Newcastle University Ethics Policy for Research, Teaching and Consultancy

1. Purpose

The purpose of this document is to promote awareness of ethical principles and ethical issues, clarify the rights and obligations of the staff and student body at Newcastle, and to outline the ethical framework for their consideration.

Ethical consideration of activities is part of the overall governance framework at the University. As a responsible public body, Newcastle 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. The key means by which it does this are:

- Through the application of a robust and proportionate ethical review process.
- By adopting and implementing legislation, best practice guidance, funder requirements, concordats and other key standards.
- Generating its own internal standards outlining its expectations.
- Providing support such as guidance, training and signposting to the staff and student body 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 attempts to strike a balance between the need to ensure that ethics is duly considered and ensuring that the processes do not impose an undue burden on the units, services and staff responsible for implementing them.

2. Scope

This policy applies to all members of the University including; staff, students (undergraduate & postgraduate) 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. The key activities covered by the policy include:

- **Research activities**
- **Teaching and learning activities**
- **Consultancy and other external work**

NB. This policy does not relate to acceptance of Corporate Gifts and Donations.

See: http://www.ncl.ac.uk/alumni/get-involved/fundraising-guidelines/ethical-policy/

This policy does not relate to consideration of any ethical issues relating to strategic projects requiring a specific business case. Such issues should be considered via University Executive Board.

3. Organisational Structure & Responsibilities
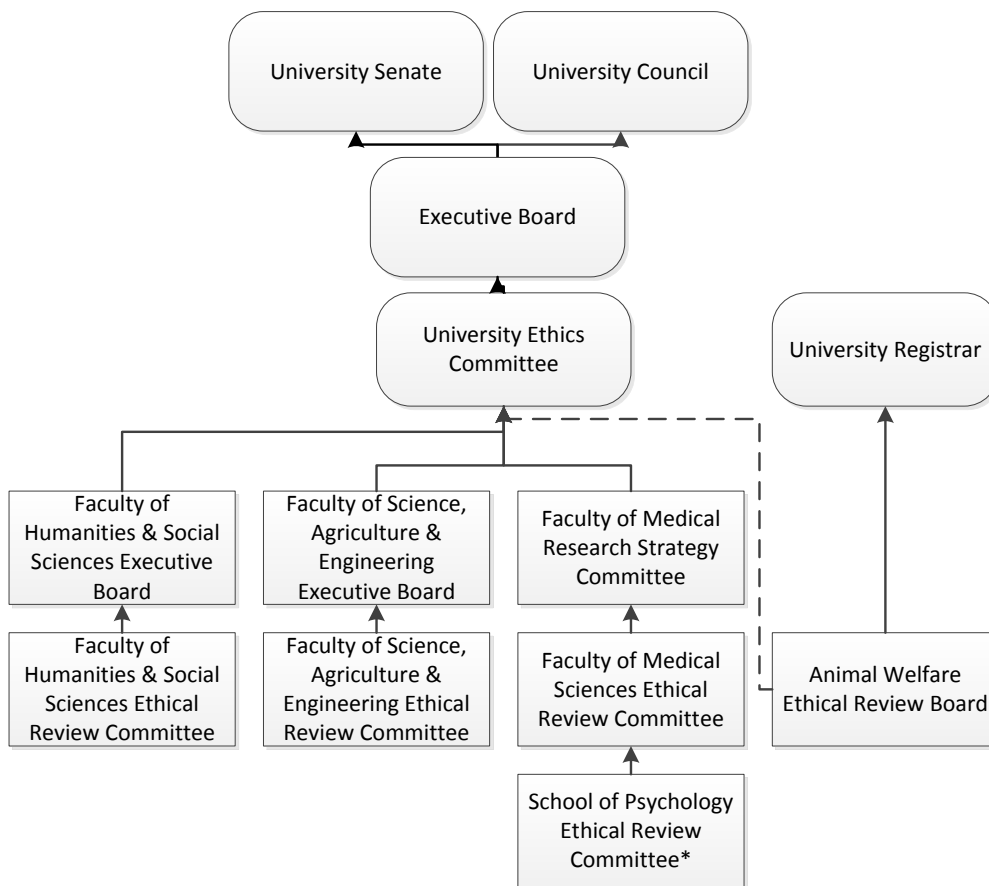
The Faculty of Medical Sciences Ethical Review Committee has devolved responsibility for the review of undergraduate projects under its remit to the School of Psychology Ethical Review Committee

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

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

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

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

- Institutional oversight of the ethics process relating to research, teaching and consultancy / external activities.
- Implementing the policy set by University Council
- The strategic management of ethics relating to research, teaching and consultancy /external activities at Newcastle
- Monitoring compliance with the policy
- The operational framework for ethics relating to the aforementioned activities in the University.

The University Registrar has overall responsibility for:

- Ethical conduct of the staff and student body
- Ensuring the institution's compliance with legislation
- Research which comes under the Animal Scientific Procedures Act 1986 (this is covered under the remit of the Animal Welfare Ethical Review Board) as dictated by the Home Office.

Faculty Executive Board(s) 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 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 process.
- Putting in place structures which support the staff and student body.

Faculty Ethics Committee(s) are responsible for:

- Formal ethical consideration of activities which represent an enhanced ethical risk.
- 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.
- Overall operational management of ethics support and services within their faculty.
- Provision of faculty specific advice and guidance about ethical matters.
- Ensuring that reviewers have access to appropriate training to enable them to discharge their duties competently and with confidence.

Ethics Committee Members / Ethics Reviewers 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 of the wider community.

Animal Welfare Ethical Review Board (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 animal work as covered by the Animal Scientific Procedures Act 1986 (ASPA).
- The review of activities involving animals (not under ASPA) but which give rise to concerns for animal welfare, specifically where those activities are unregulated by UK law.
- 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.

(AWERB explicitly do not cover activity that is only agricultural at the University farms. Animal welfare in this environment is covered by UK Government codes of practice.)

Research & Enterprise Services are responsible for:

- Co-ordinating the University's requirements and those of significant others (e.g. funders)
- Provision of general (University wide) resources, advice and guidance
- Management of the University ethics processes

- Providing support to the faculty ethical review committees and AWERB in regards to ethical, governance and integrity issues
- Ensuring all appropriate governance and ethics requirements are in place before any contractual work begins (specific to funded projects).
- Managing the ethical appeal process on behalf of University Ethics Committee

Staff 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 projects receive ethical approval from the appropriate body before work begins.
- Ensuring that the scientific methodology of the activity has received adequate peer review.
- In their capacity as academic supervisors, they are responsible for ensuring that all student projects have received appropriate ethical consideration.
- Module Leaders / Degree Programme Directors, are responsible for ensuring appropriate consideration of ethics in their programmes and by their students.

Students are responsible for:

- Familiarising themselves with all of the appropriate University, legal and funder policies and 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 review committee.
- Ensuring ethical approval from the appropriate body is in place before beginning work.

4. Ethical Risks & Principles

The University sees the following principles as fundamental.

- *Welfare:* Those undertaking the activity should have the welfare of participants as a goal of their activity.
- *Autonomy*: Those undertaking the project should be honest, act to protect others (as well as themselves) and ensure they have informed consent from participants.
- *Justice*: there should be a fair distribution of effort, costs and benefits.

The range of the University's activities is exceptionally broad and the potential ethical hazards equally so. The University has based its ethical review framework on that used by the [Economic & Social Research Council](). Its key areas of concern are:

1. [Patients, staff or other resources of the National Health Service / Social Care Providers]()
2. [Humans in a non-clinical setting where there are enhanced risks]()
   - This includes the use of Human Tissues such as blood, saliva and bone
3. [Animals as defined by the 'Animals Scientific Procedures Act' or any animal involved in an atypical or non-regulated activity]()
4. [The viewing, transfer or usage of sensitive / regulated data]()
5. [Significant damage to the environment or which takes place in a protected area]()
6. [Work outside the European Economic Area where the legal framework or design creates an enhanced risk]()

These areas are covered in detail on the [University Ethics Form](#) and in the associated guidance in the [Ethics Toolkit](#). There are however additional considerations which although not covered explicitly should be examined. These include the origin of funding (Appendix One), the end-use of outputs for illegal / immoral purposes (Appendix Two), ensuring the risks of the activity are proportionate to the potential benefits, and ensuring the activity (especially research) is designed according to the best scientific practice.

The University wishes to support its staff and student body to undertake purposeful and well considered activities. In order to do so it provides toolkits / resources and expert review and advice via its various ethical review committees. Where the guidance is not clear or where there is a conflict the University expects the responsible individual (in concert with the appropriate committee) *to balance qualitatively different values*. In such cases, they are obliged to make judgements that cannot be derived from first principles and should be prepared to draw upon objective advice.

5. Ethical Review Process

The ethical review process varies depending on the risk profile, body responsible for the approval and whether the project is externally funded. However all projects start the process in the same way, by completing the University Ethics Form(s). The form should ordinarily be completed by the project lead. They can delegate the responsibility for completing the form but the project lead remains responsible overall

NB. The University will normally only review work undertaken by its own staff and student body so the form should be completed to explicitly show what the ethical approval is being asked to cover.

The process works in two parts. In the preliminary part a series of multiple choice questions prompts for further details on the scope of the project, mapped around the University high risk areas. From the responses a risk profile is built up and depending on this the approval request will be directed in one of five ways:

a. **The project already has approval in place**
   The University adheres to a principle of single review i.e. it will accept ethical review from other committees (e.g. other Universities)., but only where the scope of the application covers the work at Newcastle and its staff and student body and where it is confident of the standards of the other organisation's processes and procedures. This must be agreed on a case by case basis with the relevant Faculty Representative (the academic unit of the Newcastle principal investigator drives the responsible faculty).

b. **The project is low risk**
   I.e. there are no significant ethical issues (and therefore no further review is needed)

c. **The project involves the NHS / Social Care**
   These are reviewed by committees governed by the Health Research Authority.

d. **The project involves animals**
   These are reviewed by the Animal Welfare Ethical Review Board.

e. **The project involves (any other) high risk area**
   These are reviewed by the relevant Faculty Ethical Review Committee

In the cases where (a) approval is in place, (b) the project is low risk or (c) the project involves NHS / Social Care then the applicant leaves the University process after the preliminary stage. In the first two cases ethical approval is granted by default, and there is no further action required. Those projects involving the NHS, however, should seek (and gain) approval from the Health Research Authority before beginning work.

In cases where (d) animals are involved or (e) which is high risk for another reason, the applicant will be prompted to provide additional information. This will then be sent to the appropriate ethical review committee for consideration and decision.

- No work should start until the project has received ethical approval and all relevant permissions e.g. from external bodies are in place.
- Where significant changes are subsequently made to a project it is the responsibility of staff members to ensure that further ethical review is sought. In the case of student projects it is the responsibility of the student to bring changes to the attention of their supervisor and then (if required) the relevant review committee.

6. Right of Appeal

In cases where a member of staff is dissatisfied with the opinion of one of the faculty ethical review committees then in the first instance the applicant should appeal this to Chair of that Committee. This must be done via the Faculty Ethics Co-ordinator / Committee Secretary. The Chair can reject, uphold or ask for an alternative review from within their own committee or the equivalent committee in another faculty. If the applicant is still dissatisfied then the matter can be referred for consideration by the Chair of University Ethics Committee. Their decision is final. No work should start until the appeal has been resolved.

7. Sanctions

Any deliberate or negligent breach of the University Ethics Policy, whether through omission, misdirection or fraud is a serious disciplinary matter. Significant breaches of this policy will be investigated by University Ethics Committee, or its agents and where deemed necessary these will be dealt with (in the case of staff) under the Disciplinary Procedure or (in the case of students) under the relevant academic conduct regulations.

Where an investigation finds that a breach has indeed occurred then the University will (in line with its contractual responsibilities) inform any relevant funders or professional associations. Additionally where a breach concerns a staff member substantively employed elsewhere the University may pass the factual details of the case to the primary employer (this is specifically relevant to Clinical Staff with honorary/associate contracts).

8. Monitoring, Compliance & Disclosure

Responsibility for the implementation, operation and support of the policy as well as compliance to it is devolved to the Faculty Ethical Review Committees and the Research & Enterprise Services (RES). Institutional compliance will be monitored through periodic audit at both institutional and faculty level. Any highlighted issues will be brought to the attention of University Ethics Committee at its next scheduled meeting. If an issue is significant i.e. it has a direct effect on the wellbeing of participants or staff and / or a potentially significant reputational impact then it will be brought to the attention of the Chair of University Ethics Committee within 10 working days.

Where a member of staff or student is aware of activities being carried out without the appropriate ethical approval he/she is encouraged to disclose this information to his/her Manager or Tutor/Supervisor in accordance with the University's policy on Public Interest Disclosure.

9. Summary

This document outlines the broad process and ethos of the University, it should be read in conjunction with other key documents such as the Code of Good practice in Research, The Concordat to Support Research Integrity, Student Regulations and any other subject specific documentation.

Approved by Executive Board: 21 February 2017
Approved by Senate: 7 March 2017
Approved by Council: 3 April 2017

Appendix One: Funding

Given the very wide range of ethical issues that can arise in considering whether or not to accept funding for specific university activities, it is difficult to formulate a policy that can be used in all cases. Nevertheless, the University takes the view that some guidance to staff is essential, particularly in view of the fact that some large donors are now beginning to insist that specific ethical policies must be in place.

The guidance below is intended to direct staff in their dealings with external funders. It should be emphasised that the guidance below is not intended to prevent individual members of the university carrying out an activity, but is intended to ensure that the interests of the University are safeguarded where it acts as a corporate body accepting funding or sponsoring an activity.

Considerations

The key questions that must be asked about the acceptance of any funding for any purpose in the University are:

- What are the motives of the sponsor?
- To what extent are these motives consonant with the University's main mission of furthering excellence in Scholarship, Teaching and Research?
- To what extent are any restrictions placed on publication and exploitation of the results of the funded work likely to lead to ethical problems and difficulties?
- Will accepting funding lead to a bias (perceived or actual) in the design of the activity or dissemination of the outcomes?

The policy of the University is not to accept funding for any aspect of its activities where;

- the motives of the funder are believed to be inconsistent with the University's main aims and objectives
- the suppression of the results of any funding is likely to lead to substantial ethical difficulties
- undertaking the activity could materially damage the reputation of the University and its faculty

Before engaging in any activity the project/activity lead should consider a potential funder's declared ethical policy and its ethical record. They should also consider the nature of the activity and the potential applications of the outcomes. These issues should be considered as part of the ethical review process at application stage.

In cases where an issue is known or suspected, the project lead should first raise any concerns with their Head of Academic Unit. If the Head of Unit agrees that further review is needed then the matter will be referred to the relevant Faculty Ethical Review Committee who will then give an opinion in line with their standard review process. In problematic cases this Committee has the option to escalate the matter to University Ethics Committee. There will be some cases, for example where the work poses a significant risk to the reputation of the University, where the issue is strategic rather than ethical. In these cases the final decision will be taken by the appropriate Executive Committee.

Appendix Two: Ethical Application of Outputs

The University has a moral and (in some cases) legal responsibility to ensure that its activities contribute positively to the wider community. The motivation of external parties for working with the University, and

their likely application of any outputs should be considered at the earliest possible opportunity and, in particularly sensitive areas, throughout the duration of the activities.

One of the key areas the University is concerned about is the transfer of technology or knowledge which can be used in the development of Weapons of Mass Destruction Programmes or have military applications which might:

- contravene the UK's international commitments (e.g. breach of applicable arms embargoes or other sanctions)
- be used for internal repression or the abuse of human rights
- provoke or prolong armed conflicts or aggravate existing tensions in the destination country
- be used aggressively against another country
- adversely affect the national security of the UK or allies
- be to a destination where the behaviour of the buyer country raises concerns with regard to its attitude to terrorism or respect of international law
- be diverted or re-exported under undesirable conditions
- In the case of developing countries, seriously hamper the sustainable development of the recipient country. Exports can also be refused on other national security grounds or where an export is contrary to stated Government policy.

Useful resources can be found on the http://www.ncl.ac.uk/research/ webpages, specifically the '[Higher Education Guide on Export Controls and the ATAS Student Vetting Scheme'](#).

In cases where an issue is known or suspected, the project lead should first raise any concerns with their Head of Academic Unit. If the Head of Unit agrees that further review is needed then the matter will be referred to the relevant Faculty Ethical Review Committee who will then give an opinion in line with their standard review process. In problematic cases this Committee has the option to escalate the matter to University Ethics Committee. There will be some cases, for example where the work poses a significant risk to the reputation of the University, where the issue is strategic rather than ethical. In these cases the final decision will be taken by the appropriate Executive Committee.

In the context of the above, the University's PREVENT guidelines should also be referred to which state that, in accordance with the provisions contained within the Counter Terrorism and Security Act 2015, the University has a duty to have due regard to the need to prevent people from being drawn into terrorism. In the case of Newcastle University 'People' are our staff and students or those who represent the University. See further: https://newcastle.sharepoint.com/hub/prevent/Pages/default.aspx (internal access only).

Appendix Three: Policy regarding the participation of volunteers

Material from Research & Enterprise Services webpages and appendices. Available at:

http://www.ncl.ac.uk/media/wwwnclacuk/research/files/volunteer-policy.pdf

Appendix Four: Consideration of research at Branch Campuses.

Material from Research & Enterprise Services webpages. Available at:

[Ethical Approval of Research at International Branch Campuses](#)

Appendix 6: Newcastle University Ethical Approval Process
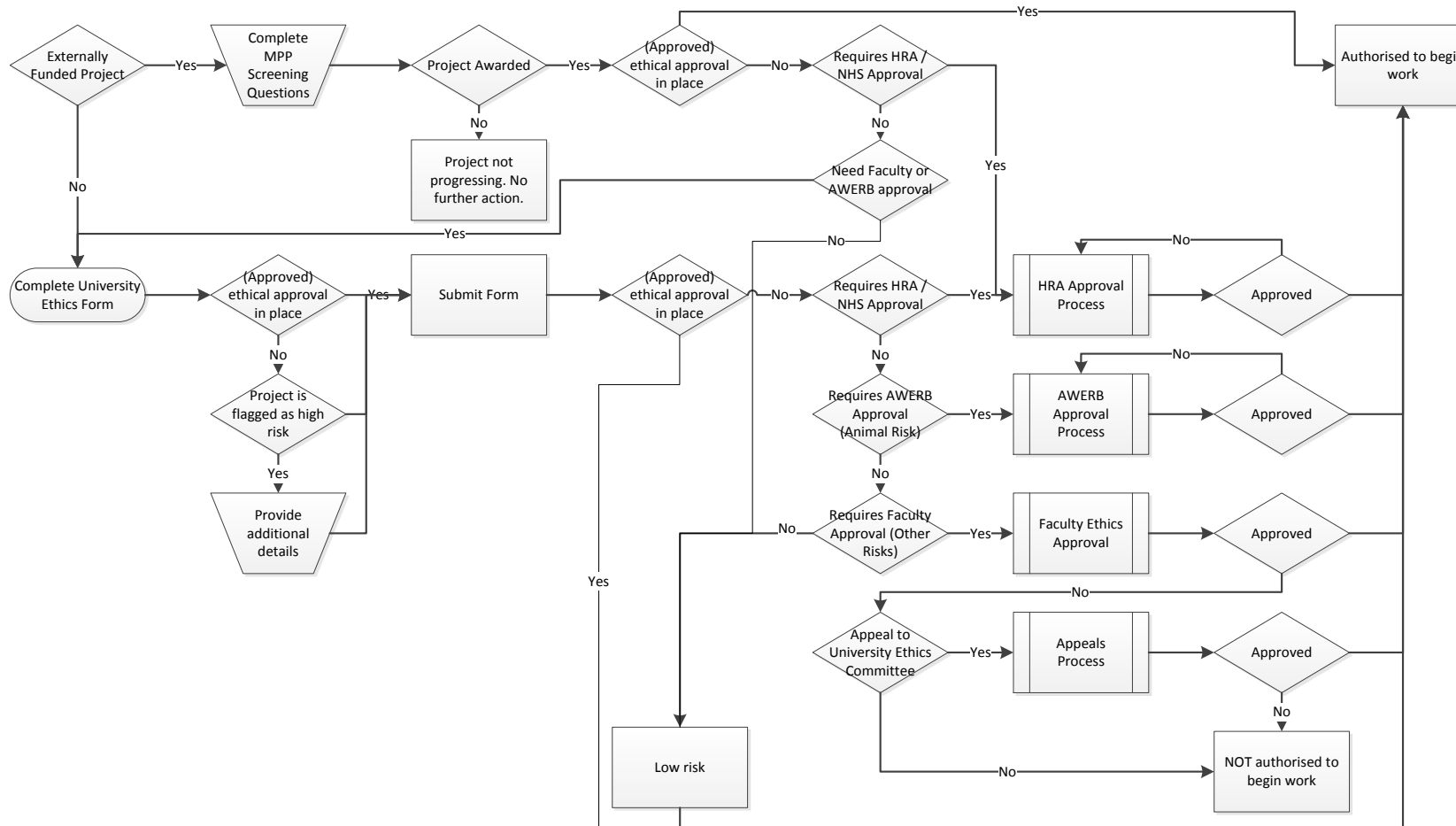
Abbreviations:

MyPP: MyProjects Proposals (the University's proposal generation system for research, commercial and teaching projects)

HRA: Health Research Authority

AWERB: Animal Welfare Ethical Review Board