

Research Ethics Policy

NB. This policy is available on the University of Cumbria website, and it should be noted that any printed copies are uncontrolled and cannot be guaranteed to constitute the current version of the policy.

current version of the policy.				
Document Control Information				
Document Name	Research Ethics Policy			
Owner	Research and Knowledge Exchange Directorate			
Document Location	RKE Staff Hub page and			
	https://www.cumbria.ac.uk/research/research			
	-ethics-and-integrity/			
Lead contact	Director of Applied Research and Knowledge			
	Exchange – Prof Karen Shaw			
Approved By	Research & Knowledge Exchange			
	Committee			
Approval Date	March 2018 – V1.5			
	June 2024 - V1.6			
Date of implementation	April 2018			
	August 2024 – V1.6			
Version Number & Key Amendment	V1.5			
	 V1.6 Policy Scope has been expanded to include joint work with third party organisations, and notes what does not fall under the policy purview. Accountability for research ethics specifically mentioned in section 'When to Request Research Ethics Review". New sections added: 'Research Involving Social Media', 'Research Involving Generative AI', 'Research Involving Animals', 'Environment and Sustainability', 'Third-Party Interactions and Reputational Protection', 'Research Involving Genetic Modification'. Clearer signposting within the Policy document to principles of good ethical 			

	practice and correlation to the <u>UoC Research</u>		
	<u>Code of Practice</u> .		
	 Updated language around inclusivity and EDI 		
	and explicit reference to the UoC EDI Policy.		
	 Sections on informed consent and confidentiality expanded upon with specific 		
	clarity on the use of the terms 'anonymous',		
	`anonymised' and `confidential'.		
	• Sections of the Policy relating to roles and		
	responsibilities have been rewritten, with		
	further clarifications and logical sub-headings		
	with the flow of the document.		
	Updated list of reference documents. Deduction information in Vithing Training/		
	Redrafted information in `Ethics Training'		
	section for clarity and emphasis of staff		
	responsibility to undertake training.		
	Redrafted 'UG & PG Students Taught Degree		
	Programmes' section to clarify process and role of Institutes.		
Date of Last Davison			
Date of Last Review	February 2024		
Date for Next Review	August 2025		
Related University Policy	Code of Practice for Research		
Documents	Collaborative Working in Research		
	Postgraduate Research Code of Practice		
	Lone Worker Procedures for Researchers		
	Health and Safety Policy Statement		
	Student Code of Conduct		
	Code of Conduct for Employees		
<u> </u>	Equality, Diversity and Inclusion Policy		
Review interval	Annual – refreshed March 2024, by Paul K.		
	Miller, Karen Shaw, Anish Kurien, and Holly		
	Huddart		

Contents Page

Scope of this Policy	2
When to Request Research Ethics Review	3
Research Ethics Panel: Roles and Responsibilities	4
Responsibilities of all Researchers	5
Undergraduate and Postgraduate Students on Taught Programmes	6
Research Involving Social Media and Internet Resources	7
Research Involving Generative AI	8
Research Involving Animals	8
Research Involving Human Tissue Samples	9
Research Involving Genetic Modification	
Sustainability	10
Third-Party Interactions and Reputational Protection	
Ethics Training	11
Process and Procedure for Research Ethics Review	
Principles of Good Ethical Practice in Research	13
General Principles of Data Confidentiality and Access	15
Reporting and Monitoring Relationships of Committees	15
Failure to Comply with this Policy	16
Reference documents:	16
Other relevant guidance:	17
Appendix A: Research Ethics Panel Terms of Reference and Membership	18

Research Ethics Policy

- 1. This Research Ethics policy reflects the principles set out in the University's Code
 of Practice for Research. The code of practice demonstrates our commitment to the Concordat to Support Research Integrity (UUK, 2019), which seeks to provide a comprehensive national framework for good research conduct and its governance. The Research Ethics policy sets out in detail the requirements for ethical review for all research activity at the University of Cumbria. The policy must be read in conjunction with the Code of Practice for Research. In particular, the University's processes for dealing with misconduct in research are set out in the Code of Practice for Research.
- 2. Research integrity and good conduct are crucial aspects of research at the University, and core elements of a sustainable research culture. The University of Cumbria is fully committed to ensuring the good conduct of all research undertaken by its staff and students, and through its engagement with external research collaborators and stakeholders. High standards and integrity are of central importance to our commitment to research, and it is the responsibility of all members of the academic community engaged in research activity (hereinafter referred to as 'researchers') to maintain professional standards.
- 3. Researchers in the University are duty bound to society, their profession, the University and (where relevant) the funders of their research to accept responsibility for their own research conduct and practice, the activities of any staff and/or students researching under their supervision, and for making best efforts to provide value for public or private funds invested in their research.
- 4. This policy reflects the requirements set out in the <u>General Data Protection</u>
 <u>Regulation</u> (GDPR), and the <u>UK Data Protection Act 2018</u>.

Scope of this Policy

- 5. This policy is applicable to all of the below (henceforth 'researchers'):
 - a. Academic and relevant support staff employed by the University, and other individuals carrying out research at, or on behalf of, the University.
 - b. Students at the University undertaking research, and their supervisors.
 - c. Individuals holding honorary titles who are conducting research within, or on behalf of, the University.
 - d. All University staff, student and honorary researchers working jointly with third-party organisations.
- 6. Concerning honorary titleholders or other researchers undertaking activity in collaboration with the university, ethical consideration should be managed in accordance with this policy or the equivalent at another institution where applicable.
- 7. Ethical review is prospectively required for any research and experimental development (R&D) work carried out by researchers at, or linked to, the University of Cumbria. For the purposes of this policy, research and R&D work (henceforth 'research') will be taken to include all systematic creative activities manifestly designed to increase the stock of knowledge, and the use of such knowledge in the development of new applications.
- 8. Ethical review is unambiguously required for any research which involves any one or more of the features below:
 - a. Human participants, including all types of interviews, observation,

- surveys/questionnaires, focus groups, experiments and quasi-experiments etc.;
- b. Materials that could potentially identify human participants, i.e. sensitive/unredacted personal data;
- c. Human cells or tissues, other than those established in laboratory cultures;
- d. Animals;
- e. Clear risk to members of the research team, such as lone-working or chance of physical/emotional distress;
- f. Social media and/or online datasets from sources that could be regarded as private, and/or where Acceptable Usage Policies are complex, and issues of Intellectual Property / ownership may need to be checked and/or monitored;
- g. Active and/or potential threat(s) to the environment;
- h. Potential conflict(s) of interest;
- Research topics, methodologies, outputs, research partners and/or research funding sources that could be considered controversial, with reputational implications for the institution.

When to Request Research Ethics Review

- 9. All projects determined to be research within the Scope of this Policy must undergo ethical review. The relevant application process must be completed.
 - a. Concerning research undertaken by members of staff, it is the ultimate responsibility of the Principal Investigator (PI) to determine whether ethical review is required.
 - b. Concerning research undertaken by postgraduate (PG) students registered on a pure research degree (e.g. PhD) or entering the formal research component of a MRes, DBA etc. (henceforth PGRs), it is the ultimate responsibility of the research supervisor to determine whether ethical review is required.
 - c. Concerning research undertaken by undergraduate (UG) and PG students reading for taught degrees, it is the ultimate responsibility of:
 - i. The research supervisor to determine whether ethical review is required, and;
 - ii. The leader of the module within which the research is conducted (henceforth the Research Module Leader) to ensure that a review system is in place which complies with this Research Ethics Policy and other relevant guidance.
- 10. National Health Service (NHS) Research Ethics Committees (RECs) review research taking place in or through the NHS, and other health and social care research as required by law or policy. Projects potentially requiring NHS ethical review and clearance should firstly follow the most recent guidance provided by the Health Research Authority (HRA) with regard to submission to the relevant procedures, through the Integrated Research Application System (IRAS). IRAS is a single online system for applying for permissions and approvals for health and social care/community research in the UK. Where NHS REC review is not required, then review internal to the university should be sought.
 - a. Note: there is a separate <u>HRA toolkit</u> for research of this order conducted by UG and PG students reading for taught degrees.
- 11. Where a project involving UoC staff or PGRs as part of the research team has obtained ethical clearance through an external agency (e.g. the NHS, another HEI), the project should nevertheless be registered with RKE using the

established online system.

- 12. The same form should also be used to register projects (involving UoC staff or PGRs as part of the research team) determined by the PI to not require ethical clearance from any agency.
- 13. Ethical review is generally deemed unnecessary for research projects that clearly do not meet the definition of research as specified in the Scope of this Policy, nor involve any of the key listed features. These typically include:
 - Systematic, scoping and narrative literature reviews that draw on published academic materials in the public domain and/or behind a publisher's paywall.
 - b. Service evaluations and audits designed and conducted only to define/judge current systems or policy implementation(s), and/or to inform the delivery of system or policy implementation(s), and which do not meet the definition of research posited in the Scope of this Policy, provided that collected data are not to be used for purposes other than those of the core audit/evaluation (e.g. academic conferences and/or publications) at any point at that time or in the future.
 - c. Studies that draw on documentary materials already in the public domain, and/or with an explicitly stated Acceptable Usage Policy. For example, published biographies, clinical audits, newspaper accounts of an individual's activities, published minutes of a meeting, interviews broadcast on radio or television or online and diaries or letters in the public domain, or historical records authorised for public access by record offices.
 - d. Non-academic data collection concerning business partnerships, procurement or investment.
 - e. Impact projects to gather evidence for REF Impact Case Studies, or other funder reporting requirements, provided that collected data are not to be made available to an audience beyond the research team and/or used for purposes other than impact assessment (e.g. academic conferences and/or publications) at any point at that time or in the future.
 - f. The provision of expert advice, where based on existing knowledge (henceforth 'Consultancy'). The purpose of undertaking consultancy is not manifestly to generate original knowledge, although new information may emerge as an unanticipated latency.
- 14. Where it is unclear to the researcher(s) whether a proposed project requires ethical review, they should seek guidance from the Chair of the Research Ethics Panel via the Research Office.

Research Ethics Panel: Roles and Responsibilities

- 15. The University of Cumbria Research Ethics Panel (henceforth REP) is a sub-committee of the Research and Knowledge Exchange Committee (henceforth RKEC), which implements policies and procedures for undertaking research. The REP is responsible for ensuring that proposed research submitted for consideration meets required ethical standards, and that feedback to applicants will help support and develop their understanding of good ethical research conduct.
- 16. The REP itself is primarily concerned with research undertaken by:
 - a. University staff, on any form of contract.

- b. PGRs.
- 17. The REP is tasked with ensuring that the dignity, rights and welfare of research participants are protected.
- 18. The REP will provide training materials on ethical research practice for all staff and PGRs.
- 19. The REP will scrutinize the ethical issues raised by research proposals from staff and PGRs involving research with humans and non- humans in accordance with this policy and with specific reference to the University of Cumbria's:
 - Code of Practice for Research
 - Lone Worker Procedures for Researchers
 - Safequarding and Prevent
 - <u>Data Protection Policy</u>
 - Consultancy Policy
 - Information Security Policy
 - Computer Acceptable Use Policy
- 20. The REP will identify staff and PGR projects for which ethical issues raised are such that monitoring during the life of the research is required. In such cases, monitoring will become a condition of approval.
- 21. It is the responsibility of the REP to consider which projects could impose a high risk from an ethical standpoint, including any reputational risk to the University, and the political sensitivity of the research.
- 22. The REP is tasked with ensuring that research at/with the University is, if and where relevant, aligned with the <u>Human Rights Act</u>, <u>Nagoya Protocol</u>, the <u>UK Trusted Research Agenda</u>, the <u>Animals (Scientific Procedures) Act</u>, <u>The Animal Welfare Act</u>, the <u>National Security and Investment Act</u>, the <u>Human Tissue Act</u> and any other applicable treaty or policy with direct import for the conduct of the specific work.

Responsibilities of all Researchers

- 23. All researchers at the University covered within the Scope of this Policy are required to:
 - a. Have undertaken all available Ethics Training before embarking on any research activity;
 - b. Ensure that their research, if and where relevant, aligns with the <u>Human Rights Act</u>, <u>Nagoya Protocol</u>, the <u>UK Trusted Research Agenda</u>, the <u>Animals</u> (<u>Scientific Procedures</u>) <u>Act</u>, <u>The Animal Welfare Act</u>, the <u>National Security and Investment Act</u>, the <u>Human Tissue Act</u> and any other applicable treaty or policy with direct import for the conduct of the specific work;
 - c. Follow the appropriate process for submission of their proposed research;
 - d. Ensure that all research which requires ethical review has received ethical review, and gained full and explicit approval for before proceeding with any data collection;
 - e. Undertake a Privacy Impact Assessment and/or Health and Safety Assessment, where determined to be necessary by the PI or research supervisor, alongside any assessment of any ethical review required;
 - f. Ensure that all data are securely stored and preserved unambiguously in concert with the <u>UK General Data Protection Regulation</u>, and as further

- detailed below;
- g. Monitor the conduct of research that has received ethical approval. For UG and PG students on taught programmes and PGR students, this would be in consultation with their supervisor(s). The researcher must ensure that there is an appropriate continuing review of the research, taking into account any possible changes that may occur over the duration of the research project.
- h. Seek explicit permission to make any changes to an ethically approved project from the body that originally approved it prior to those changes being made.
- Inform participants and partners/stakeholders in an approved project if the project is (for any reason) substantially altered, paused or terminated.
- j. Provide participants and partners/stakeholders with accessible summaries of all findings/results of the project.
- 24. All researchers at the university have a duty to report any unethical practices they encounter, in research conducted at the University or elsewhere, to the University's confidential liaison on Research Integrity.
- 25. The University is covered by a wide range of insurance documents and policies including but not limited to Travel, Motor, University Property, Personal Effects, Liability Insurance, Student Placements (UK and Abroad), and Reciprocal Agreement with the IOM & Channel Isles. It is the responsibility of all researchers to obtain the relevant forms before commencing any research fieldwork.

Undergraduate and Postgraduate Students on Taught Programmes

- 26. For UG and PG students registered on a taught programme (e.g. BSc., MSc, BA, MA), ethical review of research projects should be sought through programme tutors for research ethics review as outlined below.
 - a. Review of research undertaken by PGRs should be sought from the UoC REP and supported by doctoral supervisors.
- 27. There are specific <u>research ethics application forms</u> for taught degrees (UG and PG), that should be completed for all proposed studies that fall under the Scope of this Policy.
- 28. There is a different set of research ethics application forms that should be completed for all proposed studies that directly involve animals. These should be completed with further regards to the section of this policy directly addressing Research Involving Animals.
- 29. In the broad health/social care domain, all new research proposals/ideas with clear or potential links to the NHS should first be checked for feasibility and guidance by students and supervisors using the HRA student toolkit, and all given instructions followed carefully.
- 30. Where the HRA student toolkit is not applicable, or the seeking of internal (UoC) ethical approval is recommended by the toolkit, applications should be managed at the level of the student's taught programme, with the named Research Module Leader holding ultimate operational responsibility for organizing the review process.
- 31. This research ethics review process as conversant possible with the institutional Process and Procedure for Research Ethics Review.
 - a. It is, however, understood that not all programmes/modules will have the available staff and/or resources to, for example, double-review all student applications.

- 32. Key governing principles for ethical review of taught UG and PG applications are as follows:
 - a. Research Module Leaders (and ideally all research supervisors) should be current with all ethics training made available by and within the university.
 - b. Research Module Leaders should assign at least one member of staff to review each pertinent student proposal, providing clear guidance on the form and content of feedback, and mechanism and timeframe for its delivery. These matters should also be communicated to the student in advance.
 - c. While the student's research supervisor(s) should work closely with the student on their application, the same supervisor(s) must not provide the ethical review and/or approval itself. This could represent a serious conflict of interest.
 - d. Where it does not conflict with the precepts of a validating professional body or academic society, each research module should clearly specify a formal terminal point for ethical approval to be obtained.
 - This will prevent students from continuing to pursue ethical approval for a proposed project into a timeframe where that project could no longer reasonably be completed.
 - ii. An alternative research approach that does not require ethical approval (e.g. a systematic or scoping review) should be advocated and supported where ethical approval is not obtained by the terminal point.
- 33. The REP has broad oversight as regards taught degree research ethics processes, but no operational role in designing or policing them. It is the responsibility of all involved teaching staff to remain current with all training and policy, and to work in compliance with it.
- 34. While ethics applications from taught UG and PG students are reviewed at programme level, each Research Module Leader can raise or report any serious ethical issues or items for consideration directly to the REP, via the Research Office, as necessary.

Research Involving Social Media and Internet Resources

- 35. Ethical review will be required for any research involving social media and/or human participants recruited/identified through the internet.
 - a. For the purposes of this policy, social media are defined by the core components of <u>user-generated content</u>, and the <u>possibility of many-to-many communication</u>. Social media platforms include Twitter (X), Facebook, videobased sites (e.g. YouTube), blogging sites, discussion forums, online messaging services (e.g. Whatsapp), and similar other platforms that follow from these.
- 36. Any study involving online interviews, focus groups or any other data collection technique using private or semi-private online tools is considered to involve contact with human participants, and therefore requires full ethical review.
- 37. Ethical review is required if the understanding of privacy in an online research setting could prove contentious, e.g. where there could emerge a contradiction between what researcher(s) and posters of online materials consider to be 'public'.
- 38. Ethical review is also required for web-based research in which:
 - a. Sensitive issues are discussed.
 - b. Quotes and/or images the researcher intends to use could feasibly be used to identify individuals without their explicit written permission.

- 39. It is the responsibility of researcher(s) to be aware of the legal terms and conditions of any relevant online source, and to act fully within them.
- 40. All applications for ethical review must make unambiguous how matters of privacy, intellectual property and data security are to be managed in the conduct of the proposed research.

Research Involving Generative AI

- 41. Ethical review will be required for any research involving/using Generative AI.
 - a. For the purposes of this Policy, Generative Artificial Intelligence (GAI) is taken to constitute any <u>Large Language Model (LLM) technology that has been trained on huge data sets</u>, such as ChatGPT (powered by ChatGPT and GPT4), Bing, and Google Bard, and similar technologies that follow from these.
- 42. Confidential information (i.e. personal and/or unredacted data of any kind) should not be inputted into public GAI tools, even if such information has itself become publicly available. Such tools currently provide limited transparency and user control regarding how information is shared, and with whom. The security of information storage, and the length of the period for which information is retained, are also typically opaque. These issues are central to compliance with GDPR.
- 43. Applications for ethical review should reveal and describe in depth any intended usage of GAI tools in any part of a proposed research project, including:
 - a. A clear statement on the storage and retention policy of the technology being used.
 - b. A statement (where relevant) pertaining to any likely commercial exploitation of this incidence of GAI-usage in the future, in line with the Third-Party Interactions and Reputational Protection section of this policy.
- 44. All human research participants should be made fully aware of any intended usage of GAI tools in any part of a research project, the exact character of this usage, and any likely consequences of this usage.
- 45. There should be no representation of GAI-created or GAI-augmented reportage of research outcomes as the exclusive work of the author(s). This will be taken to constitute academic malpractice, in line with Article F10.2 of the University's Malpractice Regulations, which states:
 - a. Malpractice includes all forms of cheating, plagiarism, collusion, fabrication and falsification and impersonation (including unattributed content created by artificial intelligence or any other content generating technology).
- 46. It should be further noted that many publishing houses and other gatekeepers to research dissemination will not currently accept manuscripts wholly or partially written using GAI tools. Producing outputs that cannot be disseminated may, in some circumstances, constitute a breach of ethical approval, not least as participants may then consider that they have been actively misled about data usage and distribution.

Research Involving Animals

- 47. Ethical review will be required for any research which could cause harm (including death), suffering, discomfort or disruption to animals, as defined in the Animals (Scientific Procedures) Act 1986 (Amended 2012) ASPA or intervene in any way their extant habitats or routines, natural or domestic.
- 48. As clarified in the ASPA, three licences are required before any active <u>testing</u> on animals is permitted. These are:
 - a. personal licence for each person carrying out procedures on animals;

- b. project licence for the programme of work;
- c. establishment licence for the place at which the work is carried out.
- 49. Observational studies involving animals that do not involve performing any regulated procedures are not usually covered by the ASPA. These may be for the purposes of documenting animal behaviour in the wild or their interactions with humans, and/or to help facilitate species conservation. This type of work must nevertheless:
 - a. be subject to ethical review;
 - b. comply with, and demonstrate how it will comply with, all relevant statutory legislation, including The Wildlife and Countryside Act (1981)) and The Wild Mammals (Protection)) Act (1996).
- 50. The official <u>Home Office Guidance for Research Involving Animals</u> should be followed absolutely in any pertinent research conducted under the auspices of the university.
- 51. All researchers should use the <u>dedicated materials</u> for ethical review applications around research involving animals.
 - a. All UG and PG students reading for a taught programme, ethical review should be sought via the relevant Research Module Leader. It is imperative that assigned reviewers in this domain are experienced in matters of animal-related research.
 - b. For staff and PGRs, ethical review should be sought via the REP.
- 52. In any pertinent application for ethical review, the involvement of animals must be fully justified, and all mechanisms for the avoidance of unnecessary harm made transparent.

Research Involving Human Tissue Samples

- 53. A <u>HTA licence</u> is necessary for the storage of material for use in <u>unspecified</u> research. The University of Cumbria does not presently hold a HTA licence. Any research conducted under the auspices of UoC involving human tissue which will be kept for the duration of a project must, therefore, be subject to <u>NHS REC review</u>.
 - a. Note: HTA licenses cover any material/sample which is known to contain even a single cell that has come from a human body.
- 54. All research of this order must be designed and (where ethically approved) conducted in strict compliance with the 2004 UK Human Tissue Act and the Human Tissue Authority (HTA) Code of Practice on Research.
- 55. Specific research projects using human tissue which have been approved by NHS REC <u>do not require a HTA licence</u>, though the tissue may only be stored for the length of time specified in the NHS REC ethical approval.
 - b. Note: Such human tissue cannot then be stored for future unspecified projects.
- 56. If fresh NHS REC approval has not been sought/obtained before the expiry of the original ethical approval, samples will need to be destroyed or transferred to HTA-licensed premises until new approval is secured.
- 57. Further information on the ethical implications of the Human Tissue Act for research can be found at: https://www.hta.gov.uk/guidance-professionals/regulated-sectors/research/research-faqs.

Research Involving Genetic Modification (GM)

- 58. Precursory to any ethics applications being considered for routine clinical research in the GM domain, any use of GM animals, plants and/or micro-organisms for research on UoC premises, and/or by UoC staff, must be covered by either:
 - a. An approved risk assessment for contained use work, via the <u>Health and Safety</u> <u>Executive</u>, or;
 - b. A licence for deliberate release work, via the **Genetic Modification Inspectorate**.
- 59. The management of any such research (where ethically approved) must also be in full compliance with the <u>Health and Safety at Work Act</u>, the <u>Genetically Modified Organisms (Contained Use) Regulations</u> and all other relevant legislation, including the <u>Regulations of the Health & Safety Executive</u>, its <u>Advisory Committee on Genetic Modification</u> and, where appropriate, the <u>Ministry of Agriculture</u>, <u>Fisheries and Food.</u>
- 60. All storage, use or disposal of genetically modified animals, plants and/or microorganisms must be approved by the relevant Biosafety Committee before the material is imported to or created on UoC premises.
- 61. All standing institutional and national requirements for biohazardous work must also be applied.

Sustainability

- 62. Researchers are encouraged to reflect on matters of sustainability throughout the research process. This is pertinent:
 - a. In the substance of research (e.g. ontological and epistemological questions about how the subjects of the research are understood; matters of social or environmental justice involved in the design);
 - b. In the processes involved (e.g. the carbon footprint of data collection, meetings, vivas or knowledge sharing).
- 63. Researchers are encouraged to review the <u>UN Sustainable Development Goals</u> to help them to reflect on their plans, and (wherever possible) orient to these in their applications for ethical approval, and subsequent research activities.
- 64. All formal research training in the university will emphasise practical courses of action regarding sustainability, and how these might be managed at all stages of the research process.

Third-Party Interactions and Reputational Protection

- 65. Ethical review will be required for any research in which the topic, methodology, output(s), research partners and/or funding sources could be considered controversial, with reputational implications for the institution.
- 66. Before entering into any relationships with third parties, researchers covered by the Scope of this Policy must carefully consider the impact that this could have on the University and its reputation before entering into them. This includes such impacts as, but not limited to:
 - a. Potential malevolent usage of research output(s);
 - b. Potential pressure to find particular results or kinds of result (i.e. interference in the academic process itself);
 - c. Potential restrictions on free dissemination of research findings.
- 67. All research of this order must be designed and (where ethically approved) conducted in strict compliance with the <u>UK Trusted Research Agenda</u>.

Ethics Training

- 68. It is the responsibility of all researchers at the university to have undertaken all available ethical training before beginning any research activity, research supervision and/or research evaluation.
 - a. For staff, this training will encompass both ethics for research and ethics for taught programme supervision, will be provided via the REP itself, and routinely advertised via formal channels.
 - b. For PGRs, this training will be provided via the Graduate School, with input from the REP.
 - c. It is the responsibility of Research Module Leaders on taught programmes (UG and PG) to ensure the provision of at least one session, seminar or support session that covers research ethics. All taught degree students undertaking research for a dissertation or thesis should have access through their Research Module Leader for appropriate advice and support in relation to research ethics. The precepts of this policy document should be formally incorporated into all undergraduate/postgraduate training programmes, and/or documentation.
- 69. Once available training has been undertaken, researchers must responsibly consider whether their comprehension of that training sufficiently qualifies them to evaluate the ethical implications of their research. If not, they should seek appropriate advice from within their institute and/or from colleagues within their discipline with specific expertise in relation to research. Thereafter, in the event of any remaining uncertainty as to the propriety of their research, they should contact the Chair of the Research Ethics Panel via the Research Office for further advice.
- 70. All PIs and research supervisors will be required to self-certify that their training is up-to-date when they (or a supervisee) makes an ethics application. Misrepresentation of this will be considered research malpractice.
- 71. All academic members of the RKEC, as well as Directors of Institutes and all those involved in the ethical review of staff or student proposals, are required to:
 - a. Have undertaken appropriate and up-to-date training before taking up their responsibilities.
 - b. Refresh this training at least annually, or when the available training itself is updated (whichever is more frequent).

Process and Procedure for Research Ethics Review

- 72. The Chair of the REP will initially screen all submissions to ensure that basic ethical and document quality thresholds are met.
- 73. Where these thresholds are not met, the forms will be returned to applicant(s) with minimal and standardised feedback, encouraging the applicant(s) to undertake a substantial rewrite before resubmitting them. This order of response should reasonably be expected within five working days of the Chair receiving the documentation, though a longer wait can be anticipated during vacation periods.
- 74. Where these thresholds are met, the forms will be passed to two members of the panel, who will review them and provide feedback independently. Once the reviews are complete and returned, the reviewers can (upon request) be passed

- each other's comments, anonymously or otherwise depending on individual preference.
- 75. The Chair of the REP will then consider the feedback from the reviewers, add any additional comments they deem to be important, and the collated advice and/or required amendments will then be electronically detailed to the applicant(s). This order of response should reasonably be expected within thirty working days of the Chair initially receiving the documentation, though a longer wait can be anticipated during vacation periods.
- 76. The outcome will be one of the following:
 - a. Approval granted with no changes or amendments required.
 - b. Provisional approval granted on condition of minor amendments or changes made to the application. This level of amendment can be checked by the Chair alone and will not need to be returned to the original reviewers.
 - c. Approval not granted as major amendments or changes would be required for the project to proceed. A revised application would need to be resubmitted for further consideration by the original reviewers, or new reviewers if the former are unavailable.
- 77. In cases where applicants feel that reviewers' feedback is unclear or unsatisfactory, they should open a dialogue with the Chair via the Research Office.
- 78. In circumstances where the Chair is (a) unavailable, or (b) a named member of a research team on a submission, the Vice-Chair will undertake the Chair's duties. If both Chair and Vice-Chair are unavailable (or both are named on a submission), then an experienced member of the REP will undertake the Chair's duties.
- 79. Most research which requires ethical review and involves human participants will be of minimal risk. The following kinds of research may, however, involve more than minimal risk, and this will be highlighted to the reviewers:
 - a. research involving vulnerable groups for example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship;
 - research involving sensitive topics for example participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status;
 - c. research involving groups where permission of a gatekeeper is normally required for initial access to members; for example, professionals working with children or older people, research in communities where access is not possible without permission of another adult or community leader, employees recruited through their work place, online or otherwise;
 - d. research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out;
 - e. research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals;
 - f. research which would induce psychological stress, anxiety or humiliation or cause more than minimal pain;
 - g. research involving intrusive interventions for example, the administration

of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy.

Principles of Good Ethical Practice in Research

- 80. Research should be ethical in purpose as well as in the processes involved. All applications to the REP need to transparently address (where relevant):
 - a. How appropriate informed consent will be obtained;
 - b. How the rights of participants will be protected;
 - How the freedom of refusal to participate, and/or to withdraw from the study, without consequence, will be made clear to all (potential) participant(s);
 - d. The degree to which confidentiality can be offered/assured;
 - e. If and how participants will gain from taking part, or can see the value of their contribution;
 - f. How participants, the public, and/or any communities likely impacted by the research, will be involved in the research design itself (or why this is not viable), and how the findings are to be communicated to all stakeholders;
 - g. How the integrity and independence of the research community will be maintained;
 - h. How it will be ensured that any sources of funding are ethically acceptable.
- 81. The following principles should be considered at all levels of all research, where relevant to the study design:
 - a. Informed Consent: The researcher should inform potential participants in advance of any features of the research that might reasonably be expected to influence their willingness to take part in the study. This should be done in language that will be completely unambiguous to the prospective participants, and includes, but is not limited to, a full account of:
 - i. All agents that will have direct access to both unredacted and redacted data during the research process, not least all members of the research team, trusted transcribers and any Generative AI.
 - ii. All possible uses of the data, in terms of where/how it might be disseminated, and if any or all parts of it might be uploaded to public repositories.
 - iii. When/how any identity-compromising data will be redacted, and when/how redacted data will finally be destroyed.
 - b. Confidentiality: The results of research should be communicated in such a way as to protect the identities of participants insofar as is practically possible, and always at least as far as promised in all participant-facing documentation. Researchers are required to ensure consistent management of unredacted data throughout the conduct and reporting of the research. Any risks to confidentiality should be clearly and unambiguously communicated to potential participants in advance, as part of the informed consent process. To this extent:
 - i. The terms 'anonymous', 'anonymised' and 'confidential' should be used only where entirely appropriate, and in a manner unlikely to

- imply a higher level of identity-protection to participants than is factually the case.
- ii. Truly anonymous participation is taken only to occur where the participants' identities are opaque to the researcher(s) as well as other participants and potential consumers of the research.
- iii. Truly confidential participation is taken only occur where participants' identities are known to the researcher(s), but there is no risk at all that other participants or potential consumers of the research could identify them.
- c. **Accountability:** Researchers should consider, from the outset, the potential beneficiaries of their research.
- d. **Openness and Honesty:** Researchers should be open and honest about the research, its purpose and application with participants and peers alike, though it is accepted that for a limited range of research designs, short-term deception of participants may be necessary.
- e. **Anti-Discriminatory Practice:** Researchers should have a value-base that rejects discrimination against a person in any form on grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief (including those without religion or belief), sex, sexual orientation , and (where feasible given the research design) should seek to make a contribution to social justice.
- f. **Protection from Harm:** Researchers must endeavour to protect participants from unnecessary physical and psychological harm at all times during the investigation.
- g. Environmental Respect and Sustainability: Researchers must design and execute projects with a view to creating no greater negative environmental impact than is absolutely necessary. This includes but is not limited to avoiding making carbon-creating journeys where alternative means of interaction are entirely feasible, avoiding printing of transcripts and questionnaires where electronic formats are equally practical, and using online interfaces for surveys rather than distributing large numbers of email attachments.
- h. **Effective Debriefing:** Researchers should, (where possible), provide an account of the purpose of the study as well as its procedures. If this is not possible at the outset, as a consequence of design necessities, then ideally it should be provided as soon as possible after a participant has completed their contribution.
- i. Reciprocity: Research (wherever feasible) should be based on dialogue between researcher(s), participant(s) and any public/community groups who may be involved in or impacted by the outcomes. To this extent, community concerns should be actively and transparently incorporated into research at all stages, from initial design to final dissemination, and researchers should ideally seek to ensure that results can be used for the common good. Where this order of reciprocity is feasible but not practical, researchers should be prepared to account for the pragmatic circumstances in their ethics application.
- j. Honouring of Professional Values: Professions have their own ethical codes of conduct. Professional values should not be undermined or subverted by research.
- k. **Accessibility:** All research should be capable of being disseminated in the

 Research Ethics Policy

public domain by being saved in the institutional repository <u>Insight</u>, and be appropriate to the teaching and learning role of the University.

General Principles of Data Confidentiality and Access

- 82. All legal requirements pertaining to privacy and intellectual property should be met in accordance with the University's policies in these areas. Data supplier access requirements with regard to the secondary use of datasets must be complied with at all times, including any provision relating to presumed consent and potential risk of disclosure of sensitive information.
- 83. The general principles of data confidentiality and access are contained within the <u>Code of Practice for Research</u>. However, researchers must ensure data relating to identifiable individuals must be held in accordance with the principles of data confidentiality legislation and any guarantees given to data subjects. Such data must be redacted to the strongest practical degree before it is made publicly available and researchers may place an embargo on access when anonymity and confidentiality cannot be guaranteed.
- 84. Research activity must comply with any requirements of the General Data Protection Regulation and the Freedom of Information Act. Due consideration must be given to any implications of Intellectual Property legislation.
- 85. The UK <u>General Data Protection Regulation</u> requires that personal data are:
 - a. processed lawfully, fairly and in a transparent manner in relation to individuals;
 - collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes;
 - c. adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
 - accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;
 - e. kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals; and
 - f. processed in a manner that ensures appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

Reporting and Monitoring Relationships of Committees

86. The REP will keep under review relevant University policies and guidance and will report its actions to the RKEC.

- 87. Academic Board can request that the REP periodically conduct a selective audit of current research projects.
- 88. Where significant concerns have been raised about the ethical conduct of a study, the RKEC can request a full and detailed account of the research for a further ethical review.

Failure to Comply with this Policy

- 89. It is expected that all research at the university will be carefully undertaken in accordance with the detail of this policy. The principles outlined herein should inform all levels of research design, execution and, where relevant, ethics review. While it is understood that some minor deviations from ideal principles will be unavoidable in some practical circumstances, significant deviations from core guidance may be considered to constitute research misconduct. The four key areas most likely to be considered misconduct are:
 - a. Failure to provide an appropriate system for ethics review (typically within a taught programme) where one is required;
 - b. Failure to seek ethics review where it is required;
 - c. Fabrication of information on an ethics application, including whether it has been peer-reviewed, self-certification of training etc.
 - d. Breach of conditions of ethics approval, including making changes to design or procedures without first seeking clearance from the pertinent reviewing body.
- 90. The courses of action that will be pursued in cases of research misconduct are detailed in the Code of Practice for Research.

Related University of Cumbria Documents:

Code of Practice for Research

Collaborative Working in Research

Postgraduate Research Code of

Practice

Lone Worker Procedures for Researchers

Health and Safety Policy Statement

Student Code of Conduct

Code of Conduct for Employees

Equality, Diversity and Inclusion Policy

Reference documents:

There is further information on research integrity and good research conduct in the following documents:

UK Concordat to Support Research Integrity (2019)

Singapore statement on Research Integrity (2010)

Montreal Statement on Research Integrity (cross-border collaboration

(2013) European Code of Conduct for Research Integrity (2011)

Department for Business, Energy & Industrial Strategy: Rigour, Respect,

Responsibility: a Universal ethical code for scientists (2007)

UK Research and Innovation Research Integrity

Concordat to support the career development of researchers

(2019) Concordat on Openness on Animal Research in the

UK (2014) General Date Protection Regulation (2018)

Nagoya Protocol on access and benefit sharing (ABS)

Trusted Research Agenda

Animals (Scientific Procedures) Act 1986

National Security Investment Act 2021

Human Tissue Act 2004

Human Rights Act 1998

Other relevant guidance:

Prevent Duty Guidance: for higher education institutions in England and Wales

Appendix A: Research Ethics Panel Terms of Reference and Membership

RESEARCH ETHICS PANEL

Parent Committee

Research and Knowledge Exchange Committee.

Scope

Ethical approval is required for all research carried out by staff and students at the University of Cumbria and it is the responsibility of the research supervisor (at both undergraduate & postgraduate level) to ensure that research complies with University ethical guidelines. The Research Ethics Panel is primarily concerned with staff and postgraduate student research, and is tasked with ensuring that the dignity, rights and welfare of research participants are protected. The Research Ethics Panel will scrutinise proposals for research involving human participants (that are not otherwise subject to Health Research Authority (HRA) ethical approval) and where appropriate, non-human animals as identified. Proposals requiring NHS ethical clearance should follow the most recent guidance provided by the NHS Research Ethics Service (NRES).

Terms of Reference

The Research Ethics Panel will scrutinise the ethical issues raised by research proposals from research students and staff involving research with humans and non-humans with specific reference to:

- The University's Research Ethics Policy Framework.
- Home Office guidance on research and testing using animals.
- The University's Policy for Safeguarding of Children and Young Persons.
- The University Code of Conduct for Research.

The Research Ethics Panel will also keep under review relevant University policies and guidance and will report its actions to the Research and Knowledge Exchange Committee.

Membership

Vice Chair

Senior Lecturer in Radiography & IS Dr Lisa Booth

Academic Institute Representatives

Business, Industry & Leadership Dr Raye Ng

Dr Demos Parapanos Dr Maria Mouratidou Christopher John Dr Stephen Taylor

Pam Hearne

Health Associate Professor Liz Bates

Dr Alison Buckley

Associate Professor Tom Davidson

Dr Lindy Hatfield Shelley Smart Jane Lancaster Dr Jez Colclough

Institute of Education, Arts & Society

Rebekah Ackroyd (Staff PgR)

Dr Alison Jackson Claire Vuckovic Ann Kendrick

Science & Environment

Dr Angus Carpenter

Research & Knowledge Exchange Directorate Prof Karen Shaw

Prof Karen Shav Anish Kurien

Postgraduate Research Representative

PgR Student Representatives

Paula Moses (PgR Lancaster)

External Representatives

University of Sunderland North West Deanery Professor Peter Smith, Emeritus Professor

Dr Thomas McConnell

In Attendance (by invitation according to items under discussion)

Cumbria Partnership NHS Foundation Trust

University of Cumbria University of Cumbria

Professor Dave Dagnan, Director of Research Professor Chris Loynes, Emeritus Professor

Sam Carr, Senior RKE Officer

Secretary

RKE Administrative Assistant

Yarrow Maxwell

Quoracy

50% of membership + 1.

Frequency of Meetings

Two 1-hour meetings per year in October and April, plus a two-hour meeting in January.

Reporting

Decisions, recommendations and proposals of the Research Ethics Panel are reported to the Research and Knowledge Exchange Committee and Academic Board.

Data Responsibilities

Basic statistics recorded and reported.

Key Institutional Policies

Internal:

- Research Ethics Policy
- Code of Practice for Research
- Lone Worker Procedures for Researchers
- Brief Guide Collaborative Working in Research

• Safeguarding: UoC Children, Vulnerable Groups and Adults at Risk Policy (incorporating the Prevent Duty and Modern Slavery) 2021-22

External:

• Home Office guidance on research and testing using animals

<u>Status</u>

Permanent establishment.