Research Ethics Policy

Document Control

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Approved by	Research and Enterprise Committee
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Policy development steps

Action	Description of steps taken
Legal implications of this policy area	This policy was created by a working group of interested parties and approved by Senate in 2016, a light-touch review was undertaken in 2019. In 2021 it received updates to ensure it was in line with the latest legislation and guidance. This version implements changes identified through a Gap Analysis and to facilitate the implementation of Infonetica, the new Research Management Platform.
Consultation for this policy	Amendments to this version of the policy implement changes that have been reviewed by and received input from: • Research and Enterprise Committee • Members of the University Ethics and Integrity Committee • Members of the Research Integrity Working Group • Research Ethics, Governance and Integrity Team

Version History

Version 1 – June 2016	First version of the policy
Version 2 – May 2019	Light-touch review including minor revisions and updating of references
Version 3 – June 2021	Transfer to new template and separation of policy from procedure. Updating of titles for committees, departments etc. Minor changes to wording for clarification, including definition of Research. Inclusion of details regarding: • Researching Sensitive, Extreme or Radical Material
Version 4 – May 2023	Update to facilitate the implementation of Infonetica the new online research ethics and approvals platform. Changes to the way applications are allocated to RECs and reviewers. Moving to a defined risk-based approach. Addition of guarantee of autonomy for RECs to make judgements within their scope as defined within the Terms of Reference.

Related procedures/guidance:

Research Code of Conduct

Policy on Researching Sensitive, Extreme or Radical Material

1. **Introduction**

   1.1. The University is committed to maintaining the highest ethical standards and principles in the conduct of its research. This Research Ethics Policy sets out the principles underpinning the ethical conduct of research. It defines the principles for the objective and rigorous ethics review of research which falls within its scope. The Research Ethics Policy must be read in conjunction with the Research Code of Conduct which sets out the University's commitment to research integrity.

   1.2. This Research Ethics Policy has been drawn up to conform with the principles laid out in other relevant policies, guidelines and codes of conduct, including those issued by external bodies such as the Economic and Social Research Council, the Wellcome Trust, and the Universities UK's Concordat to Support Research Integrity.

   1.3. This policy establishes a guarantee from Senate that each ethics committee has the freedom to make ethical judgements within their scope, as defined within their Terms of Reference.

2. **Scope and background**

   2.1. This Policy applies to all researchers, supervisors and students conducting research under the auspices of the University.

   2.2. This Policy applies to all research, enterprise and consultancy activity undertaken by University staff and students in collaboration with other organisations, such as collaborative research projects, and to individuals from other organisations who are undertaking or supervising research at or for the University. This includes, but is not limited to, funded and unfunded research projects, consulting within and outside the University, and exploitation and knowledge transfer activities.

   2.3. All Researchers are expected to familiarise themselves with this Policy and observe the principles to embed good ethics practice in all aspects of their work before commencement of, and during the conduct of, the research.

3. **Legal Implications**

   3.1. All research must comply with all relevant legislation, such as the General Data Protection Regulations, Data Protection Act, Mental Capacity Act, Medicines for Human Use Act. There is no specific legislation which directs ethical review; however, it is a requirement of researchers as set down by various bodies, such as the Department of Health and Social Care in the UK Policy Framework for Health and Social Care Research.

4. **Monitoring and review:**

   4.1. Each Research Ethics Committee will submit a written annual report to the

University Ethics and Integrity Committee for review. The annual report will contain: summary data on the projects reviewed (number, discipline/ type, outcome of review process); information on any strengths, issues or trends identified; and a random sample of approved applications and, in some cases, disputed applications.

4.2. The University Ethics and Integrity Committee reports to the Research and Enterprise Committee and will routinely submit minutes of its meetings. In addition, it will submit an annual report drawing on the reports from the Research Ethics Committees.

4.3. The University Ethics and Integrity Committee will submit reports to the University Audit Committee as appropriate.

4.4. The University Ethics and Integrity Committee will oversee light-touch reviews of this policy, and any sub-policies listed in section 14 bi-annually to include minor revisions and updating of references. Where the need for more major revisions to all or part of the Policy is identified, for example to reflect changes to legislation or changes to funder regulations, the Committee will be responsible for revising the policy and requesting approval from Research and Enterprise Committee and Senate.

5. Definitions

5.1. For consistency, definitions and meanings of other key words in the Research Ethics Policy shall have the same meaning and definition as those found in the University Research Code of Conduct. Those relevant to this policy are detailed below:

5.2. **'Researcher'** indicates an individual involved in research, including, but not limited to:

- staff in any of the University's job families including Honorary Staff and Emeritus Professors;
- staff visiting from other institutions or companies undertaking or supervising research at or for the University;
- undergraduate and postgraduate students (both taught and research), whether registered here or on temporary placement.

This term also covers those involved in fundraising, providing consultancy, innovation, commercial and analytical services and those involved in the setting up and running of University spin-out companies.

5.3. **'Research'** is defined according to the internationally accepted OECD Frascati Manual as "creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to

devise new applications of available knowledge."

The term Research covers different types of activity including but not limited to basic research, applied research, experimental development and service evaluation where the results are likely to lead to shared practices and improvements (i.e., wider dissemination of results beyond the local organisation). Some of the above activities may also be referred to as Enterprise activity.

Research is to be distinguished from other types of activity which may not require a positive ethics opinion, such as Patient and Public Involvement (PPI) to inform future research, audit and service evaluation (where the results will be limited to implementation at the local organisation).

5.4. **'Research Ethics'** refers to the moral principles and actions guiding and shaping research from its inception through to completion, the dissemination of findings and the archiving, future use, sharing and linking of data. Principles underpinning ethical conduct are outlined in section 7.

5.5. **'Student'** covers any person who has registered on a programme of study with the University, which can include undergraduate, postgraduate taught and postgraduate research programmes. This also includes students from elsewhere visiting as part of an exchange or similar programme. A 'Research Student' is a student who is registered on a research-based programme of study, such as an MPhil, MRes, professional doctorate or PhD.

5.6. **'Supervisor'** covers any person or persons who are responsible for oversight of other researchers.

5.7. **'Minimal Risk'** describes any project that poses little risk to participants, researchers or the public. Guidance on what may make a project more than minimal risk is provided in the [university guidance on assessing risk](#).

5.8. **'Light-Touch Review'** may be undertaken where the project is assessed as being 'minimal risk' by Supervisors or committee members as appropriate in line with university guidance on conducting a light-touch review.

5.9. **'Full Review'** includes a review by a quorate committee, either virtually or in person.

6. **Duties and Responsibilities**

6.1. It is the duty of all those subject to this Policy to ensure that they abide by the principles set out below.

6.2. Researchers must ensure that they build good ethical practice into their project design. They must also ensure that they seek ethical review and receive a positive ethical opinion prior to beginning any data collection.

6.3. Supervisors must ensure that their students build good ethical practice into their

project design. They must ensure that for Undergraduate and Postgraduate Taught projects they provide timely ethical review and escalate any applications which are more than 'Minimal Risk' to the Research Ethics Committee for review. They are responsible for the conduct of the project throughout its lifecycle, including meeting with the student, reviewing their conduct, data collection and outputs to ensure robust research.

6.4. Supervisors must ensure that their students comply with all relevant legislation, such as data protection.

6.5. Research Ethics Committee Members must ensure timely review of applications allocated to them, declaring any conflict of interest and applying the principles detailed below in a fair and consistent manner.

6.6. Research Ethics Committee Chairs must ensure the smooth running of their committees, monitor reviews, provide expert advice and guidance as well as author an annual report.

7. Principles underpinning ethical conduct at all stages of research

7.1. Researchers must abide by the following principles at all stages of the research lifecycle. This includes the planning stage, applying for funding, the conduct and later stages of the project, such as dissemination and impact activities.

7.2. Researchers must respect the rights, interests, dignity of participants and related persons in research.

7.3. Research must be undertaken in accordance with any relevant common law or legislation.

7.4. Full informed consent should normally be obtained from participants to enable participants to take part voluntarily. Consent/assent should be given freely without force or coercion.

7.5. Researchers have an obligation to protect research participants wherever possible from significant harm.

7.6. The confidentiality of information supplied by research participants and any agreement to grant anonymity to respondents must be respected.

7.7. Care must be taken with collecting, handling and storing sensitive, classified and/or personal data. Such data should be kept securely and protected from unauthorised access. Particular care should be taken to ensure that human data cannot be linked back to individuals unless by authorised persons. It is essential that all sensitive, classified and /or personal data are disposed of appropriately in line with legal and funder requirements.

7.8. Both the design of research and its conduct should ensure integrity, quality and provide benefits that outweigh potential risk or harm.

7.9. Research shall be undertaken subject to the principle of academic independence. Where any conflicts of interest or partiality arise, these must be clearly stated prior to ethical approval being obtained.

7.10. The same high ethical standards shall apply wherever in the world the research is being undertaken.

7.11. The researcher and the research team shall be responsible for determining what ethical issues emerge from the proposed project and for obtaining ethical approval of the project.

7.12. Research, as defined in section 5.3, must not start unless the researcher is in possession of a positive ethical opinion.

7.13. Research that does not involve humans but raises ethical issues or concerns is also subject to ethical review.

7.14. Researchers are responsible for ensuring the project is only undertaken as approved by the University research ethics approval process and in compliance with any legal or organisational requirements.

7.15. Any divergence from the approved project must be subject to further ethical approval and the researcher is responsible for acquiring further ethics approval before continuing with the research.

8. Committees

8.1. University Ethics and Integrity Committee (UEIC)
The UEIC oversees the ethics approval system at the University, and provides guidance on ethical issues. It is responsible for the development of policies relating to research conduct and ethics. It scrutinises applications for ethics review which have been referred from Research Ethics Committees, and considers appeals from researchers whose applications have been rejected by Research Ethics Committees.

The University Ethics and Integrity Committee reports to the Research and Enterprise Committee, which has overall responsibility on the behalf of Senate for the University's research strategy.

8.2. Research Ethics Committees (RECs)
RECs provide ethics scrutiny of research projects. Usually, this will be based on the Online Ethics Form submitted by the researcher, though applicants may request to make applications in person, and the committees may request researchers attend a meeting in order to clarify details on an application.

In exceptional cases, the Research Ethics Committees may refer an application to the University Ethics and Integrity Committee for further scrutiny.

The University Ethics and Integrity will constitute RECs as required to service the needs of the University.

8.3. Research Integrity Working Group (RIWG)

The Research Integrity Working Group was set up in March 2014 in order to consider the University's response to the Concordat to Support Research Integrity. The Group meets as required to review new research integrity guidance and recommend the implementation of changes to policy and procedures as required.

The RIWG is a working group of the UEIC.

8.4. Advisory Group on Sensitive, Extreme and Radical Material

The Advisory Group on Researching and Handling Sensitive, Extreme or Radical Material leads the development and implementation of policy with regard to researching and handling sensitive, extreme and radical material. Members offer scrutiny of applications to research Sensitive, Extreme or Radical Material. Members are selected to ensure there is a wide range of relevant expertise.

The Advisory Group on Sensitive, Extreme and Radical Material reports to the UEIC.

8.5. The UEIC and RECs operate in accordance with principles of equality and non-discrimination. The UEIC and RECs must also be multi-disciplinary, including at least one lay member and be led by a Chair.

8.6. The Chair of the UEIC is appointed by the President and Vice Chancellor of the University, and the Chairs and members of the RECs are appointed by the Heads of Colleges in consultation with Heads of School/Department. The appointment of these posts shall be for three years in the first instance, with the possibility of renewable for another three-year-term if deemed appropriate.

9. **Scope of ethical review**

9.1. Ethical review is required for:

- Research involving human participants, human tissue, material or remains, personal data; and

- Any other types of research that might not involve humans but still raises ethical issues or concerns. For example, the research or results of the research may pose a risk of damage to the environment, cause political or social tensions or sensitivities, or may impact on cultural heritage.

9.2. Animal research ethics is regulated by the [University's Policy Statement on Research Involving the Use of Animals](#) and applicable statute and is not covered by this Policy.

9.3. Legislation or Government bodies may require ethical review to be conducted by a specific ethics committee. Examples include, the Human Tissue Act, the Mental Capacity Act, or the Medicines for Human Use [Clinical Trials] Regulations 2004 (as amended), the Department of Health's UK Policy Framework for Health and Social Care Research, or where research is funded by the Ministry of Defence.

In these cases, ethics review by, for example, the NHS Research Ethics Committee takes precedence over the University ethics system. Researchers should avoid duplication of ethical review.

10. Ethical Review

10.1. This section sets out the principles of ethics review at the University. Full details of the procedures for ethical review of applications can be found on the University webpages.

10.2. Ethics applications must be made using the University's Online system.

10.3. Projects are allocated to RECs based on the needs of the research project, for example if the project is to be run in line with the principles of Good Clinical Practice it will be allocated to the Medical and Biological REC

10.4. Projects are categorised into Application Types based on the information provided in the application form:

10.4.1. Enhanced Review:

Projects identified as posing:

- the highest risk to the rights and wellbeing of participants;

- significant ethical or legal issues which require discussion amongst a group of REC members

These projects will be determined by meeting predetermined criteria, agreed by the REC and listed on SharePoint.

Projects of this Application Type will be reviewed at a REC meeting (either face to face or online)

The RECs will aim to turn around decisions within two weeks of the REC meeting.

10.4.2. Standard Review

Projects not meeting the definition of Enhanced Review, Proportionate Review or Governance Review

Projects of this Application Type will be reviewed by two authorised people.

- Staff or Postgraduate Research applications - two REC members

- Undergraduate or Postgraduate Taught students – their Supervisor and a REC member

Reviews will occur asynchronously via the online system in line with the ['Light](‘Light

Touch' review guidance.

The RECs aim to turn around decisions within three weeks.

10.4.3. Proportionate Review

Projects where ethics review is required but the risk to the rights and wellbeing of the participants are minimal or there are very limited ethical considerations

Examples include projects with no processing of personal data (e.g. anonymous questionnaires where the researchers cannot identify the data subjects), or where the data processing is minimal to facilitate the project (e.g. anonymous, non-controversial questionnaires where the researchers may be able to identify the participants).

The RECs aim to turn around reviews within two weeks.

10.4.4. Governance Review

Projects not requiring ethics review as defined by this policy but they do require a review to ensure that all legal matters have been considered as not being legal would be unethical. Examples could include projects where the Nagoya Protocol is applicable.

The Governance Team aim turn around reviews within one week.

10.5. Allocation to an Application Type will be initially undertaken automatically by the online system; however, this will be reviewed by the REC admin and amended where required. Where there is ambiguity as to the Application Type the appropriate REC Chair will be consulted and their decision will be final.

10.6. In exceptional cases, applications may be escalated to the UEIC.

10.7. The REC or UEIC must be quorate before making a decision on any application which requires an Enhanced Review. Each REC will determine in their Terms of Reference what their quoracy criteria are.

11. End of Study Reporting

11.1. All projects must complete an end of study report as required by their REC, if no other requirements are laid down by the REC this must be within 14 days. Reporting must be undertaken in line with the REC requirements generally via the online system Infonetica (this will be different for external RECs).

12. Exceptional General Approval

12.1. Exceptional General Approval may be granted where the same research is likely to be undertaken repeatedly by a group of researchers, such as students on field trips.

12.2. Exceptional General Approval will be given for a maximum period of three years and researchers will need to reapply for approval should they wish to continue after this period.

12.3. Full details of the procedures for ethics review of applications can be found in the via the University webpages.

13. Training

13.1. The University Ethics and Integrity Committee will ensure that researchers are provided with adequate and regular training in research ethics as is appropriate for their level of expertise or study and subject discipline.

13.2. Supervisors must provide and ensure students participate in appropriate training or experience in the ethical implications of research and on all aspects of this Policy.

13.3. Researchers and students must undertake appropriate training or experience in the ethical implications of research and on all aspects of this Policy.

13.4. If there is any doubt about the scope of applicability of this Policy, or about the need for appropriate ethics review, advice should be sought from a member of the relevant Research Ethics Committee or a Departmental Ethics Officer.

14. Complaints Procedure

14.1. The University takes ethics and ethical standards very seriously. Any complaint of misconduct in research concerning anyone covered by this policy, or regarding the University's ethics review process must be made to the Nominated Individual for an initial assessment of the nature and severity of the complaint. Details of the Nominated Individual are provided on the University website.

14.2. Further details on investigating an allegation of misconduct can be found in the Research Code of Conduct.

15. Other University policies and guidance

15.1. Research Code of Conduct

The University is fully committed to the principles of research integrity. The Research Code of Conduct provides a clear and public statement of the University's research policies and practices. The Code of Conduct sets out the obligations on researchers, in all disciplines, to be aware of the policies governing research at the University and to comply with institutional and regulatory requirements.

15.2. Policy on Sensitive, Extreme and Radical Material

It is a duty of the University to ensure research into radical, sensitive or extreme material, including chemicals or organisms that can be used as weapons, is carried out appropriately and with due regard to safeguarding the individual and others.

The Policy on Sensitive, Extreme and Radical Material details how the University discharges its duties in this area.

15.3. From time to time, the University Ethics and Integrity Committee may issue guidelines or guidance for staff and students on such issues as: informed consent; internet research; recruiting online; recruiting vulnerable participants; and recognition of another institution's ethics approval. Any guidelines approved by the University Ethics and Integrity Committee will be uploaded on the [University webpages](#) and circulated appropriately.

16. External Codes

16.1. Researchers must adhere to any regulations laid down by their professional body and any legal requirements relating to their research, such as Acts of Parliament or statutory regulations.

16.2. Reference should be made to different funder and professional ethical codes in relation to different subject areas where this is appropriate. This policy gives regard to those codes detailed in Annex 1.

17. Annex 1: Ethics Codes

17.1. This list is merely illustrative and not exhaustive:

- ICH Good Clinical Practice
- ESRC Framework for Research Ethics
- Code of Ethics and Conduct Guidance: Ethics Committee of the British Psychological Society
- Code of Ethics: British Society of Criminology