

Newcastle University Research Ethics Policy

Effective from 01/04/2024

1. Purpose

The purpose of this policy is to promote awareness of ethical principles, clarify the expectations of colleagues and students, and to outline the research ethical review procedure at Newcastle University.

Ethical consideration of activities is part of the overall governance framework at the University. As a responsible public body, Newcastle University aims to maximise the benefit and minimise the potential harm to all those involved in its activities, whether as project leaders, facilitators, participants, funders, or in any other significant capacity. It does this by:

- The application of a robust and proportionate ethical review process.
- Adopting and implementing legislation, best practice guidance, funder requirements, concordats and other key standards.
- Generating its own internal standards outlining its expectations.
- Providing guidance, support and training to colleagues and students to enable them to both understand and meet their obligations.
- Embedding a culture across the institution in which ethical working is the norm.
- Communicating the University's ethos and standards beyond the institution to related parties including research participants, funders, collaborators, and the public.
- Ensuring all relevant activities are compliant with the University's standards.

This policy is intended to strike a balance between the need to ensure that ethics is duly considered, whilst ensuring that the processes do not impose an undue burden on units, services and colleagues responsible for implementing them.

2. What is covered by the policy?

2.1 The key activities covered by the policy include:

- Research activities including both internally and externally funded research projects.
- PhD student research projects.
- Undergraduate and Masters student projects completed as part of a teaching programme.
- Research-related activities such as consultancy and Continuing Professional Development (CPD).

2.2 This policy **does not** cover:

- The approval of taught programmes at Newcastle University.
- Market research activities

- Internal consultation with students and colleagues to support the evaluation of a programme or service. However, these activities should be carried out with due regard to ethical principles such as voluntary participation, consent and data protection.
- The acceptance of Corporate Gifts and Donations. Please refer to the University's [Policy for the Acceptance of Donations](#) for further guidance.
- The consideration of any issues relating to the source of external funding or strategic projects requiring a specific business case. These issues should be considered via the relevant Approving Officer through the completion of a due diligence report. High-risk activities will be escalated to University Executive Board in accordance with the [Due Diligence Framework for External University Activity](#) (internal web page).

3. Who does the policy apply to?

This policy applies to all members of the University community, including undergraduate and postgraduate students, colleagues and any other person or body which represents the University. It applies equally to work undertaken at Newcastle University, its branch campuses and at other locations.

4. Roles and Responsibilities

An organisational structure diagram is provided at [Appendix 1](#).

University Council is the senior body responsible for ethics in the University and has overall responsibility for setting policy and ensuring that it is adhered to.

University Senate is the supreme governing body for all academic matters and is kept informed of ethical matters in the University.

University Executive Board is a joint Committee of Senate and Council and has central oversight of the day-to-day business of the University.

University Research Ethics Committee is Chaired by the Pro-Vice Chancellor for Research and Innovation and is a sub-committee of University Executive Board. It has one statutory meeting per annum and is responsible for:

- Maintaining overall ethical standards for the University's research and research-related activities, including the research components of teaching programmes, consultancy and Continuing Professional Development (CPD), but excluding those activities explicitly covered by the Animal Welfare Ethical Review Body (AWERB) and NHS Research Ethics Committees.
- Monitoring, reviewing and reporting on research ethics in the University to Senate and Council via Executive Board.
- Institutional oversight of the University's research ethics procedure.

The **University Registrar** has overall responsibility for:

- The ethical conduct of the staff and student body.
- Ensuring the institution's compliance with legislation.
- Research covered by the Animal (Scientific Procedures) Act, which comes under the remit of the University's Animal Welfare Ethical Review Body (AWERB).

Faculty Executive Boards are responsible for:

- Monitoring compliance with the University policy across their academic units.
- Adequate resourcing of ethics support and services within the Faculty.
- Promoting responsible ethical conduct within their Faculty.
- Ensuring that University Research Ethics Committee is kept aware of the requirements of key external stakeholders, such as research funders.
- Assuring Senate and Council that they are operating an effective ethical review procedure.
- Putting in place structures which support the staff and student body.

Faculty Research Ethics Committees are responsible for:

- Evaluating potentially high-risk activities and providing feedback to applicants.
- Ensuring that all work under their remit has appropriate ethical approval in place, either through direct review or by accepting the review of another body.
- Operational management of ethics support and services within their Faculty.
- Providing of local advice and guidance within their Faculty.
- Ensuring that reviewers have access to appropriate training to enable them to discharge their duties competently and with confidence.

Ethics Committee Members are responsible for:

- Reviewing applications submitted to their Committee.
- Identifying ethical issues involved in the activity.
- Ensuring that any issues have been fully considered.
- Protecting the interests of the project team, participants, the University and the wider community.

Animal Welfare Ethical Review Body (AWERB) is responsible for the formal ethical consideration of activities conducted by University staff/students that involve animals, specifically:

- The review of any projects involving regulated procedures on animals as covered by the Animal (Scientific Procedures) Act and the Animal Welfare (Sentience) Act, as well non-regulated research activities in the UK and abroad.
- Providing advice to colleagues and students applying for Personal and Project licenses.
- The provision of guidance to the Establishment Licence holder (the Registrar).
- The promotion of the ethical principles of Reduction, Replacement and Refinement ('the 3Rs') in animal research activities.

Research and Innovation are responsible for:

- Managing the University's ethical review procedure in accordance with legal and regulatory requirements, funder policies and professional guidelines.
- Managing the formal appeals procedure on behalf of University Research Ethics Committee.
- Provision of University level resources, advice and guidance.
- Providing ad hoc advice to Faculty Research Ethics Committees and the AWERB.

- Monitoring and reporting on compliance with this policy.
- Managing complaints or expressions of concern about research ethics at Newcastle University.

Researchers are responsible for:

- Familiarising themselves with all of the appropriate University, legal and funder policies / guidance relating to their activity.
- Identifying any relevant actual or potential ethical issues.
- Ensuring that the appropriate ethical and regulatory approvals are in place before work begins.
- Ensuring that any amendments to the approved protocol are submitted to the Committee which provided ethical approval for the study.
- Ensuring that the scientific methodology of the activity has received adequate peer review.
- As academic supervisors, ensuring that all student projects have received appropriate ethical consideration.
- As Module Leaders / Degree Programme Directors, ensuring appropriate consideration of ethics in their programmes and by their students.
- Ensuring that key documents relating to high-risk activities are retained by the academic unit prior to leaving the University.

University Students are responsible for:

- Familiarising themselves with all of the appropriate University, legal, and funder policies / guidance relating to their activity
- Highlighting any actual or potential ethical issues arising from their work and bringing them to the attention of their supervisor and then (if required) the relevant Ethics Committee.
- Ensuring that the appropriate ethical and regulatory approvals are in place before work begins.
- Ensuring that any amendments to the approved protocol are submitted to the Committee which provided ethical approval for the study.
- Ensuring that key documents relating to high-risk activities are retained by the academic unit prior to leaving the University.

Academic units are responsible for:

- Promoting awareness of this policy through student / colleague induction processes.
- Overseeing local research governance arrangements.
- Identifying training needs through the annual appraisal process.
- Supporting audit requirements by providing a unit level data repository for key documents for high-risk projects following the departure of the investigator from the University.
- The discussion of local data retention requirements prior to student graduation / as part of an exit interview.
- Taking local action in response to ethical concerns raised via the central complaints route.

5. Policy

5.1 University expectations

- 5.1.1 All students and colleagues are responsible for undertaking research and research-related activities to the highest ethical standards and demonstrate due consideration of ethical principles and risks.
- 5.1.2 An online ethics form should be submitted for all projects within the scope of this policy. However, the University will not conduct a duplicate review of any projects which have already been approved by an external body such as an NHS Research Ethics Committee.
- 5.1.3 Ethical approval must be in place before work commences. Failure to comply will be considered a form of research misconduct.
- 5.1.4 All researchers are expected to abide with the approved protocol in accordance with the University's [Code of Good Practice in Research](#). The appropriate Ethics Committee should be notified of any amendments to the approved protocol.
- 5.1.5 The University adheres to a principle of single review and will accept ethical approval from other universities or external Research Ethics Committees provided that:
- (i) The organisation's ethical policies and procedures meet the standards of the University, and
 - (ii) The scope of the application covers the work package that will be carried out by Newcastle University.

This must be agreed on a case-by-case basis with the relevant [Ethics Committee](#) and evidence of external ethical approval provided.

- 5.1.6 It is generally considered best practice to apply for ethical approval for an individual project. However, Module Leaders / Degree Programme Directors may wish to apply for block approval for Undergraduate / Masters student projects with a similar research design and methodology. Applicants should consult with their local Faculty Research Ethics Committee for guidance.
- 5.1.7 It is the researcher's responsibility to maintain a record of ethical approval alongside other project documentation such as the research protocol, Participant Information Sheets and evidence of consent. For externally funded projects, the terms of the grant may include certain data retention requirements. For audit purposes, the University recommends that all project documentation should be stored securely for a period of 10 years. Where appropriate, academic units should ensure that this information is retained locally following the departure of a colleague or student from the University.
- 5.1.8 Most research projects which are approved by Newcastle University are automatically covered by the University's indemnity insurance policy. However, certain types of activities (such as clinical trials or overseas fieldwork) carry additional risks. Colleagues and students should contact the University's [Insurance Office](#) (University login required) to ensure that the appropriate level of cover is in place.

5.2 Ethical principles

The ethics framework at Newcastle University is based on the following principles, which are adapted from the [UKRI Framework for Research Ethics](#):

- **Benefice and non-maleficence:** research should aim to maximise benefits and minimise risks and harm to individuals and society.
- **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:** the 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.

5.3 Potentially high-risk activities

The risk profile of each activity will depend on a range of factors, including the scale of the project, the research methodology and the subject discipline. The following activities are defined as potentially high-risk in accordance with professional guidelines, legal and regulatory frameworks.

5.3.1 **Healthcare research** involving NHS sites, patients, their tissue or their data, offenders or GP services must comply with the [UK Policy Framework for Health and Social Care Research](#). These types of projects require a formal Research Sponsor and can only be approved externally by an NHS Research Ethics Committee (REC). The research governance arrangements must also be approved by the Health Research Authority (HRA) including, where appropriate, the registration of the research project on the University or appropriate NHS organisation Data Protection Security Toolkit (DPST). Clinical trials of Medical Devices or Investigational Medicinal Products (CTIMPs) are also subject to Medicines for Human Use (Clinical Trials) Regulations and must be approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA). The HRA has developed an [online decision tool](#) to identify when NHS REC approval is required and an [Integrated Research Application System](#) (IRAS) to facilitate applications to the various regulatory bodies.

Invasive procedures on healthy volunteers on University premises should be carried out in accordance with the [Policy regarding the Participation of Volunteers in Research](#). Specific ethical considerations and research governance arrangements also apply to the collection, storage and disposal of human tissue samples (such as blood, saliva and bone) under the Human Tissue Act.

5.3.2 **Social care research** involving residents and users of adult social care services is also covered by the [UK Policy Framework for Health and Social Care Research](#) and must be approved by an NHS REC. Researchers should take steps to protect the dignity, rights and welfare of participants. Capacity to consent must be assessed in accordance with the provisions set out in the Mental Capacity Act.

5.3.3 **Research involving the use of animals** is subject to approval by the University's Animal Welfare Ethical Review Body (AWERB). This includes all vertebrates, cephalopod molluscs (e.g. octopus, cuttlefish, squid) and decapod crustaceans (e.g. lobster, crab). Colleagues and students should consider the Reduction, Replacement and Refinement of animals (the 3Rs) and employ strategies to enhance the welfare of animals in research. Research involving regulated procedures requires both a Personal and a Project Licence issued by the Home Office in accordance with the Animals (Scientific Procedures) Act. Internal training is provided by the University to support training and competency requirements. The AWERB also consider animal welfare and ethical standards in relation to non-regulated activities such as tracking, observation and the capture and release of animals in pursuit of advancing scientific knowledge.

5.3.4 **Research involving working with human participants**, particularly but not exclusively in the social sciences, involves a number of potential risks. Whereas basic questionnaires which do not capture any personal data are usually considered low-risk, other types of qualitative research methods such as interviews, focus group, internet research and covert observational studies may carry additional risks. There are also ethical considerations associated with working with vulnerable adults, children and young people. Please refer to the University's [Informed Consent Guidelines](#) for further details. Researchers working with children are also required to complete Disclosure Barring Service (DBS) checks. Researchers should also be aware that they have a legal duty to report any concerns regarding potential abuse to the University to notify the relevant authorities. For further information please refer to the University's [Safeguarding Policy](#).

Participation should be voluntary, and participants should have the right to withdraw at any point in the study. To avoid coercion, the use of a third party or "gatekeeper" to access potential research participants should also be carefully considered. Except where the nature of the research makes this impossible, participants should be provided with information about the purpose, methods and intended use of the research and Informed Consent fully documented.

5.3.5 **Personal and sensitive data** should be treated confidentially, stored securely and disposed of securely at the end of the project in line with legal and funder requirements. Under the Data Protection Act and the UK General Data Protection Regulation (GDPR), personal data should be used solely for the purpose it was collected for and disclosed only with the agreement of the individual. Any data sharing arrangements should therefore be captured in the Participant Information Sheet and Privacy Notice and agreed as part of the Informed Consent process. To protect confidentiality, personal data should be fully anonymised prior to the publication of research results.

All research involving working with personal data requires a Data Protection Impact Assessment (DPIA) and a Data Management Plan (DMP). Research projects involving patient data may also require registration with the University / NHS organisation Data Protection Security Toolkit (DPST). For further information please refer to the University's [Data Protection Policy](#) and [Research Data Management Policy and Code of Practice](#).

5.3.6 **Environmental impact** should be minimised, wherever possible. Researchers should consider the impact of fieldwork on the landscape, infrastructure or local community as well as the potential harm caused by gas, noise, particulates, chemicals or ionizing particle emissions. Special permission may also 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).

5.3.7 **International research** may also involve ethical considerations due to the research design, local laws, customs and religious beliefs within a particular country. Investigators should consider how their research could impact the populations they are studying and whether the research will benefit participants or put them at risk of harm in any way. All animal work conducted overseas should also be carried out in accordance with UK standards. In addition to obtaining ethical approval, colleagues and students should refer to the latest foreign travel advice and complete a Travel Risk Assessment Form prior to conducting fieldwork abroad. Depending on the level of risk, additional insurance cover may be required. In accordance with the University's [Trusted Research process](#), formal due diligence must also be completed for all research proposals involving international funders or collaborators where there is a potential national security risk.

5.3.8 **Defence and security research and innovation** projects involving human participants which is externally funded by the Ministry of Defence (MoD) requires external ethical approval from the MoD REC. Newcastle University does not support research that is intended to support direct offensive military activities. However, the University acknowledges that a wide variety of research may have indirect military applications (including 'dual-use' technologies). The ethical considerations, benefits and risks of individual projects will therefore be assessed on a case-by-case basis by the appropriate Faculty Research Ethics Committee.

5.4 University colleagues and student participants in research

On occasion, colleagues and students may be invited to participate in research projects at the University. In these cases, the principles regarding voluntary participation, informed consent and the right to withdraw also apply to internal participants. The decision not to participate should not affect the individual's employment or academic assessment in any way.

6. Related regulations, statutes and policies

- [Code of Good Practice in Research](#)
- [Ethics Guidance Note: Impact and Engagement Activities](#)
- [Informed Consent Guidelines](#)
- [Policy and Procedure for Investigating Allegations of Research Misconduct](#)
- [Policy regarding the Participation of Volunteers in Research](#)
- [Policy for the Responsible use of Animal Images](#)
- [Safeguarding of Young People \(under 18\) and Vulnerable Adults Policy](#)
- [University Guidance on the Ethical Approval of International Research and Research at International Branch Campuses](#)

7. Procedure to implement the policy

7.1 Ethical Review Procedure

The University has developed a robust ethical review procedure based on a proportionate approach to risk. The purpose of the ethical review procedure is to:

- Assess the level of risk associated with research and research-related activities.
- Improve the quality of research.
- Ensure compliance with legal and regulatory frameworks.

- Provide assurance to research participants, funders and publishers.
- Protect the reputation of the researcher, supervisors and the University.

7.1.1 A flow chart illustrating the University's ethical review procedure is provided at [Appendix 2](#). There is a single route of entry via the University's online [Research Ethics Form](#). Although the Principal Investigator has overall responsibility for ensuring ethical approval is in place prior to work commencing, responsibility for submitting an ethics application may be delegated to another member of the project team.

7.1.2 The applicant is asked to provide some basic information, including the title of the project and a description of the activity. A series of preliminary questions provide a risk profile, based on the potentially high-risk activities outlined in Section 5.3.

7.1.3 Based on the information provided by the applicant, the application will be directed in one of the following five ways:

a) The project already has approval in place

Evidence of external ethical approval has been provided and accepted by the relevant Ethics Committee. Automatic approval is granted by the University Research Ethics Committee and no further action is required. Colleagues and students are encouraged to download a copy of the completed application and retain a copy of the ethical approval email for their records.

b) The project is low risk

There are no significant ethical issues. Automatic approval is granted by the University Research Ethics Committee and no further action is required. Colleagues and students are encouraged to download a copy of the completed application and retain a copy of the ethical approval email for their records.

c) The project involves the NHS / Social Care

The University is not able to approve these types of projects. An application for external ethical approval must be submitted to an NHS Research Ethics Committee.

d) The project involves animals

The application is routed to the Animal Welfare Ethical Review Body for further review.

e) The project is potentially high-risk and requires further review

If the activity covers any other high-risk area, the application is routed to the relevant Faculty Research Ethics Committee for further review.

7.1.4 If the application is flagged for further review by a sub-committee, the applicant will be prompted to provide additional information. Additional documentation may also be uploaded to support the application.

7.1.5 Following submission, a representative will confirm receipt and forward the application for review by members of the Committee. In some cases, amendments may be required prior to approval by the Committee. However, the ethical review procedure is designed to be helpful and supportive and provide constructive feedback to applicants on how to improve the research design and methodology.

7.2 Timescales

The University aims to provide applicants with a response within 21 working days, although most projects are approved within a shorter timeframe. An appropriate lead-time should be built into the project plan as ethical approval must be in place before work commences.

7.3 Right of Appeal

On rare occasions, a Committee may decide to reject an application. However, the Committee would normally work with the applicant to address the concerns raised through revisions to the application. There is no right to appeal against the decision of the Animal Welfare Ethical Review Body (AWERB). If an applicant is dissatisfied with the opinion of a Faculty Research Ethics Committee, they have the right to appeal on the basis of:

- (i) Procedural irregularities, or
- (ii) Prejudice or bias.

The request should be submitted to the Chair of the relevant Committee in the first instance. The Chair can reject or uphold the original decision or ask an alternative Ethics Committee to provide a secondary opinion. If the applicant is dissatisfied with the outcome, the matter may be referred to the Chair of the University Research Ethics Committee for consideration. Their decision is final. No work should begin until the appeal has been resolved.

7.4 Training, tools and resources

7.4.1 The University is committed to providing colleagues and students with the necessary training, tools and resources to comply with this policy. Further information on internal and external resources is available on the University's [Research Integrity webpages](#). Including details on how to submit an ethics application, guidance on high-risk activities and research governance arrangements via the online [Research Ethics Toolkit](#).

7.4.2 Advice on the application of this policy is available from Research and Innovation (email: res.policy@ncl.ac.uk). Advice to applicants on developing an ethics application is available from the appropriate sub-committee.

7.5 Complaints

A primary contact should be identified within the project team who can be approached regarding questions, comments and complaints. Research and Innovation may also be listed as a secondary contact for complaints (email: research.integrity@ncl.ac.uk). Complaints or expressions of concern about research ethics at the University will be addressed by Research and Innovation via the process illustrated in [Appendix 3](#).

8. Monitoring and reporting on compliance

8.1 University Research Ethics Committee has overall responsibility for the implementation, operation and compliance with this policy with the support of Research and Innovation. In practice, this responsibility is devolved to each of the sub-committees, who are responsible for the implementation of this policy within their local areas.

8.2 Institutional compliance will be monitored via the annual ethics audit and the findings presented to University Research Ethics Committee to consider training needs. In the event that a significant issue is identified via the annual ethics audit, immediate action will be taken to minimise / prevent harm to research participants, animals or the environment. Where

appropriate, the University will also notify the external funder and / or regulatory body of any action taken. The matter will also be investigated internally via the University's [Policy and Procedure for Investigating Allegations of Research Misconduct](#).

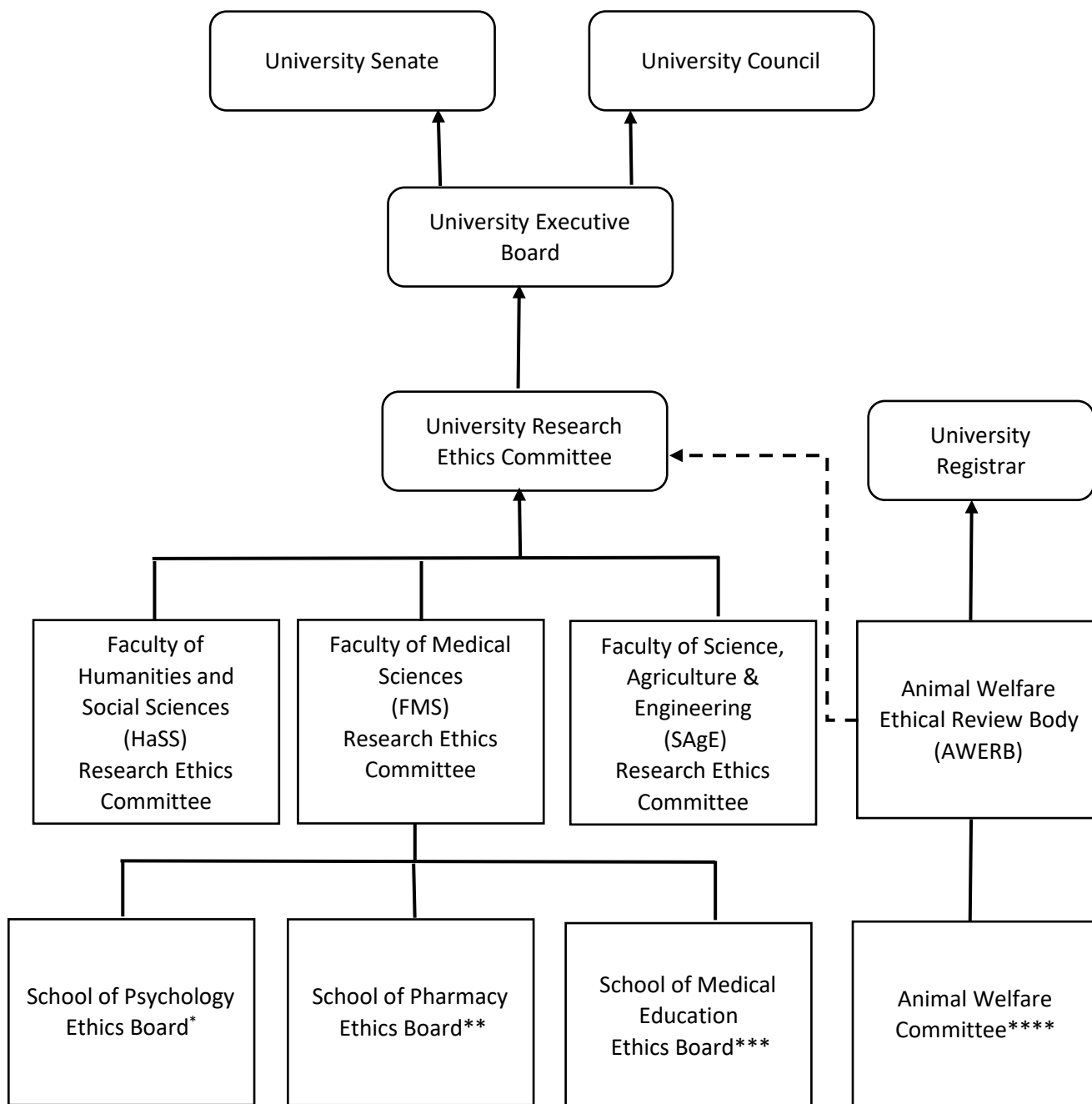
What will be monitored?	Frequency	Method	Who by	Reported to
Implementation of University policy and procedure within each of the sub-committees	<i>Annual</i>	Annual report	Faculty Research Ethics Committees / AWERB	University Research Ethics Committee
Timescales for approval	<i>Annual</i>	Consultation with Faculty Research Ethics Committees	Research Integrity and Governance Manager	University Research Ethics Committee
Low risk projects automatically approved by the University to assess whether the information entered by applicants is correct.	<i>Annual</i>	Sample selected from applications submitted via online Ethics Form.	Research Integrity and Governance Manager / Faculty Research Ethics Committees	University Research Ethics Committee.
Externally funded projects on NU Projects where the applicant has indicated that ethical approval is not required or already in place.	<i>Annual</i>	Sample selected from NU Projects.	Research Integrity and Governance Manager / Faculty Research Ethics Committees	University Research Ethics Committee
Documentation of informed consent procedures for projects involving working with human participants.	<i>Annual</i>	Sample selected from applications submitted via online Ethics Form.	Research Integrity and Governance Manager / Faculty Research Ethics Committees	University Research Ethics Committee

9. Failure to Comply

Failure to comply with this policy may be considered a form of research misconduct. Action will be taken in accordance with the University's [Policy and Procedure for Investigating Allegations of Research Misconduct](#) and may result in disciplinary proceedings.

Document control information		
Does this replace another policy? Yes / No If yes please state. Ethics Policy for Research, Teaching and Consultancy (2017)		
Approval		
Approved by:	<u>University Council</u>	Date: <u>30th January 2023</u>
Effective from:	<u>1st April 2023</u>	
Review due –	<u>1st April 2026</u>	
Responsibilities		
Executive sponsor:	<u>Pro-Vice Chancellor Research and Innovation</u>	
Policy owner: (This maybe an officer or Committee)	<u>Research Policy, Information and Ethics Team</u>	
Person(s) responsible for compliance:	<u>Research Integrity and Governance Manager</u>	
Consultation		
Version	Body consulted	Date
Version 1	AWERB	31.10.2022
Version 1	Faculty Research Ethics Committee Chairs / Heads of Faculty Research	31.10.2022
Version 1	Information Governance Officer	31.10.2022
Version 2	UREC (full membership)	02.11.2022
Equality, Diversity and Inclusion Analysis:		
Does the policy have the potential to impact on people in a different way because of their protected characteristics? Yes/ No/ Unsure		
If yes or unsure please consult the Diversity Team in HR for guidance		
Initial assessment by:	<u>Research Integrity and Governance Manager</u>	Date: <u>25.10.2022</u>
Key changes made as a result of Equality, Diversity and Inclusion Analysis N/A		
Document location		
https://www.ncl.ac.uk/research/researchgovernance/policies/		

Appendix 1: Organisational Structure Chart



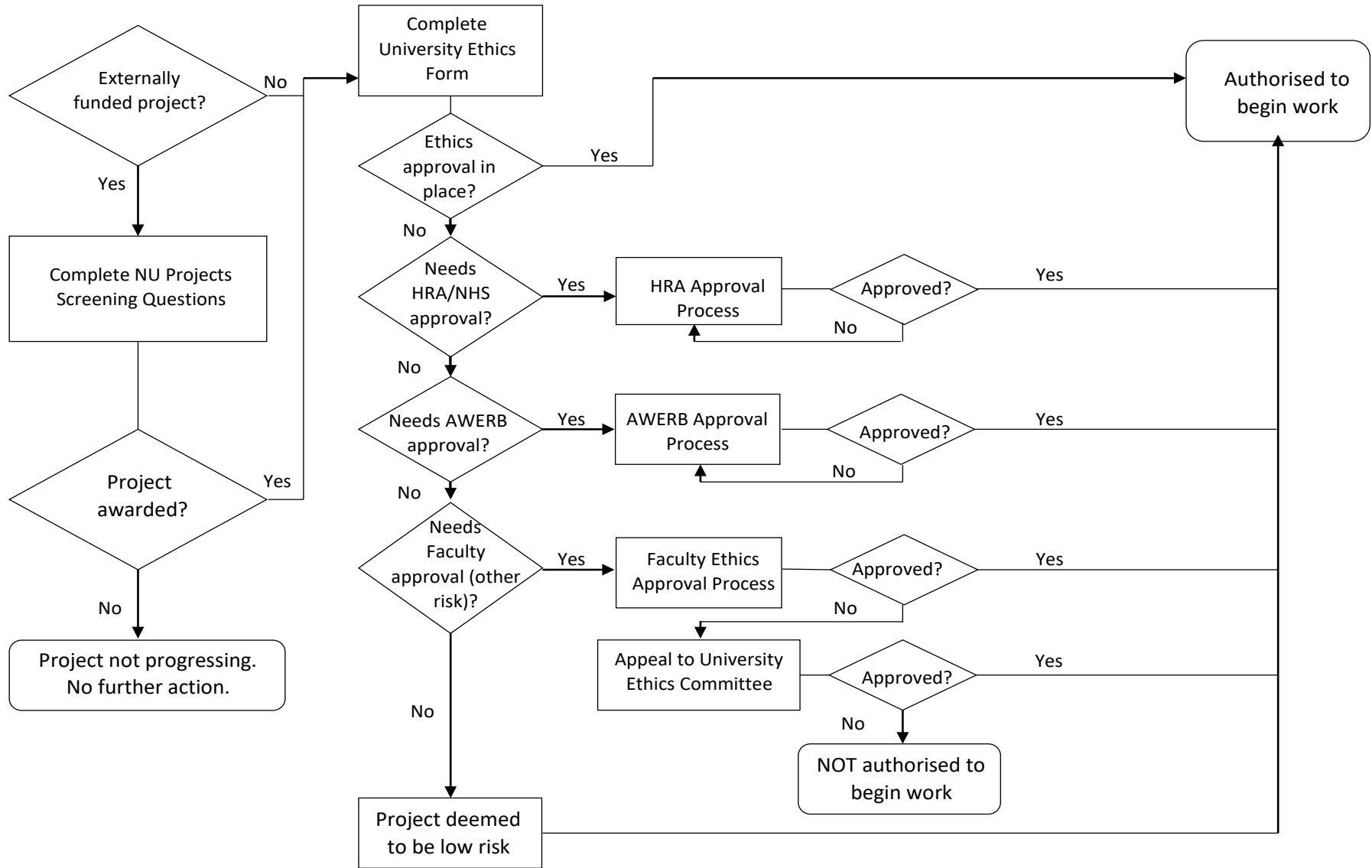
**The School of Psychology Ethics Board has devolved responsibility for the review of Undergraduate student projects under its remit.*

*** The School of Pharmacy Ethics Board has devolved responsibility for the review of Undergraduate student projects under its remit.*

****The School of Medical Education Ethics Board has devolved responsibility for the review of Masters student project under its remit.*

*****The Animal Welfare Committee has devolved responsibility for the review of non-research activities involving the use of animals at Newcastle University.*

Appendix 2: Newcastle University Ethical Approval Process



Appendix 3: Complaints flow chart

