Code of practice and principles for good ethical governance

1. Purpose and scope

- 1.1. The University exists to advance and disseminate knowledge and learning while maintaining proper ethical standards.
- 1.2. The purpose of this Code is to establish an ethical framework for the conduct of academic activity under the auspices of the University. It articulates a set of principles and standards to help identify and address ethical considerations, and sets out the procedures for conducting ethical review on behalf of the institution wherever such considerations have been identified, including formal approval where necessary.
- 1.3. This Code applies to all academic activity undertaken in the University's name or on its behalf, including research, teaching, consultancy and outreach work. This includes collaborative work even where the University is not the lead collaborator. It applies to all staff, students (including postgraduate researchers), visiting or emeritus staff, associates, honorary or clinical contract holders, contractors and consultants, across all subject disciplines and fields of study. All those involved in carrying out the activity are responsible for adhering to the principles outlined in this Code and abiding by the outcome of ethical review. Those undertaking academic activity on University premises using its facilities but not in the University's name are expected to abide by the standards outlined in this Code of Practice, although formal ethical review and approval might be carried out via other routes as appropriate.
- 1.4. In relation to research, this Code sits within the broader framework of guidance for the conduct of research articulated in the University's <u>Code of Practice on Research Integrity</u>.

2. Ethical principles and standards

- 2.1. The ethical framework sits alongside the need to comply with statutory and regulatory requirements, and with the requirements and standards of practice set out in guidelines published by scientific societies, funding agencies and other relevant professional bodies. In order to avoid a 'box-ticking' approach, the framework consists of principles and standards as opposed to rules, against which each case should be considered on its own merits.
- 2.2. 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 and interests of human participants (whether participating actively or through observation)
 - The welfare and interests of those carrying out the activity
 - Animals
 - Cultural heritage

- The natural environment
- The reputation of the department, the University and academia as a whole
- The reputation of research partners, both individuals and organisations
- The welfare and interests of the wider community.

Activities should neither include practices which directly impose a risk of serious harm nor be indirectly dependent upon such practices.

- 2.3. For research or further activity drawing on research involving humans (including participation, observation and/or data), the default position is that informed written consent is required from those involved and/or their representatives. 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. Consent should be granted voluntarily. Where research involves vulnerable groups (e.g. children, prisoners, those suffering mental or physical illness), particular care should be taken to safeguard their welfare and interests; and additional safeguards such as Disclosure and Barring Service (formerly CRB) checks should be implemented as appropriate. In line with the University's Code of Practice on Research Integrity, participants and/or their representatives should be provided with details of a first point of contact through which any concerns can be raised: usually the Head of Department and/or the Pro-Vice-Chancellor for Research.
- 2.4. Researchers should plan in advance how potential incidental findings relating to the welfare of participants or third parties are to be handled, within the boundaries of the law, and incorporate this into the consent process.
- 2.5. Particular care must be taken with collecting, handling and storing personal and special categories of personal data, in line with the Data Protection Act (2018) and the UK General Data Protection Legislation (GDPR), associated University Policy. Procedures and Guidelines, and the University's Information Security Policy. 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. Particular 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 appropriately, securely and auditably at the end of their lifespan, in line with legal and funder requirements. Further guidance is provided in the Information Classification Scheme and the University's suite of Information policies.
- 2.6. The confidentiality of information should be respected within the boundaries of the law. Where applicable, consent procedures should make it clear that if something potentially or actually illegal is discovered in the course of a project, it may need to be disclosed to the proper authorities.

- 2.7 In considering the welfare of all those involved in a project, including the researchers themselves, individuals should be aware of and comply with the University's Health, Safety and Welfare Policy Statement and associated Management Procedures, and any specific departmental policies and procedures relating to health and safety, as well as the basic legal requirements articulated in the Health and Safety at Work Act (1974). Where relevant, risk assessments should be carried out for those conducting or participating in a project or affected by its conduct, and in relation to any impact on the environment. Appropriate insurance should be put in place, in consultation with the University's Insurance Officer (via standard departmental procedures where these exist).
- 2.8. The use of human tissue and fluid samples in research should undergo rigorous ethical scrutiny (including by the University), and must comply with all statutory controls and codes of practice, including under the provisions of the Human Tissue Act (2004) and the <a href="Human Fertilization and Embryology Act (2008). Where regulatory approvals, licenses and/or permissions are required, these should be secured in a timely fashion prior to the commencement of the research and in accordance with the relevant University and/or departmental procedures.
- 2.9. The use of animals in academic work should 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. All statutory controls and codes of practice must be observed, including the Animals (Scientific Procedures) Act (1986) especially with regard to minimising the number of animals used and having regard for their welfare. Where regulatory approvals, licenses and/or permissions are required, these should be secured in a timely fashion prior to the commencement of the research and in accordance with the relevant University and/or departmental procedures. Animals protected under the Animals (Scientific Procedures) Act are living vertebrates other than man, and living cephalopods. However, research on other organisms may raise ethical concerns if unusual procedures or particularly large numbers are involved, or if the organism is endangered in the wild. More information about the University's research involving animals can be found on the webpage on animal research.
- 2.10. It is fundamental to academic freedom that the interests of funders and other stakeholders should not bias the design, conduct or findings of research. It is also a fundamental principle of academic research that researchers should be able to publish their results freely. Funders may wish to impose restrictive clauses that allow delays in publication, for example to allow protection of intellectual property to capture commercial value. Where such clauses do not infringe the fundamental freedom of the researcher to publish their findings, they can be accepted: 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 reasonably and without undue delay, but with appropriate regard for openness, transparency and the Freedom of Information Act (2000). The University's Code of

<u>Practice on Research Integrity</u> provides further guidance on undertaking and publishing research.

- 2.11 The University is bound by Section 202 of the Education Reform Act 1988 which states that academic staff have freedom within the law to question and test received wisdom, and to put forward new ideas and controversial or unpopular opinions, without placing themselves in jeopardy of losing their jobs or any privileges they may have at the University. With regard to research and other academic activities, staff must ensure that they are working within relevant local legislation. Where research deals with controversial or sensitive subjects, Local Research Ethics Committees should make the Academic Ethics and Compliance Committee aware. It may also be appropriate to inform External Relations prior to dissemination. See the University's Regulations regarding Freedom of Speech within the University.
- 2.12. The University does not bar academics from working with the defence sector. However, 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. Particular 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 (see 2.5 above) in order to avoid misuse.
- 2.13. The University does not work with or accept funding from the tobacco industry.
- 2.14. Activities conducted overseas should take account of political, social and cultural sensitivities in their design and conduct. Regarding countries/regimes with a poor human rights record or identified as dangerous by the Foreign Commonwealth & Development Office, particular care must be exercised in relation to the welfare and interests of all those involved, both the participants and those carrying out the activity. With respect to countries with emerging economies, the activity should involve reasonable use of local resources, and benefit to the local community should be ensured. Activities 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. In planning activities, individuals should take account of the ethical standards and processes of the country/countries in question as well as those of the University. Consideration should be given to how the local political, social and cultural environment might present unfamiliar safeguarding challenges. See the University's Guidance on ethics governance requirements for research conducted outside the UK.
- 2.15. The quality and robustness of a research proposal may carry ethical implications in that any shortfall undermines the investment made by participants, funders and other stakeholders, and harms the reputation of the department, the University and academia as a whole. The primary mechanism for assuring the quality of research proposals is departmental peer review; however, where proposals have been referred for ethical review in response to other elements of the University's ethical framework, concerns relating to quality and robustness can legitimately be raised as an ethical issue.

- 2.16. In the context of the <u>Prevent Duty</u>, particular care needs to be taken with regard to research and other academic activities related to extremism and terrorism. The ethical considerations relating to such activities must be identified to, and reviewed by the relevant local research ethics committee; in addition, the chair of the local research ethics committee should inform the Secretary of the Academic Ethics and Compliance Committee that a proposed activity of this nature has been submitted. Wider legal considerations relating to the creation, accessing, storage and dissemination of extremist-related matter in the course of these activities (see the Terrorism Acts 2000 & 2006, the Counter-Terrorism and Border Security Act 2019), should be referred for approval via the Secretary of Academic Ethics and Compliance Committee to the University Secretary as Prevent Lead. Further useful guidance may be found in the UUK Guidance on Security Sensitive Research.
- 2.17 The University's IT firewall has mechanisms in place to block illegal content, including extremist and terrorist related material. Further information on this is set out separately to this Code.

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3. Ethical management

- 3.1. All academic activities which have an ethical dimension should undergo formal ethical review and signoff. The cornerstones for the management of ethical issues in the University are self-reflection, explicit discussion, institutional accountability, and proportionality. That is to say, individuals should take responsibility for actively considering whether their activities fall within the scope of the University's ethical framework, and where this is the case, the activities should be formally considered and signed off through the University's governance structures as outlined below, with regard to the degree and risk (including the impact and/or likelihood) of potential harm. The purpose of ethical review is not to deter challenging activities, but to enable it to take place on a sound ethical footing and ensure that the University can defend the work carried out in its name and on its premises, and those involved, should the need arise.
- 3.2. All research undertaken in the University's name or on its behalf, regardless of funding source, falls within the scope of the University's ethical framework should be submitted for review and formal approval via the ethics governance structures outlined below. Ethical approval should be in place prior to the commencement of the activity to which it applies. Retrospective ethical approval is fundamentally unethical and is not permitted.
- 3.3. The majority of academic activities which have an ethical dimension will undergo formal ethical review via the University's internal ethics governance structures. However, in some instances, research will require ethical approval by an outside body (e.g. the NHS or a partner organisation). For staff-led research, where the external ethical framework and process is commensurate with that of the University in terms of scope and rigour (e.g. the NHS or a research intensive UK HEI), internal ethical review is not a University requirement. However, the relevant local research ethics committee may

recommend an additional internal review if deemed appropriate according to the scale of risk. To this end, where the University is relying upon an external process to carry out due ethical scrutiny, the York project lead should ensure that the relevant local research ethics committee is informed of the proposed activity in a timely fashion. In all instances, the final outcome of external ethical scrutiny should be reported by the York project lead to the relevant internal ethics committee for its records. Clear and accessible supporting records for the ethical approval should be maintained by the York project lead (cf the University's Code of Practice on Research Integrity, paragraph 3.7.4).

Where the external ethical framework and process concerned is not commensurate with that of the University, the matter should in addition be referred for review via the University's internal ethics governance structures. Where a judgement is required regarding the parity of an external ethical framework and review process, this should be made in consultation with the chair of the relevant local research ethics subcommittee.

Where research projects transfer part-way into the University owing to staffing changes and fall within the scope of the University's ethical framework, the York lead should inform the Chair of the relevant local research ethics committee of the ethical scrutiny which the project has undergone, and the ethics committee Chair should decide with reference to the above principles whether further scrutiny on behalf of the University is necessary.

- 3.4. The fundamental responsibility for identifying ethical considerations and referring them for review lies with the individual initiating and/or leading the activity. The University Senate has agreed that it is important not to take such responsibility from individuals who need to be proactively engaged with any potential ethical issues in their own work. Where an activity is initiated by a student and falls within his/her programme of study, this responsibility is shared between the student and the member of staff overseeing the activity. These individuals should consider whether their activity falls within the scope of the University's ethical framework, and refer it for ethical review if so, prior to commencement. As far as possible, ethical considerations should be identified and addressed within the proposals submitted for review. A checklist is provided as Appendix A to this Code, indicating where ethical considerations are likely to arise. Where in doubt or in need of further advice, researchers should seek guidance from the relevant University local research ethics committee in the first instance, referring on to the Chair/Secretary of the Academic Ethics and Compliance Committee for particularly complex or unusual cases. Ethical considerations should be kept in mind throughout the lifetime of the activity and if circumstances change (e.g. significant amendments to the approved protocol for a project), additional ethical review/approval should be sought as necessary from the body/bodies which originally considered the proposal. Where this involves a body external to the University, the relevant local research ethics committee should be notified and records maintained as set out in 3.3 above.
- 3.5. It is important that the University is aware of all projects with ethical implications being undertaken under its auspices. Local research ethics committees should therefore maintain clear, regular and proportionate lines of communication with the Chair(s) of the relevant departmental research committee(s) regarding the outcomes of its

research-related business. This is particularly important in the case of local research ethics committees that undertake ethical review for more than one department. Departmental research committees also play a role in supporting the identification of ethical considerations and referral for ethical review through procedures for planning and reviewing research such as peer review. It is recommended that an appropriate representative from the local research ethics committee mostly closely associated with the department sits on its departmental research committee.

3.6. The University operates a devolved structure for conducting ethical review and approval, comprising an overarching Academic Ethics and Compliance Committee and a number of departmental/subject-level ethics subcommittees known as local research ethics committees (LRECs), as outlined in Appendix B.

Local research ethics sub-committees should have at least 6 members. One member should be a lay member to provide additional assurance in respect of objective oversight and unbiased scrutiny. The lay member must not be an academic and should have no affiliation to the University. Committees should also include a postgraduate research student representative, and should consider the need to include an undergraduate student representative. Consideration should however be given to the extent of student and lay members involvement in reviewing individual projects, in particular those of their peers or where there may be a conflict of interest. Exceptionally, where a sub-committee deals with a small community or a focussed area of activity, a smaller committee may be appropriate. A quorum of 4 members is required. Additional members may be co-opted, particularly where specialist expertise in a given area is required or where there is potential for conflict of interest on the sub-committee.

3.7. The terms of reference for the ethics sub-committees are:

- To ensure that the principles and standards articulated within the University's
 ethical framework are upheld in relation to all academic activity undertaken under
 the University's auspices, including teaching, consultancy, outreach and
 research;
- 2. To consider and provide guidance on ethical issues arising from academic activity (e.g. in relation to the funding, conduct, dissemination, collaboration or application of these activities);
- To consider for formal approval academic activities which fall within the scope of the University's ethical framework, following statutory frameworks where these apply;
- 4. To refer cases that raise substantial, complex or difficult issues to the Academic Ethics and Compliance Committee, as appropriate;
- 5. To participate in the sharing of practice between subcommittees in order to ensure the quality and equity of ethical decision-making;

- 6. To work with departmental research committees to raise awareness and understanding of the University's ethical framework amongst those to whom it applies, and to offer informal advice in response to queries;
- 7. To remain abreast of national and international requirements and standards for ethical review (e.g. emanating from funding bodies) and to facilitate discipline-specific training and guidance within the department/subject area as appropriate;
- 8. To maintain clear, well-documented and easily accessible audit trails of decisions made by and on behalf of the Committee, including the original proposal, ethics approvals, and any subsequent modifications;
- 9. To report annually to the Academic Ethics and Compliance Committee on the business undertaken by the subcommittee, drawing attention to any general issues.

Further details relating to the work of these sub-committees and their procedures for review can be found via:

https://www.york.ac.uk/staff/research/governance/research-integrity-and-ethics/academi c-ethics-compliance-committee/#tab-4

- 3.8. While certain departments are linked to particular ethics sub-committees, there may be occasions when the specialist knowledge of a particular sub-committee would make it more appropriate for the review to be undertaken by a different sub-committee. Where this occurs, the agreement of the Chairs of the appropriate sub-committees should be sought in advance.
- 3.9. Local research ethics subcommittees may agree to undertake expedited reviews where, for example, the ethical considerations relating to the activity carry only a minimal risk or the work has similarity to projects previously approved. Ethics sub-committees should draw up clear procedures as to when such reviews would be permitted, and ensure that where devolved decision-making takes place, it is undertaken by those with sufficient knowledge and understanding of the ethical and statutory frameworks involved. The outcome of all ethical reviews undertaken on the sub-committee's behalf should be reported back to the sub-committee and recorded as part of its decision-making audit trail.
- 3.10. The Head of Department may additionally be involved as a first port of call in addressing discrete issues such as acceptance of funding or handling conflicts of interest, working with the relevant subcommittee. Further guidance on routes of referral is provided below, including a flowchart of the process in Appendix C.
- 3.11. The Academic Ethics and Compliance Committee's terms of reference. See

https://www.york.ac.uk/staff/research/governance/research-policies/ethics-code/

Further information can be found at:

https://www.york.ac.uk/staff/research/governance/research-integrity-and-ethics/academice-ethics-compliance-committee/.

3.12. The University is responsible for providing support for those in key leadership roles within the governance structure for ethics, including committee members, ensuring that they have access to the necessary knowledge and skills training in order to perform their role effectively. It should also take the lead on bringing this policy to the attention of all those to whom it applies (e.g. through central induction provision), and ensure there are adequate provisions made for training and development to enable staff and students to understand what is expected of them.

4. Funding

- 4.1. Potential ethical issues can arise in the context of the acceptance of external funding of any variety, whether for research, teaching projects or general departmental/University development (e.g. in the form of benefactions; If funding is offered in the form of a gift, advice should be sought from the Director of Philanthropic Partnerships and Alumni as a matter of course). Particular attention should be paid to overseas funding sources.
- 4.2. When faced with a decision about whether to accept funding from a particular source, the following questions are paramount:
- (a) Might acceptance of this funding potentially bring my department, and by extension the University, into disrepute?
- (b) Might acceptance of this funding detrimentally affect other existing relationships within the University?
- (c) In the case of funding for research, consultancy or other such work, might the outputs or results be:
 - used by the funder to enhance practices which raise ethical concerns?
 - subject to influence and/or limitations on dissemination or approval by the funder?
- 4.3. If the answer to any of these questions is 'yes', the matter should be discussed further with the Head of Department, liaising with an appropriate member of the relevant local research ethics committee. If no decision can be reached, the issue should be formally referred to the local research ethics committee for review. If the local research ethics committee is unable to resolve the matter, and there is prima facie evidence that a substantial ethical issue is involved, the local research ethics committee should refer the case in question to the Academic Ethics and Compliance Committee which may in turn consult with relevant senior staff to make a ruling and, if appropriate, recommendations to the University Council.

- 4.4. In the case of research proposals, it is up to the individual to decide in consultation with the Head of Department and the Chair of the relevant local research ethics committee whether it would be more appropriate to consider the funding issue separately as a preliminary issue via this route, or to incorporate it into the formal ethical approval process for the project as a whole, referring to the Academic Ethics and Compliance Committee and Council as appropriate.
- 4.5. If it is agreed that the organisation or individual offering funding is involved in activities that raise ethical concerns, there is a presumption against accepting the funding where the results of the research could be used to enhance practices which go against the University's ethical framework. In some cases this presumption may be over-ridden, for example where the organisation has acknowledged the problem and is already attempting to eliminate it. In all such cases, however, the matter must be referred to the Academic Ethics and Compliance Committee.

5. Handling conflicts of interest

- 5.1. Conflicts of interest, whether actual or perceived, can damage the credibility of an individual's activities, and also that of the discipline, the University and the academic community as a whole. The University requires Heads of Departments to maintain a local Register of Interests of staff within their department, which should be updated annually, in line with the Policy on declaring interests, managing conflicts of interest, and gifts and hospitality
- 5.2. Individuals have a responsibility to identify and declare any conflicts of interest i.e. any situations where their interests or those of others involved in their activity whether financial, institutional, academic, political, personal or otherwise are in conflict to the extent that they might impede or be seen to impede the validity and integrity of the work in question. Where a potential conflict of interest exists it should be handled in line with the Policy on declaring interests, managing conflicts of interest, and gifts and hospitality. Conflicts of interest should be satisfactorily addressed, through declarations and/or special safeguards where possible, before activity commences. For research projects, these measures should be considered explicitly as part of the formal ethical approval process.

6. Breaches of this Code

- 6.1. In the event of an alleged breach of the principles, standards and/or procedures laid out in this Code, the following procedures apply:
 - Alleged breaches relating to research will be handled according to procedures
 laid out in section 7 of the University's <u>Code of Practice on Research Integrity</u>,
 including referral to the University's <u>Research Misconduct Policy and Procedure</u>
 as appropriate.

- Other alleged breaches should be referred to the Chair of the Academic Ethics and Compliance 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 the Chief Operating Officer in the first instance, who will consider the need for police involvement.
- 6.2. Reporting concerns as a result of reasonable and honest suspicion is a service to the University and to the wider academic community, and the University will protect the interests of those who draw attention to possible ethical breaches and ensure that they do not suffer any loss, detriment, harassment or victimisation, as laid out in the University's Speak up (public interest disclosure)

Approved by:

Academic Ethics and Compliance Committee: 14 September 2021

University Research Committee: 2 February 2022

Senate: 10 May 2022 Review cycle: 3 years Date of next review: 2024