

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 activities undertaken by University employees, or on University premises, involving human participants-and/or personal data as the subject of research are undertaken in a way that safeguards the dignity, rights, health, safety, freedom of expression 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 outside the University and overseas by University employees and students when conducted within the course of their employment and/or studies at the University of Cambridge. 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, freedom of expression 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 and the understanding of research ethics varies considerably across disciplines and that Schools will necessarily have differing approaches to ethical review and the framing of ethical guidance. Set out below are the broad principles that the University generally expects its researchers to abide by. Given this, subject specific guidance should be obtained by researchers from their Department, Faculty or School.

- a) **Risk of harm to research participants must be minimised** in line with department guidance. Participants should be warned in advance about any potential risks of harm. Where the risk of harm to research participant is considered by the researcher to be warranted (e.g. as result of disclosure of criminal activity or public corruption) researchers should seek advice.
- b) Any non-harmful burdens to participants (e.g. travel expenses, inconvenient study site, invasive questions/ procedures, a lengthy study duration etc.) involved in research should be minimised. If a less burdensome means of conducting research is not feasible, the participants should be appropriately informed of the burdens involved.
- c) **Researchers are required to consider the ethical risk of any procedure within a research project which involves human participants or personal data**, consulting relevant Faculty, Department, School and University policies and, if necessary, personnel before any work is undertaken. Advice should be sought in case of doubt.
- d) Where more than minimal ethical risk is identified, reasonable independent ethical review (which may be expedited review where appropriate) must be carried out prior to research work commencing.
- e) **Significant risks that become apparent during research should be communicated** to the appropriate person which may include the Chair of the relevant Research Ethics Committee and/or other relevant personnel. Advice should be sought as necessary.
- f) **Researchers must respect a participant's right to withdraw from active participation in research** without adverse consequences to the participant. In some circumstances, for instance where the participant opts to withdraw after the data has been aggregated and can no longer be related to the individual, retaining the data will be unavoidable.
- g) In general, **informed consent must be obtained from any participants in research** at an appropriate point in the research process. Projects in which informed consent is impracticable due to the nature of the research or 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.
- h) Research must be designed, reviewed and undertaken in a way that maintains **academic independence, integrity and quality**.
- i) Research methods and the process of ethical review should be **open, independent and transparent**.
- j) **Research should be carried out consistently with all relevant principles set out within current UK law**.
- k) **University sponsored research carried out overseas must uphold the University's ethical standards**. Research must adhere to local expectations, practices and laws, without compromising University standards.

- l) **Confidentiality of information given by participants, and the anonymity of participants, must be respected** at all times and documentation protected accordingly except where participants have agreed otherwise or disclosure is required by law.
- 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 which is private and confidential**.
- n) Research involving **participants under the age of 18, vulnerable groups and those lacking the capacity or opportunity to consent requires specifically considered protection**, including appropriate ethical review. Research involving vulnerable participants should only be undertaken when a project cannot reasonably be carried out with non-vulnerable participants or where the research has the potential to benefit that vulnerable group. **Researchers undertaking such research should also be aware of and abide by the University's Children and Vulnerable Adults Safeguarding Policy** and the Mental Capacity Act. In cases where a vulnerable participant over the age of 18 lacks the capacity to consent, researchers must seek review from the Health Research Authority (HRA).

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 many cases independent ethical review will not be necessary. However, it expects all researchers embarking on research involving human participants or personal data as the subject of research to consider the ethical risks of their work consulting, where necessary, with their Supervisor, Faculty and/or Departmental policies and/or the Departmental/Faculty staff member identified as responsible for research ethics.

3.3 Any project that is identified at the outset (by the researcher, supervisor, Faculty or Department) as raising significant ethical risks 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 the HRA, should be identified and referred to that body as early as possible in the review process. The Clinical School Research Governance team will provide up-to-date guidance to assist this process.

3.5 Local and School-level Research Ethics Committees may review, and give favourable opinion to projects through 'light-touch' expedited review (e.g. by the chair), 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 ensure 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 bodies, organs and/or tissue and identifying information derived from it, whose work does not come under the remit of the HRA, **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 ethical opinion 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, inadequate review or review which does not comport with the standards of proportionality and reasonableness required by this Policy.

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 Serious cases of a failure to apply for ethical review where required or the breach of the approved terms of a project may 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 favourable review has been obtained. Advice should be sought where necessary.

4.3 It is the responsibility of supervisors of students or Principal Investigators (as appropriate) 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 privileged 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 at the University involved in:

- a) Research within the course of their employment and/or studies at the University of Cambridge;
- b) University-led research studies whether or not the research is conducted on the University premises or using the University's facilities;
- c) Research studies which are led by other institutions except where there is a collaboration agreement that researchers will adhere to the lead institution's policies and these policies are sufficiently robust to meet the University's standards and expectations.

5.2 The policy will also apply 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.

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: July 2020

Date of Next Review: July 2023