight Committee.

3. RELATED POLICIES AND PROCEDURES

- Research Strategy
- Code of Good Research Practice
- Research Data Management Policy
- Health & Social Care Research policy
- Research Misconduct Procedure
- Any other related policy

4. REVIEW, APPROVAL & PUBLICATION

This policy is the property of Keele University and the content cannot be reproduced without specific permission from the owner.

Printed versions of this document are uncontrolled and cannot be assured as the current version. Always check that the most up to date version is being used by only accessing via the web link.

The latest version of this policy can be found at <https://www.keele.ac.uk/policyzone/> Any superseded versions of this document need to be promptly withdrawn from use.

Equality issues have been taken into account during the development of this policy and all protected characteristics have been considered as part of the Equality Analysis undertaken.

This policy has been developed and approved by the Ethics Oversight Committee and reviewed and recommended for approval by University Research Committee and approved by Senate.

5. DOCUMENT CONTROL INFORMATION

Document Name	Research Ethics Policy
Owner	Head of Project Assurance
Version Number	2.0

Equality Analysis Form Submission Date	22/09/2023
Approval Date	11/10/2023
Approved By	Senate
Date of Commencement	11/10/2023
Date of Last Review	25/11/2024
Date for Next Review	25/11/2025
Related University Policy Documents	<ul style="list-style-type: none"> • Research Strategy • Code of Good Research Practice • Research Data Management Policy • Health & Social Care Research policy • Research Misconduct Procedure
<i>For Office Use – Keywords for search function</i>	

Annex A

Definition of terms

Animals (Scientific Procedures) Act 1986 – ASPA: regulates the use of animals used for research purposes in the UK

Central Research Ethics Committee (C-REC): oversees the ethical review of higher-risk research projects conducted across the university. CREC ensures that research adheres to rigorous ethical standards, safeguarding the well-being of participants and the reputation of the institution.

Ethics Oversight Committee: has overall accountability for all Keele University Research Ethics Committees (C-REC, FREC, SPEC)

External bodies: Organisations or individuals who wish to conduct research involving the University's staff, students, facilities and/or data, or any other thing owned or controlled by the University.

Faculty Research Ethics Committee (FREC): responsible for reviewing research applications within their respective faculties to ensure ethical compliance and protect participants, researchers, and the university's reputation. Each FREC focuses on the specific needs of its academic disciplines, providing tailored expertise and oversight..

Favourable opinion: Formal confirmation that a research ethics committee has reviewed and reached an opinion that the research may be conducted.

Health Research Authority (HRA): protects and promotes the interests of patients and the public in health and social care research.

Research: is defined as any form of disciplined enquiry that aims to contribute to a body of knowledge or theory. A more comprehensive definition may be found in the [Frascati Manual 2015](#).

Researcher(s): Any person(s) who conducts research, including but not limited to an employee; an independent contractor or consultant; a student; a visiting or emeritus member of staff; or a member of staff on a joint clinical or honorary contract.

Senate: is the academic governing body of the University. Its responsibility is to direct academic policy in relation to teaching and research and to assure itself that the University's academic standards are properly observed. Degrees, Diplomas, Certificates, Fellowships, Scholarships, prizes, and other distinctions of the University are awarded by the Senate.

Student Project Ethics Committee (SPEC): responsible for ensuring that all undergraduate and taught postgraduate student projects involving human participants are subject to ethical review

Annex B

Organogram of Keele University Research Ethics Committee Structure

