

UNIVERSITY RESEARCH ETHICS COMMITTEE

University of Cambridge Policy on the Ethics of Research Involving Human Participants and Personal Data

1. Policy Statement

1.1 The University is fully committed to the advancement of high quality academic research and to ensuring that all research activities undertaken by University employees, or on University premises, involving human participation or personal data are undertaken in a way that safeguards the dignity, rights, health, safety, and privacy of those involved. This commitment extends to participants, researchers, students and third parties.

1.2 The University expects its employees, or any other person conducting research on University premises, to abide by the University's normal expectations of good practice in research and to take all reasonable steps to ensure that ethical conduct of research involving human participants and personal data is observed at all times. This includes research undertaken by University employees outside the University and overseas. To facilitate this, the University will:

- a) Foster a research culture that embraces the principles set out in this Policy as well as all obligations set out in relevant legislation governing the protection of the dignity, rights, safety and privacy of those involved in research;
- b) Provide clear and easily accessible guidance on best ethical practice and regulatory requirements;
- c) Offer support and training to staff and students and any others engaged in University research projects to maintain awareness and high ethical standards;
- d) Maintain an ethical review process that enables research projects to be subject to a level of scrutiny in proportion to the ethical risk;
- e) Maintain an oversight of the policies and practices of Department, Faculty, School or equivalent-level Ethics Committees and to take appropriate action where there is evidence that the University's policy is not being followed.

1.3 This policy should be read in conjunction with the University's [Good Research Practice Guidelines](#) and the [University Research Integrity Statement](#).

2. Guiding Principles

2.1 The University recognises that ethical issues raised by research vary across disciplines and that Schools will necessarily have differing approaches to ethical review. Set out below are the guiding principles that the University expects its researchers to abide by; subject specific guidance must be obtained by researchers from their Department or School:

- a) **Harm or burden to those involved in or affected by research must be minimised** in all instances and all participants must be warned in advance about any potential risks of harm, however slight these might seem.
- b) **Researchers are required to consider the ethical risk of any procedure within a research project which involves human participation or personal data,**

consulting the relevant Faculty, Department, School and University policies and personnel, before any work is undertaken. Advice must be sought in case of doubt.

- c) Where more than minimal risk is identified, **reasonable and proportionate independent ethical review** must be carried out prior to research work commencing.
- d) **Risks which become apparent during research require immediate full consideration** and the relevant Head of Department/Chairman of Faculty Board, as well as the relevant Research Ethics Committee must be consulted forthwith.
- e) **Researchers must respect the participant's right to withdraw from research** at any time without adverse consequences to the participant.
- f) Except where the nature of the research or participants makes this impossible, **free and informed consent must be obtained from all participants in research** at an appropriate point in the research process. Projects in which this cannot be obtained, due to the nature of the research or the participants, must undergo the appropriate ethical review process. Participants and research staff should be informed of the purpose, methods and intended use of the research.
- g) Research must be designed, reviewed and undertaken in a way that maintains **academic independence, integrity and quality**.
- h) Research methods and the process of ethical review should be **open, independent and transparent**.
- i) **Research must comply with all current legislative requirements**.
- j) **University sponsored research carried out overseas must uphold the University's ethical standards**. Research must also be cognisant of local expectations, practices and laws, without compromising University standards.
- k) **Confidentiality of information given by participants, and the anonymity of subjects, must be respected** at all times and documentation protected accordingly.
- l) **Research evidence should be retained for peer review**, subject to conditions imposed by legal and funder regulations
- m) While anonymisation of stored research data is encouraged, it should be recognised that this does not guarantee privacy and consequently every effort should be made to ensure **effective protection of stored data**.
- n) Research involving **vulnerable groups and those lacking the capacity or opportunity to consent requires specifically considered protection**, including review by an appropriate research ethics committee. Research involving vulnerable groups should only be undertaken when a project cannot be carried out with a non-vulnerable group or where the research has the potential to benefit that vulnerable group.

3. University Ethical Review Process

3.1 The University is committed to providing a rigorous and independent ethical review process that is proportionate to the potential risk.

3.2 The University recognises that in a significant number of cases the involvement of an ethics committee may not be necessary. However, it expects all researchers embarked on research involving human participants or personal data to consider the ethical risks of their work and, in case of doubt, to seek confirmation from their Supervisor, and/or the Faculty or Departmental staff member identified as responsible for research ethics that further review is unnecessary.

3.3 Any project that is identified at the outset (by the researcher, supervisor, Faculty or Department) as requiring ethical review should be referred to the appropriate local Research Ethics Committee in the first instance. Where local review is not available or insufficient, review should be sought at a School level.

3.4 Research that requires review by an external body, such as a National Research Ethics Service (NRES) Committee, should be identified and referred to that body as early as possible in the review process. The University will provide up-to-date guidance to assist this process.

3.5 Normally local and School-level Research Ethics Committees may review, and approve, projects through 'light-touch' expedited review, checklist review or through full Committee review. Ethical review need not be exhaustive, but it should be reasonable and proportionate to any perceived risk. Committees should give timely review and provide applicants with clear guidance on the likely timetable for review. Any agreed timetable should allow for flexibility where this is required to ensure the quality of the review.

3.6 In accordance with good practice, Research Ethics Committees should consult with Committees operating in cognate areas, and also refer projects that are beyond their expertise to a more appropriate ethical review group.

3.7 All applicants intending to carry out research using human subjects or research involving human-derived materials, whose work does not come under the remit of NRES, **must** seek ethical approval in proportion to the level of risk and comply with the Human Tissue Act (2004).

3.8 Where local Research Ethics Committees consider that they are unable to provide the level of necessary review they will normally be expected, in the first instance, to refer the case to the relevant School-level Research Ethics Committee. Where circumstances make it impossible for a School-level Committee to review a project, typically when the project is beyond the expertise of the Committee members, this case should normally be referred immediately to the Secretary of the University Research Ethics Committee. The University Research Ethics Committee expects such occurrences to be rare and will expect that School-level Committees, in their constitution and procedures, meet the standards necessary to enable them to provide valid ethical approval for all forms of research in their field.

3.9 A researcher may appeal the decision of any local and/or School-level Research Ethics Committee on any of the following grounds:

- a) That there existed material circumstances relating directly to the case of which the reviewing committee was not aware;
- b) That procedural irregularities occurred in the review process, which were of such a nature as to cause reasonable doubt as to whether the Committee would have reached the same conclusion had the irregularities not occurred; and
- c) That there is demonstrable evidence of prejudice, bias, or inadequate review.

Under any of these circumstances, an appeal may be made to the University Research Ethics Committee within the time limit and arrangements set out on the University Research Ethics Committee website or available from the Committee Secretary. If the University Research Ethics Committee are of the view that a complaint does not fall within any of the grounds specified above, they will dismiss the complaint and inform the complainant accordingly. Dissatisfaction with the decision of a local or School-level Research Ethics Committee alone is not sufficient grounds for appeal.

3.10 The University Research Ethics Committee may also review the decisions of a local or School-level Research Ethics Committee without referral or appeal where there are grounds for reasonable doubt concerning the appropriateness or correctness of a decision made by a Research Ethics Committee. This might, for example, be where subsequent information becomes available, either through documentary evidence or through a whistle-blower.

3.11 Complaints, or expressions of concern about research ethics at the University, can also be made to the University Research Ethics Committee, which will refer cases to the University's Misconduct Procedures when appropriate. The Committee welcomes approaches from whistleblowers with information concerning research ethics at the University. Staff are protected under the University's ['Whistleblowing' Policy](#).

3.12 To ensure a consistency of standard and approach, the University Research Ethics Committee will monitor the ethical review system through receipt of annual reports from all University Research Ethics Committees.

3.13 Failure to apply for ethical review or the breach of the approved terms of a project will be addressed through the University's established [misconduct procedures](#).

4. Areas of responsibility for ethical review

4.1 Both the individual researcher and the University have responsibilities in ensuring the ethical conduct of research.

4.2 Individual researchers must take personal responsibility for the conduct of their research. The University expects researchers to familiarise themselves with this policy and accompanying guidance, as well as any subject specific material. Researchers undertaking a project that involves human participation or personal data that requires ethical review must

not begin their research project until approval has been obtained. Advice must be sought in cases of doubt.

4.3 It is the responsibility of supervisors of students undertaking research to ensure that their students become familiar with this policy and accompanying online guidance.

4.4 It is the responsibility of Heads of Department and Chairmen of Faculty Boards to ensure that members of staff and students, and other researchers with access to the Department's premises and facilities, are aware of this policy and also for ensuring the effective implementation of the ethical review process in their academic institution.

4.5 Local and School-level Research Ethics Committees are responsible for ensuring that proposals referred to them receive valid, sufficiently comprehensive, independent and timely ethical review. Research Ethics Committees may also advise, where appropriate, on the wider ethical issues raised by research projects and their potential outcomes (for example dissemination, data use and archiving).

4.6 The University Research Ethics Committee has overall responsibility for the implementation of this policy. It will also offer advice on best practice in research ethics training. The Committee will report to the General Board annually and will recommend any changes that are considered necessary in the light of experience.

5. Application of the policy

5.1 This policy will apply to all members of staff and students, as well as to other persons engaged in a University-led research project who, as a condition of being granted access to University facilities or premises, have agreed in writing that this policy will apply to them. The policy applies whether or not the research is conducted on the University's premises or using the University's facilities.

6. Policy review

6.1 As part of the University's commitment to ethical research, this policy will be reviewed every 3 years, or more frequently in the event of a major policy change by a significant stake-holder or the identification of a significant weakness in the policy as it stands.

Policy Owner: Secretary of the University Research Ethics Committee

Date Last Reviewed: October 2015

Date of Next Review: October 2018