Research Ethics Approval Code of Practice

Review

Formal Review Cycle	Three years (or earlier as required by changes to legislation, regulation or best practice)		
Latest Formal Review (date)	Sept 2024	Next Formal Review Due (date)	Sept 2027
Procedure Owner	Executive Lead for Higher Education		
Procedure Author	Christine Stretesky, Head of Corporate Governance & Policy		

Approvals

Committee	HE Board	Date approved	05 Nov 24	Additional committee	
ELT Y/N	Y	ELT date approved	17 Nov 24		

Publication

Website Y/N	Y	Unify Y/N	Y	Student VLE Y/N	Y	Other	

Change History

Version	Date Reviewed/ Revised	Description of Change	Reviewed by	Approved by
1.0	Sept 2024	New		
2.0	March 2025	Amended the process for curriculum review and approval and HE Ethics Panel review	Research Ethics Panel	HE Board

Ethics Approval Code of Practice

1. Introduction

1.1. This Code of Practice is a code of the City of Sunderland College, trading as Education Partnership North East (which includes Sunderland College, Hartlepool Sixth Form College and Northumberland College). These colleges will be referred to as "the College" throughout this document.

1.2. The College is committed to promoting high ethical standards in research and to safeguarding the dignity, rights and welfare of those involved in research and the implementation of its results.

1.3. Through this Code, the College aims to maximise the benefit and minimise the potential harm to those involved in its research activities.

2. Scope

2.1. The activities covered by this Code include:

- Research activities no matter how they are funded (internally or externally)
- Undergraduate students (including for dissertations) and under/postgraduate staff projects.
- Research related activity such as consultancy and continuing professional development.

2.2. This Code does not cover:

- Research activity that has gone through the ethical approval process of another educational institution;
- Market research activities; or
- Internal consultation with staff and students to support a programme or service. However, the expectation of the College is that these activities must be carried out in a manner with due regard to ethical principles such as voluntary participation, consent, and data protection.

2.3. This Code applies to all members to the College community, including students, staff (curriculum and business support), and any other person or group conducting research associated with the College.

2.4. The College recognises our students may be undertaking research in pursuit of degrees validated and awarded by other organisations. All research projects conducted by our students and staff must go through the College's ethics approval process and may need to go through the validated/awarding partner's procedures.

3. Underpinning Principles and aim

3.1. In line with the Economic and Social Research Council (ESRC) Framework for Research Ethics, the College's core principles for ethical research are:

- research should aim to maximise benefit for individuals and society and minimise risk and harm.
- the rights and dignity of individuals and groups should be respected.
- wherever possible, participation should be voluntary and appropriately informed.
- research should be conducted with integrity and transparency.

- lines of responsibility and accountability should be clearly defined.
- independence of research should be maintained and where conflicts of interest cannot be avoided, they should be made explicit.

3.2. When undertaking research, it is the researcher's responsibility to consider and observe ethical principles, best practice and procedure.

3.3. Review of research proposals shall be mindful of the College's support of the principles of freedom of speech and academic freedom. Our commitment to academic freedom can be found in Article 11 of the Articles and Instruments of Government.

3.4. The aim of this document is to provide the Code of practice to be followed for gaining and granting ethical approval for research projects and to set the roles and responsibilities for that process within the College.

4. Code of Practice for Obtaining Approval

4.1. Ethical approval must be in place before any work on a proposal starts. Failure to comply with this is considered a form of research misconduct.

4.2. It is generally considered best practice to apply for ethical approval for each individual proposal. However, lecturers or programme leads may wish to apply for block approval for student proposals with a similar research design and methodology. Applicants should consult with the relevant curriculum research ethics review committee for guidance.

4.3. Research applications

4.3.1. When students or staff are planning to undertake research they must consider whether any ethical issues need to be addressed before the research is started.

4.3.2. A student undertaking research will, after developing a research proposal, go through a review and approval process in their curriculum department. Once approval is received, they may apply for ethics approval from the College through a pro forma adopted by the HE Ethics Research Panel (attached as Appendix 1).

4.3.3. A member of staff proposing research will, once the research proposal is produced, apply for ethics approval through a pro forma adopted by the HE Ethics Research Panel which will specify the timing and method of submission.

4.4. Curriculum Level Review and Approval

4.4.1. Students will be supported by their curriculum department to develop research proposals that meet relevant ethical standards for the discipline.

4.4.2. Curriculum departments may develop their own process but any process developed must include at a minimum:

4.4.2.1. Development of research proposals that identify the risks involved in the proposed research;

4.4.2.2. Detailed mitigative action to address any identified risks; and

4.4.2.3. A presentation of the research proposal, participant information sheet (where appropriate) and risks to a panel consisting of the staff supervising the research and one other member of teaching staff familiar with research and ethical approval for the discipline.

4.4.3. Research proposals will be quality checked by the curriculum department with an aim to assure that the risk, burden and intrusions of proposals are minimal and

justified for the benefits of the participants, science, the environment and the community.

4.5. **HE Research Ethics Panel Review**

4.5.1. The HE Research Ethics Panel (the Panel) will be a sub-committee of the HE Board and will consist of no fewer and no more than five members. The Chair will be HE Operations Lead. Membership will include, in addition to the Chair, four programme leads or curriculum managers whose area delivers HE provision as nominated by the Faculty Directors. The Panel membership will rotate providing secretarial support.

4.5.2. Staff supervising student research and recommending the Panel approve the application shall be present at the Panel meeting hearing the student application.

4.5.3. No member of the Panel shall have a direct connection to any application under review but at least one member must be familiar with the ethical considerations for the academic disciplines and research methodologies contained within the applications.

4.5.4. The Panel will meet at least three times annually and will provide its decision on applications within 7 working days of the meeting in which the application is reviewed.

4.5.5. The Panel has the authority to approve, approve subject to modification or reject low risk proposals.

4.5.6. Where the Panel identifies a proposal as being medium or high risk, the proposal shall be denied.

4.6. Appeal

4.6.1. There is no right to appeal a decision of the Panel.

4.7. College staff and student participants in research

4.7.1. Any research intending to involve staff or students must obtain ethics approval from the appropriate body.

4.7.2. Any research proposal intending to conduct activities involving students, including surveys, must obtain approval from the College's Senior Designated Safeguarding Officer.

4.7.3. Where staff and students are invited to participate in research projects at the College, the principles regarding voluntary participation, informed consent and the right to withdraw apply. The decision not to participate should not in any way effect an individual's employment or academic assessment.

4.8. Data Protection

4.8.1. Ethics review does not, in and of itself, ensure compliance with the data protection legislation. Where staff or students are processing personal data, they must familiarise themselves with the requirements for compliance with both the GDPR and the DPA 2018. This includes obligations to provide certain information to participants, and the legal requirement to undertake a Data Protection Impact Assessment (DPIA) for any processing likely to result in a high risk to individuals. The College's Head of Corporate Governance & Policy can provide guidance and must be consulted on any DPIA undertaken.

4.9. Reporting

4.9.1. The HE Ethics Review Panel will report after each meeting to the HE Board a summary of research proposals received, the outcomes reviewed by the Panel along with a review of the College's research ethics framework.

4.9.2. The HE Board will report annually to the Executive Leadership Team on College research activity, training needs, and providing recommendation for the College's research ethics framework.

Roles/Responsibilities

4.10. **The HE Board will:**

- act as the overarching governing body with responsibility for ensuring research conducted under the scope of this procedure complies with ethical practices.
- will ensure training on research ethics and legislation related to research activity is provided to all staff and students involved in research.
- receive at least two times per year reports covering research ethics which should include the curriculum department committee reports, any necessary review of the policies, procedures, frameworks or pro-formas used, and information on any research misconduct cases investigated.
- report at least annually to the Executive Leadership Team providing recommendations to changes of research governance, policies, procedures or frameworks and information on matters that have arisen of requiring executive team knowledge including all research misconduct investigations.

4.11. **The HE Board Ethics Review Panel will:**

- meet at least twice a year to review research proposal applications or as and when required
- discuss and consider the policies and codes for ethical research within the College
- report to the HE Board after each meeting providing information on the research proposals across the College and providing feedback on the College's research framework.

4.12. **Researchers (student and staff) will:**

- consider and observe ethical principles, best practice and procedure when developing and undertaking research
- apply for ethical approval prior to undertaking research

5. Records management

5.1. The HE Research Ethics Panel must maintain all records relevant to administering this policy and procedure in a recognised Group recordkeeping system.

5.2. 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 funding may include certain data retention requirements. For audit purposes, the College recommends that all project documentation should be stored securely for a period of 10 years. Where appropriate, curriculum departments should ensure that this information is retained locally following the departure of a colleague or student from the College.

6. References

- Child Protection and Safeguarding Policy
- Data Protection Policy
- Data Protection Procedures
- University of Hull Research Ethics policies, procedures and guidance
- University of Cumbria Research Ethics policies, procedures and guidance

7. Procedure Monitoring and Review

7.1. If a complaint or feedback is received about this procedure or the topic of the procedure the College will learn from it and endeavour to improve the procedure at its next review. If a barrier to use is discovered, the procedure will be modified prior to the regular review date.

7.2. The College may audit the research ethics approval process where necessary. In most instances, this will involve a check for accuracy of relevant paperwork relating to the submission of the project for ethical approval, the procedures followed during the approval process, the timing of decision on approval, and any changes made to the project during its operational phase. Feedback will also be sought from the researcher on the quality and timeliness of the information they received during the research ethics approval process. Researchers and/or supervisors have an obligation to respond to all requests made during an audit in a timely and efficient manner.

8. Equality Impact Assessment

Have you sought consultation on this procedure? **Details:**		No consultation has been undertaken.		
Could a particular group be affected (negatively or positively)?	**Impact Y/N**	**Description of Impact**	**Evidence**	**Mitigation/ Justification**
Protected characteristics under the Equality Act 2010				
Age	N			
Disability	N			
Gender Reassignment	N			
Marriage and Civil Partnership	N			
Pregnancy and maternity	N			
Race	N			
Religion or belief	N			
Sex	N			
Sexual Orientation	N			
Additional characteristics to consider				
Young Persons in Care & Care Leavers	N			
Young Carers & Care Givers	N			
Young Parents	N			

Youth Offenders	N			
Those Receiving Free School Meals	N			
If there is no impact, please explain:				

Appendix 1a - EPNE Ethics Approval Application Form

Application for study including studies that involve Human Participants

NB: Applicants planning research that involves animals should complete a different form.

Please fully complete this form and send a copy to your research project supervisor for consideration. Once your supervisor is satisfied that ethical standards for the discipline have been met, they will recommend it to the EPNE Research Ethics Panel for approval. Ethics approval must be obtained before commencing any research activities.

All fields will expand as required.

1. Title of Project:
2. Programme title: Module/Unit title:
3. Type of study: please indicate type of study you are on by ticking/ highlighting the relevant box: □ Involves direct involvement by human subjects - (Complete all sections) □ Involves existing documents/anonymised data only - (Ignore sections 7 - 11) □ Involves fieldwork but no human or animal subjects - (Ignore sections 7 – 11)

4. Name of applicant: Student ID (if applicable):
5. Your project supervisor(s) Name(s): E-mail(s):

6. Provide a concise **summary of your research project in lay terms** (maximum length 150 words). What are you planning to do?

7. Describe the **sample of participants** (including for example, number, age, gender).
8. Explain concisely how you will **recruit the participants** (be specific).
9. Explain concisely how you **obtain informed consent from participants**. You need to ensure it is easy for people to withdraw consent and tell them how.
10. Explain how you will **maintain data protection**. State what personal and/ or sensitive data you may collect and how this will be stored (see guidance UK General Data Protection Regulations (GDPR)).
11. Explain concisely how you will offer **review opportunities**, a debrief or, follow up for participants (as appropriate).

12. Briefly describe each of your **data collection and analysis methods** (you may just have one method)	
Method 1	
Method 2	
Method 3	

13. Risks	Explain any risks that your research participants might face because of the research project (this might include psychological and reputational risks)	Describe how you will control the risks you have identified
1		
2		
3		

14. Other ethical considerations
Explain any risks that you may face as a researcher, and what steps you will take to control them.
Explain briefly any benefits that your research participants may gain from participation.

Explain briefly how you will collect each type of data– such as hard copy paper / digital / audio / video.
State a date when you will destroy by shredding, burning or deletion your data files. Note: this should be after the award of a confirmed grade for your degree.

15. Check you have considered each issue below and fully explained it in your application, then put x in the box	
I have identified and taken steps to control any physical, emotional or psychological risk to participants	
I have identified and taken steps to control any cultural offence that might be caused	
I have identified any vulnerable groups involved and taken steps to control the risks	
I have explained how I will get permission from managers to recruit participants on their premises	
I have made clear that no deception is involved in the study	
I have explained the level of anonymity for participants and how it will be maintained	
I have explained how participants will be informed and have the chance to ask questions beforehand	
I have explained how participants may make follow up enquiries after their part in the study	
I have explained how data will be kept secure and destroyed after the study	

16. Role	**Name**	**Signature**	**Date**
Student/researcher *I acknowledge that I must not progress with my research project until I have been given authorisation to do so. I also must not deviate from the approved proposal including any modifications set.*			
Research project supervisor *I hereby recommend this research project for approval at EPNE HE Research Ethics Panel having read and understood EPNE's Research Ethics Approval Code of Practice and relevant ethical standards for the discipline.*			

Supporting Materials Checklist

Please attach all necessary supporting materials and indicate in the checklist below.

Please tick as appropriate

Research protocol or research proposal	
Participant Information Sheet	
Debriefing Sheet	
Consent Form	
Letter of invitation	
Other (such as interview schedule, questionnaires, measures: please state, and explain)	

Appendix 1b - EPNE Ethics Approval Application Form

Application for study involving animals

Please fully complete this form and send a copy to your research project supervisor for consideration. Once your supervisor is satisfied that ethical standards for the discipline have been met, they will recommend it to the EPNE Research Ethics Panel for approval. Ethics approval must be obtained before commencing any research activities.

All fields will expand as required.

1. Title of Project:
2. Programme title: Module/Unit title:
3. Type of study □ 1. Observational (no physical contact) □ 2. Invasive (e.g., temporary restraint, measurement, removal of tissue/body material, etc.) Please provide further details in response to Question 11.
4. Peer Review It is expected that all research is peer reviewed before applying for ethical consideration. Please indicate who your proposal has been discussed with (Mentor, Supervisor (s), Expert in field).

Applicant information
5. Name of applicant: Student ID (if applicable):
6. Appointment/position held by applicant
8. Project supervisor(s): Name(s): _____ E-mail(s): _____
9. Appointment held by supervisor(s) and institution(s) where based (if applicable):

10. Names and appointments of all members of the research team (including degree where applicable)

The Project

NOTE: In addition to completing this form you must submit all supporting materials

11. Summary of research project in lay terms (maximum length 300 words). This **must** include reference to relevant literature regarding the proposed methods/techniques & statement of main research question(s).

12. Anticipated project dates

Start date: _____ End date: _____

13. Type of animal to be used, number and age range

Type:

Number:

Age range:

14. Location(s) at which project is to be carried out:

15. Statement of the ethical issues involved and how they are to be addressed. (This will normally cover such issues as whether the risk/adverse effect associated with the project have been dealt with and whether the benefits of research outweigh the risks)

16. Is the project covered by The Animals (Scientific Procedures) Act 1986?
Yes □ No □

17. Please explain why it is or is not so covered.

18. If the project involves animals in the wild, indicate why it is not covered by The Wildlife and Countryside Act 1980

19. What measures have been taken in this project to fulfil ethical commitments to the Reduction, Refinement and Replacement or Animals in Research?

For further information please refer to the National Centre for the Replacement, Refinement and Reduction of Animals in Research (www.nc3rs.org.uk)

20. Where relevant please provide name(s) of Day-to-day Carer(s) of the Animals involved:

A

B

C

Emergency contact phone numbers of carers, including out of office hours:

A

B

C

21. **Ownership of the Animals**

Are the animals owned?
Yes □ No □

22. If the answer to Q21 is 'Yes', has informed consent been obtained from the owner

Yes □ Please append documentary evidence to this form

No □

If 'No', please state why not:

23. **For all work on Vertebrates or Octopus species:**

Does this research involve any procedure that may have the potential effect of causing the animal(s) pain, suffering, distress or lasting harm?

Yes □ No □

Note: Under the terms of The Animals (Scientific Procedures) Act 1986 "Pain, Suffering, distress and lasting harm", encompass any material disturbance to normal health (defined as the physical, mental and social well-being of the animal). They include disease, injury, and physiological or

psychological discomfort, whether immediately (such as at the time of an injection), or in the longer term (such as the consequences of the application of a carcinogen). This regulation starts at the "skilled insertion of a hypodermic needle".

24. Does this project involve a series of otherwise non-regulated procedures that together may have the effect of causing that animal pain, suffering, distress or lasting harm? (For example, multiple or cumulative minor changes to the environment may cause sufficient disturbance to be regulated, even if the individual changes do not warrant regulation)

Yes □ No □

If 'Yes', please describe the series of procedures and the potential effects:

25. Does this project involve any procedures or interventions on the animal(s) that is not part of its/their normal management practice?

Yes □ No □

If 'Yes', please describe the procedures or interventions:

26. **If any answer to Sections 17-19 above is "Yes", please explain the relationship between the project and The Animals (Scientific Procedures) Act 1986 in more detail**

Note: The taking of a blood sample or the forceful removal of a feather to provide material solely to identify an individual, or its provenance, would not be regulated under the Act. However, the same type of sampling to provide data for an experimental or other scientific purpose (for example, to study population dynamics or to determine whether or not the animal had been genetically modified) would be regulated by the Act.

For further information relating to the interpretation of ASPA please refer to https://www.gov.uk/government/publications/operation-of-aspa

For All Work Involving British Wildlife or Studies in the Countryside:

27. Does this research involve intentional killing, injuring or taking of animals?

Yes □ No □

28. Does this research involve the possession or control of live or dead animals, their parts or derivatives?

Yes □ No □

29. Does this research involve damage to, destruction of, or obstruction of access to any structure or place used by a scheduled animal for shelter or protection?

Yes □ No □
30. Does this research involve disturbance of animals occupying such a structure or place? Yes □ No □
31. Does this research involve selling, offering for sale, possessing or transporting for the purpose of sale live or dead animals, their parts or derivatives? Yes □ No □
32. If the answer to answer to any of the Questions 26-31 is "Yes", please explain the relationship between this Project and The Wildlife and Countryside Act (1981) in more detail-which also regulates the disturbance of the plant environment *For further information on the Wildlife and Countryside Act refer to:* ***http://www.naturenet.net/law/index.html***
33. **Ethical Approval from Other Bodies** Does this research require the approval of an external body? Yes □ No □ If 'Yes', please state which body
34. Has ethical approval already been obtained from that body? Yes □ Please append documentary evidence to this form No □ If 'No', please state why not: Please not that any such approvals must be obtained and documented before the project begins.
35. What is the funding source? Internal □ External □ (specify)

16. Role	**Name**	**Signature**	**Date**
Student/researcher *I acknowledge that I must not progress with my research project until I have been given authorisation to do so. I also must not deviate from the approved proposal including any modifications set.*			
Research project supervisor			

I hereby recommend this research project for approval at EPNE HE Research Ethics Panel having read and understood EPNE's Research Ethics Approval Code of Practice and relevant ethical standards for the discipline.			

Supporting Materials Checklist

Please attach all necessary supporting materials (where relevant) and indicate in the checklist below.

Please tick as appropriate

* Proposal or Protocol of the research (**requirement for <u>all</u> applications**)	
Participant Information Sheet	
Consent Form	
Letter of invitation	
Other (e.g., questionnaire/list of questions, please state, and explain)	

Appendix 2

HE Board Ethics Approval Panel – Agreed Outcomes

Panel Members Present:

Date of Meeting:

Programmes with proposals under review:

Student/Staff **Research Question**	**Programme & Supervisor**	**Research Methodology**	**Decision**	**Comments**