Ethical Governance in Research Policy

<Ethical Governance in Research>	
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Executive Owner:	*<Chair of Research Ethics Committee>*
Business Owner:	*<Research Ethics and Integrity Manager>*
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Ethical Governance in Research Policy

1. Introduction

Northumbria University seeks to uphold the principles of research integrity in all research conducted by its staff and students. The purpose of this policy is to communicate the ethical responsibilities of staff and students undertaking research at Northumbria University. This policy provides an ethical framework for the conduct of all research activity carried out under the auspices of the University. It includes the requirements for ethical review, alignment with external regulatory frameworks (for example the Health Research Authority, the Human Tissue Act, and data protection law) and the principles set out in the Concordat to Support Research Integrity.

2. Scope

This Policy applies to all staff and students conducting research activity at Northumbria University. This policy also applies to all research activity undertaken in the University's name or on its behalf including, visiting or emeritus staff, associates, honorary contract holders, contractors and consultants, across all subject disciplines. This includes collaborative work even where the University is not the lead partner. All those involved in carrying out the research activity are responsible for observing the principles outlined in this policy, and the outcomes of any ethical review. Those undertaking research activity on university premises and using its facilities, but not in the University's name, are expected to abide by the standards outlined in this policy, regardless of whether ethical approval is required. It is the responsibility of the host to ensure they are familiar with the requirements set out in this document.

3. The Principles of Research Ethics

3.1 The policy is built upon ethical and good practice guidelines issued by UK Research and Innovation, relevant professional bodies, subject associations and learned societies, and external ethics committees. This Policy sits alongside the need to comply with statutory and regulatory requirements[1].

3.2 The principles of beneficence and non-maleficence are fundamental to all research activity. Beneficence is the requirement to promote the interests and wellbeing of others. It is the ethical principle of 'doing good' in the widest sense. Non-maleficence is the principle of 'not doing harm'. The key principle underpinning the ethical standards which apply to academic activities is that of avoidance of harm. This principle spans a broad range of considerations, including:

- The welfare of human participants (whether participating or through observation).
- The welfare and interests of those carrying out research activity.
- Animals.

[1] External approvals guidance can be found here: https://www.northumbria.ac.uk/research/ethics-and-integrity/ethics-applications-and-reviews/external-ethical-approvals/

- Cultural heritage.
- The built and natural environment.
- The reputation of the University.

3.3 Principles of Research with Human Participants

Participation in research should be based on fully informed consent, and the right to confidentiality, and to physical and personal autonomy. The respect for rights to confidentiality is essential irrespective of any characteristic of the research environment or participants and at all stages of the research process. Regardless of the nature of their work, staff and students who undertake research activity at Northumbria are obliged to consider the wider direct and indirect anticipated consequences of their work.

3.4 Mechanisms for Informed Consent

For research involving human participants (including their participation, observation and/or data), informed consent is required from those involved and/or their representatives. Consent should be granted voluntarily and be informed. Where research involves vulnerable groups (e.g. NHS patients, children, prisoners, those lacking mental capacity), particular care should be taken to safeguard their welfare and additional safeguards such as external approval (including NHS Research Ethics Committee approval) and Disclosure and Barring Service (formerly CRB) checks should be implemented as appropriate. If researchers wish to deviate from this norm, they should make a case for doing so in line with the core principles of this ethical framework and in accordance with data protection legislation, for consideration as part of the formal ethical review procedure.

3.5 Data Management

The collecting, handling, and storing of sensitive, classified and/or personal data, in line with the General Data Protection Regulations (GDPR), and Data Protection Act (2018) (hereafter together referred to as "the Legislation" All processing of personal data must be compliant with the terms of the Legislation. The level of impact the Legislation will have upon a research project will be determined by such factors as the method in which personal data is collected, the content of the information and whether an individual can be identified by it. It also affects how the results of the research can be published when looking at whether the output contains anonymised or identifiable information. Research projects sponsored by external funders may be required to follow specific procedures as dictated by the funding body. The main principles of the Legislation affecting researchers are that personal data should only be collected, recorded and processed:

Data Protection Principles	**The context for research**
Purpose limitation	Researchers must only process the personal data required for the purposes is collected for unless certain safeguards around re-use are applied.
Data Minimisation	Researchers should only collect the types of personal data relevant to the purposes it is required for.
Lawfulness, fairness and transparency	Researchers must explain to their participants at the point of data collection, how the personal data will be processed, what lawful basis is for processing the data has been identified and for what purposes the data will be used. Any research that does not source data direct from an individual, for example publicly available personal data, should still ensure that they have this information and that it is made available.
Accuracy	Researchers should ensure that the personal data they collect is correct and have in place a means to rectify inaccurate data.
Storage Limitation	Researchers should ensure that they do not retain personal

	data for longer than it is necessary unless certain safeguards around long-term storage apply. No personal data should be collected without knowing how long it will be retained for.
Integrity and Confidentiality	Researchers ensure that they have appropriate security controls in place to adequately protect personal data against unauthorised access, loss or destruction.

Such data should be kept securely and protected from unauthorised access, and there should be a clear and documented access control process for granting and revoking access to the data. Care should be given to ensuring that human data cannot be linked back to individuals' details unless by authorised persons. It is essential that all sensitive, classified and/or personal data are disposed of properly, securely and is auditable, in line with legal and any funder requirements. Further guidance is provided in the GDPR Policy.

3.6 Limits to Confidentiality and Disclosure

The confidentiality of information and research data should be respected within the limits of the law. Where applicable, consent procedures should make it clear that if something illegal, or potentially illegal, is discovered during a study, it may need to be disclosed to the proper authorities. Similarly, in order to safeguard the welfare of participants, researchers may need to share information with different authorities, should any risk, or history of harm or exploitation be disclosed during the research[3].

3.7 Health and Safety

In considering the welfare of all those involved in a project, including the researchers themselves, individuals should make themselves familiar and comply with the University's Health and Safety Policy and any specific Faculty of Departmental policies and procedures relating to health and safety. Risk assessments should be carried out for those conducting or participating in a study or affected by its conduct, and in relation to any impact on the environment. Risk assessments must be approved by the appropriate person e.g. the student's supervisor, or academic's line manager.

3.8 Research Using Human Tissue

The use of human tissue and fluid samples in research must undergo thorough ethical scrutiny and approval by the University. It must comply with all statutory controls and codes of practice, including the provisions of the Human Tissue Act (2004) and the Human Fertilization and Embryology Act (2008). Where regulatory approvals, licenses and/or permissions are required, these should be obtained prior to the commencement of the research.

3.9 Research Using Animals or Animal Products

All UK research councils, most UK medical charities and many professional organisations e.g. The British Psychological Society and the Institute of Biomedical Science provide their own guidance on the use of animals in research. Underpinning all of these guidelines is the desire to reduce the number of experiments carried out on animals and in particular those defined as protected species under the Animals Scientific Procedures Act 1986 (Amended 2012) – ASPA. The act allows the licensing of experimental and other scientific (regulated) procedures carried out on "protected animals" which may cause pain, suffering, distress, or lasting harm to the animal. All statutory controls and codes of practice must be observed, and the use of animals in academic work should always be fully justified. The University supports the principle of the three Rs – that those involved in animal research should aim at Replacing, Refining and Reducing the use of animals for research purposes. Northumbria University is not a designated establishment therefore any regulated procedures must be performed, under full licensing conditions, at an appropriate designated establishment (usually another UK university).

3.10 Due Diligence and Research with Third Parties

In addition to ethical approval, the following items (3.11 – 3.13) require due diligence and consideration of regulatory compliance matters where this has not already taken place. Due diligence is the examination, analysis or investigation undertaken prior to entering into a partnership with a Third Party to ensure that the partnership is safe and viable, aligned with the standards and values of the University, and allows the University to exercise its duty of care to staff and students effectively. It also enables the University to identify any regulatory compliance matters such as export control, sanctions, and other obligations relating to research.

The process of undertaking due diligence on research activities is supported by Research and Innovation Services. More information can be found on the RIS Due Diligence and Trusted Research intranet pages.

3.11 Research with External Stakeholders

It is a fundamental academic freedom that the interests of stakeholders in research projects (e.g. funders) should not bias the design, conduct or findings of research, nor normally restrict publication of results. If stakeholders in research require restrictive clauses for delays in publication (e.g. to permit protection of intellectual property to capture commercial value), they can be accepted, however, the University will seek to include provisions for work to be published with the minimum delays consistent with these considerations. In other cases (e.g. contract research for industry), funders may wish to make publication dependent on their consent. The University would expect these decisions to be made at the beginning of a research project, and with appropriate concern for transparency and the Freedom of Information Act (2000).

3.12 Research with Defence or Security Applications

All research involving potential or actual defence and/or security applications should undergo ethical review, i.e. including 'dual use' research, defined as research that has military as well as civilian applications. Consideration will need to be given to weighing up the benefits against the risks of direct or indirect harm. It is especially important that appropriate measures should be put in place to ensure information security to avoid misuse.

When working with international third parties in defence and/or security research areas, an export control assessment may be required to assess whether the research is 'controlled' or whether there are end-user concerns about the third party which may require an export control licence. More information can be found on the RIS Due Diligence and Trusted Research intranet pages. Any due diligence concerns must be mitigated before research commences, and before ethical approval submission.

3.13 Research outside of the UK

Researchers conducting projects outside of the UK should consider the political, social and cultural sensitivities of the areas they will be working in, in the design and conduct of their projects. Working in sanctioned geographies requires additional due diligence and compliance checks and may be subject to further approval through the University's due diligence processes. When researching in, or with organisations in countries or governments identified as high risk by the Foreign & Commonwealth Office, special attention must be exercised in relation to the welfare and interests of all those involved, both the participants and those carrying out the research. Benefits to the local community should be considered as part of the project. Research conducted overseas should comply with the statutory and regulatory requirements of the country/countries in question, as well as those which apply to the UK. For example, the University will not support work with entities or individuals who are sanctioned by UK Government. In planning the research, individuals should take account of the ethical standards and processes of the country/countries in question as well as those of the University.

3.14 Security Sensitive Research

Research and other academic activities related to security sensitive research, political extremism and terrorism. These studies must undergo ethical review, and advice should be sought from the University's Prevent Lead, and projects may need additional external approvals.

3.15 Research related to Extremism, Radicalisation or Terrorism

Accessing prohibited materials (e.g. terror manuals) requires approval via the university Prevent coordinator[1], as well as research ethics approval. Normally prohibited materials would require access via the University Safe Pod[2] which is managed through the University Library.

4. Research Ethics Review and Approval

4.1 Scope of Ethical Review

All research activities, with more than minimal ethical risk, must undergo formal ethical review and approval. For the purposes of ethics review, this includes student dissertation projects (unless using Module Level Approval), doctoral research and staff projects. However, research that has no ethical considerations (e.g. some laboratory research work that does not involve human participants; systematic reviews; meta-analyses; black letter law; statistical analysis of publicly available data sets), do not normally require ethics review.

4.2 Definition of Research

This policy applies to all individuals undertaking research at, in, or under the umbrella of the University. For the purposes of this policy the follow definition is used:

- 'Research' refers to 'a process of investigation leading to new insights, effectively shared'[3].

Broadly defined, research includes all investigation undertaken to acquire knowledge and understanding. This would also include:

- the generation of concepts, designs, objects and performances that lead to new intellectual insights.
- the reuse of existing data for purposes other than those for which it was originally intended or approved.
- the experimental use of existing knowledge to develop new materials and processes.

This definition of research would **not** normally include:

- routine audit and evaluation, such as the routine evaluation of teaching.
- the development of teaching materials that do not involve original research.
- routine testing and analysis of materials and processes.
- presenting or exhibiting at an outside location

Ethical approval must be in place prior to the commencement of the study to which it applies. Retrospective ethical approval is not permitted.

[1] https://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/governance-services/prevent-duty/

[2] https://library.northumbria.ac.uk/research-data-management/SafePod

[3] REF 2019 Annex C https://www.ref.ac.uk/media/1447/ref-2019_01-guidance-on-submissions.pdf

4.3 Module Level Approval

Although the rigour of ethics reviews must be maintained for all types of research, some Departments deal with very large volumes of research ethics applications from undergraduate and postgraduate-taught students. Where several undergraduate or postgraduate-taught students will be conducting research that is of an appropriately similar nature to be reviewed together, a single generic Module Level Approval can be submitted for review.

4.4 External Ethics Review Requirements

Most research activities will undergo formal ethical review via the University's internal ethics process. However, in some instances, research will require ethical approval by an outside body (e.g. the NHS, a partner organisation, or the Ministry of Defence). For staff and postgraduate research students, where the external ethical framework and process is commensurate with that of the University in terms of scope and rigour (i.e. the NHS or a UK HEI), internal ethical review is not a University requirement. For collaborative research projects, the lead research organisation (normally the principal investigators institution) should review the project. In some instances, it may also be advisable to undertake ethics review through Northumbria's ethics processes, if for example Northumbria staff are leading on a distinct arm of funded project.

4.4.1 For undergraduate and postgraduate taught student projects, internal ethical review must be sought before submission to an external ethics committee. In all instances, the outcome of external ethical scrutiny should be reported by the Northumbria University study lead and recorded on the Ethics Online System. It should be noted that in most cases undergraduate students cannot conduct research in the NHS or HMPSS.

4.4.2 Where the external ethical framework and procedure concerned is not commensurate with that of the University, the study should be reviewed via the University's internal ethics process. Where a decision is required regarding the equivalence of an external ethical framework and review process, this should be made in discussion with the Chair of the relevant Faculty Research Ethics Committee.

4.5 Transferring Project Reviews

Where research projects transfer part-way into the University owing to staffing changes, the Northumbria lead should inform the Chair of the Faculty Research Ethics Committee of the ethical scrutiny which the project has undergone, and the Chair should decide with reference to the above principles whether further scrutiny on behalf of Northumbria is necessary. The project should be recorded on the Ethics Online System. If the project requires HRA approval, change to Sponsor would require review and agreement according to the University's HRA sponsorship process. Projects with ethical approval can be transferred to another User in the Ethics Online System.

4.6 Responsibility for ensuring Ethics Review

The responsibility for undertaking ethical review and ensuring ethics approval or recommendation is in place before data collection begins, lies with the individual initiating and/or leading the activity. Individuals should be proactively engaged with potential ethical issues in their own work and trained appropriately to do so via University training. Where an activity is initiated by a student and falls within their programme of study, this responsibility is shared between the student and their supervisor or tutor, for managing the research and ensuring ethical review and approval has taken place.

4.7 Guidance and Support for Researchers

Ethical concerns and risks should be identified and addressed within the ethics application submitted for review and approval at prior to the project commencing. Information to support staff and students is available on the Ethics and Integrity webpages. https://www.northumbria.ac.uk/research/ethics-and-integrity/. When in need of further

guidance, researchers should seek guidance from their Departmental Ethics Lead in the first instance, referring on to the Faculty Research Ethics Director, and/or the Research Ethics and Integrity Manager for particularly complex or unusual cases. Advice can also be sought from the Legal Service and Insurance team[6] for technical questions relating to those areas.

5. Research Ethics Committee Governance

5.1 Ethical Governance Structure

The University operates a devolved structure for conducting ethical review and approval, reporting to the University Research Ethics Committee. Northumbria's framework for the consideration of ethical issues in research comprises:

a) Formal consideration of ethical issues in research at the discipline level via faculty or Departmental Ethics Review Subcommittees.
b) Monitoring at the level of the Faculty Research Ethics Committee.
c) Institutional oversight at university Research Ethics Committee.

5.2 Faculty Research Ethics Committee

It is the responsibility of each Faculty Pro-Vice Chancellor to ensure that appropriate consideration is given to ethical issues arising in and from research activity for staff and students in all disciplines within the Faculty. The Faculty Pro-Vice Chancellor will exercise this responsibility through the Faculty Research Ethics Committee with the following brief:

i. To ensure good practice and a climate of ongoing reflection with regard to ethical issues in research.
ii. To support staff and students in the consideration of ethical issues.
iii. To ensure good practice by the scrutiny of all research activity at critical points (which will be defined locally in accordance with the nature of the research activity and the discipline and as outlined by professional bodies).

Each Faculty Research Ethics Committee will:

i. Be chaired by the Faculty Director of Research Ethics.
ii. Include academic staff with a significant track record in research and teaching.
iii. Meet as frequently as required, but at least twice per year, and maintain appropriate records of the business conducted.
iv. Will be aware of the legislation and the requirements of its disciplines.
v. Undertake an annual audit to ensure that appropriate ethical standards are maintained.

[6] For advice on Legal queries please contact vc.legal.services@northumbria.ac.uk and www.northumbria.ac.uk/about-us/campus-services/insurance/ for insurance queries.

The Faculty Pro-Vice Chancellor (working with the Faculty Director of Research Ethics) is responsible for assuring the University's Research Ethics Committee that the Faculty Research Ethics Committee is operating effectively. The Faculty Research Ethics Director will submit an annual report to the Research Ethics Committee at the beginning of each academic year in a prescribed format to provide:

a) A brief statement of the local arrangements for consideration of ethical issues in research.
b) A list of those activities where ethical consideration has been required.
c) An indication of the problems which have been referred directly to another internal or external committee for their resolution.
d) Maintain records of all research projects (including dissertations) which involve ethical issues.

The Faculty Pro-Vice Chancellor can refer to the University's Research Ethics Committee any matters which cannot be satisfactorily resolved at Faculty level. The Research Ethics Committee will submit an annual report to the Research and Knowledge Exchange Committee at the beginning of each academic year.

5.3 Research Ethics Committee

The Research Ethics Committee is established as a subcommittee of the Research and Knowledge Exchange Committee, and Academic Board with the following terms of reference:

i. To provide written guidelines on ethical issues in research, for use by staff and students of the University.
ii. To take a University overview of the ethics policy implementation.
iii. To recommend policy changes.
iv. To advise on any issues of an ethical nature referred to it by the Faculty Pro-Vice Chancellor of the Faculties.
v. To receive relevant papers/information from external bodies for consideration.

Membership of the Research Ethics Committee will comprise Faculty Research Ethics Directors and other senior academic staff with a proven track record in research. The Committee will also have powers of co-option, to allow appropriate consultation with relevant experts. The Research Ethics Committee will have three statutory meetings each year but will also be convened as other business requires. The Research Ethics Committee is Chaired by the PVC Research and Knowledge Exchange.

6. The Ethical Approval Process

6.1 Ethical Approval Standards and Responsibilities at Northumbria

Northumbria University seeks to ensure that ethical standards in research are maintained consistently, and rigorously. Academic faculties and University Service Departments are responsible for ensuring that all students and staff conducting research are aware of the University's ethical standards and governance processes, and that all research conducted on staff, students and premises adheres to these. Research undertaken by or on behalf of the non-academic staff at Northumbria, are aligned to Faculties in order that any projects, that fall under the definition of research, can undergo ethical review. The Policy should be read alongside the Ethical Approvals Process documentation.

6.2 Applying for Ethical Approval

Staff and students must use the Ethics Online system to apply for ethical approval for research projects in advance of their commencement. This includes Module Level Approval (MLA) and Amendments to research projects. Except in the case of MLA applications, a new record should be created by staff and students for each individual research project requiring review. Module Level Approvals must be submitted for the cohort of students that are in scope and

repeated each time the module is taught. Students not in scope of the MLA must submit and individual application. Access to the Ethics Online System is on the Ethics and Integrity web page, through the Staff portal and the Student Portal.

6.3 Amendments to an Approved Ethics Submission

An amendment is a modification to the original approved study. Examples of modifications that require an amendment via the ethics online system, might include:

- An additional sample group or request to increase the size of an existing sample group.
- A change to research personnel.
- With agreement from the funder, extension of the study beyond the period specified in the application form.
- Minor changes to the protocol or other study documentation, e.g. minor clarifications, updating contact points.

An amendment does not involve any substantial changes to an approved study's design, methodology, theoretical framework, or participant research activities. Such changes are likely to have a significant impact on the study's outcomes. Importantly too, substantial changes may have a significant impact on participant or researcher safety, as well as compromising the approved study's risk/benefit assessment. A substantial change to an approved research study is likely to result in a new research study. This would require formal review and approval by an appropriate review body.

Amendments for NHS and Health Research Authority approved studies require Sponsorship review and approval. The process and outcome of seeking an amendment is provided here: https://www.hra.nhs.uk/approvals-amendments/

6.4 The College of Ethics Reviewers

If a research project is assessed as having more than minimal ethical risk, it is required to undergo review. Reviews are undertaken by members of the College of Ethics Reviewers. The College is recruited at the start of every academic year with the number of reviewers per department aligned with the anticipated number of applications to be submitted. However, flexibility and mobility within the College is necessary to ensure that the breadth of subject and methodological expertise is captured.

Depending on the risk of the research project a proportionate review (by one reviewer) may be undertaken, however if there are complex ethical risks the application may need to be reviewed by the faculty or departmental Research Ethics Review Subcommittee.

6.5 Ethical Review Categories

Depending on the type of research activity, ethics application will require different levels of review, in accordance with the categories below:

Review Category	Research Activity
Full Review (two lead reviewers and Sub-committee/ Chair moderation	1. Discussion (e.g. interviews) of highly sensitive topics that may cause undue stress to participants, and researchers, including, but not exclusively: sexual behaviour, drug use; abuse or exploitation; trauma; pornography. 2. Individuals or groups where permission of a gatekeeper is normally required for initial or continued access to participants (e.g. non-governmental organisation, community leaders) 3. Research with potentially vulnerable participants or groups, including people under 18 which may require Disclosure and Barring Services clearance (DBS). 4. Access to records of personal or sensitive confidential information, including genetic or other biological information concerning identifiable individuals. 5. Funding from a source that may be controversial (e.g. due to the nature of the funder, or a conflict of interest). 6. Covert methods of investigation or deception. 7. Collection of data, information, or materials relating to extremism, radicalisation, or terrorism (including extreme or terror groups) e.g., social media, personal and organisational websites (including manifestos and programmatic opinions on such topics), interviews, surveys, AI-generated content (including ChatGPT or similar, deep fake visual and audio material, and so forth), etc. 8. Work that involves direct observation of, or participation in, activities during which it is anticipated that illegal activity, or regulatory breach is likely to occur (e.g. hunting, drug dealing, accessing the dark web, hacking). 9. Research with international partners, or research undertaken outside of the UK where there may be issues of local practice and political sensitivities. 10. Intrusive interventions including the use of drugs or other substances (e.g. food, drink, placebos or drugs); and, or, procedures involving physical distress (e.g. prolonged testing) or emotional distress (e.g. stress or anxiety), that are greater than those you would encounter in everyday life. 11. Funding/ sponsorship from, or the involvement of, the UK Ministry of Defence, Military (UK and International), and or, EU Security funding call. 12. The collection of data/information that might be confidential or classified (e.g. protected by the Official Secrets Act). 13. The funding body e.g. Economic and Social Research Council funded projects require Research Ethics Committee review. 14. The collection of bodily tissue e.g. blood, saliva, urine samples from living persons (which may require licence under the Human Tissue Act and additional training). 15. Culturally sensitive art, artefacts or monuments, or sites. 16. Research with animal subjects

Proportionate review (reviewed by one reviewer from the College of Ethics Reviewers)	1. Gathering data or information from human participants (e.g. via questionnaire / interview/survey/experiment/ Virtual Reality). 2. Collecting personal data, i.e. name, email, home address, computer IP address, phone number etc. 3. Analysis of secondary data either in or outside of the public domain. 4. Participatory methodologies i.e. involvement of research participants or collaborators co-developing the research design, methods, analysis and/or impact and dissemination strategies. 5. Lab-based research. 6. The collection or use of information which is 'commercially sensitive' 7. Financial inducements other than expenses and compensation for time 8. Gathering data/information at a physical location external to Northumbria University campuses, franchised locations, and not your normal place of work 9. Collection of samples such as plants, soils etc, that might disturb the environment or archaeological remains. 10. Access to secondary materials or sources in print and online, such as news media (magazines, newspapers, TV, radio, news websites), scholarly publications, and reports by Civil Society Organisations and government agencies, relating to extremism, radicalisation, or terrorism (including extreme or terror groups).
Research that does not normally require ethics review.	1. Secondary data that is in the public domain (e.g. financial data bases). 2. Systematic Reviews. 3. Meta-analyses of secondary data. 4. Black Letter Law. 5. Literature reviews. 6. Laboratory research except where another risk factor such as patient data is present.

Research which requires external review (e.g. HRA, NHS, MOD, NOMS).	1. Research with those who might lack capacity to consent, for example, a learning disability, dementia, or cognitive impairment. 2. The use of ionising radiation on human participants. 3. Recruitment or collection of data from patients, via the NHS, and some social care settings (e.g. home, or residential care). 4. The collection of bodily tissue from deceased persons. 5. A health-related study or clinical trial of an investigational medicinal product or a medical device. 6. Direct testing on animals or materials derived from animals. 7. The prison service, offenders or participants on probation.

7. University Research Ethics Audit

7.1 The University's Research Ethics Audit is a qualitative audit that examines the research ethics practices which are applied to staff and Post Graduate Research (PGR) student research projects, and undergraduate and Postgraduate Taught (PGT) student research projects in each academic faculty. The audit is a learning process and through checking a sample of research projects enables each faculty to identify areas of good practice, which may be shared with other faculties and to identify any systemic issues that need to be addressed by either the faculty or the University. The annual ethics audit is a triennial exercise with themed audits taking place in each of the intervening years. The Research and Ethics Committee approve the themes for audits which are normally conducted between June and September.

8. Reporting Academic Misconduct in Research

8.1 In the event of an alleged breach of the principles, standards and/or procedures laid out in this policy, the following procedures apply:

- Alleged departures from accepted procedures in the conduct of research by act or omission will be handled according to procedures laid out in the University's Academic Misconduct in Research as appropriate, or student regulations.
- Where a breach constitutes an act or omission is neither reckless nor intentional but offers an opportunity to learn from and improve processes the matter will be treated as an 'ethical breach'. Such matters should be referred to the Chair of the University Research Ethics Committee who will investigate it in collaboration with the department concerned, invoking the relevant University procedures as appropriate.
- Alongside the University's internal procedures, any breaches of statutory or regulatory requirements will be handled as required by the statutory and regulatory framework. If details of the case suggest that a criminal offence has taken place, or is taking place, the matter should be referred to Head of Governance in the first instance, who will consider the need for police involvement.

Individuals reporting concerns because of honest suspicion is a service to Northumbria and to the wider academic community. The University will protect the interests of those who draw attention to possible research misconduct and ensure that they do not suffer any loss, detriment, harassment or victimisation, as laid out in the University's Public Interest and Disclosure 'whistleblowing' policy[7].

[7] Public Interest and Disclosure Policy www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/governance-services/university-policies-and-procedures/

9. Ethical Incidents and Ethical Breaches in research

9.1 Ethical incidents which may involve physical risk

An ethical incident is an untoward event or omission that could give rise to, or has the potential to produce, unexpected or unwanted effects that could be to the detriment of the safety of research participants, students or staff of Northumbria University.

9.1.1 An incident includes, but is not limited to, breaches of security, violence, physical injury and psychological distress. It includes 'near misses', where an incident had the potential to cause injury, harm or disruption had intervention or evasive action not been taken. Some examples of possible ethical incidents that may occur within research include:

- An incident involving violence or intimidation during a research interview.
- Theft or damage to property during a research activity.
- Accidental injury to a research participant or to a student or member of staff during a research activity.
- A concern or allegation becoming apparent during the course of research activities that relates to safeguarding issues (i.e. Potential abuse or neglect of a child or vulnerable adult) or Prevent related (i.e. Terrorism or the possible radicalisation of an individual).

9.1.2 The reporting of all incidents, however minor, allows Northumbria University to build up a profile of all the risks to staff, students and research participants and can help to develop good practice and create a safer working environment. It is important to ensure that lessons are learned from any events and that the safety of staff, students and participants is maintained.

9.1.3 You should complete a report on any incident, including a near-miss, as soon as possible after the event. This should include clear information about the location, timing and personnel involved in the incident, as well as its nature and impact and any immediate actions taken. A copy of the report should be received by the Faculty Pro Vice-Chancellor on behalf of the Faculty Research Ethics Committee as soon as possible.

9.1.4 To report an ethical incident, you should refer to the Ethics Online System user guide in the first instance which can be found on the Ethics and Integrity webpage.

9.1.5 In the event of an accident or near miss the University's Incident Reporting Policy must be followed.

9.2 Breaches in Ethical Process or Procedure

An ethical breach can occur when a student or staff member has not conducted their research in accordance with this Policy and associated processes or in accordance with the recommendation from the ethics review of their project (both internally and externally approved).

9.2.1 Any ethical breaches should be reported in the first instance to the PVC Research and Knowledge Exchange who will ask the Faculty Research Ethics Director or Departmental Research Ethics Lead to lead a review according to the process set out in the 'Investigating a breach of the University's Ethical Governance in Research Policy involving human participants, personal data and human tissue' (TBD). Where an ethical breach has occurred, it may be necessary to destroy any data collected. A 'lessons learned' review should complete any investigation to understand the any changes in process required to prevent a reoccurrence. It may also be necessary to inform other Services within the University, if for example a near miss of a data breach

occurred. Where the breach is found to be associated with a deliberate act or reckless omission, the Research Misconduct Policy will be invoked.

10. Roles and Responsibilities

10.1 All staff and student undertaking research activity (as defined in section 4.2) are expected to comply with this policy. The policy will be publicly available on the RIS Research Ethics and Integrity webpages and intranet site. Awareness of the policy will be supported by relevant guidance shared on the University website and via presentations and workshops.

Specific responsibilities in the policy are given to:

- PVC Research and Knowledge Exchange (5.3, 9.2)
- Ethics Reviewers (6.4)
- Departmental Ethics Leads (4.7, 9.2)
- Faculty Research Ethics Directors (4.4, 5.2, 9.1)
- Faculty Pro-Vice Chancellors (5.2, 9.1)
- Research Policy Team in Research and Innovation Services (4.7, 9.2)

10.2 Additionally, the University is responsible for providing support for those in key leadership roles within the governance structure for ethics (including committee chairs and members, Departmental Ethics Leads), by ensuring that they have access to the knowledge and skills in order to perform their role successfully. The University also raises awareness of our ethics governance processes and research integrity to all those to whom it applies (e.g. through mandatory training) and ensure there are sufficient provisions are made for training and development to enable staff and students to understand what is expected of them.

11. Applicable to

The policy is applicable to all staff and students at Northumbria undertaking research activity.

12. Related Policies, Procedures and Other Resources

- University GDPR guidance: www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/
- Safeguarding Policy: https://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/governance-services/safeguarding/
- University guidance on the Prevent Duty: www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/governance-services/prevent-duty/
- Public Interest and Disclosure Policy www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/governance-services/university-policies-and-procedures/
- The Academic Misconduct in Research Policy can be accessed via the Staff Intranet.