

Policy on the ethical conduct of research involving human participants and personal data

The University's aims

The University of Oxford seeks to protect the dignity, rights and welfare of all those involved in research (whether they are participants, third parties or staff and students) and to promote high ethical standards of research. The University achieves this by:

- fostering a culture within the University that embraces the principles set down in this policy and in the legislation to protect the rights, dignity and welfare of those involved in research;
- providing ethical guidance that communicates regulatory requirements and best practice, and offering ongoing support and training to staff and students to maintain high ethical standards; and
- maintaining a review process that subjects research to a level of scrutiny in proportion to the risk of harm or adverse effect.

This policy should be read in conjunction with the [University's Academic Integrity in Research: Code of Practice and Procedure](#) and reflects the principles and commitments outlined in the funder-endorsed [Concordat to Support Research Integrity](#).

Scope

In this policy, the term 'researcher' refers to staff and students, and to other persons engaged in a University-led research project who, as a condition of their being granted access to the University's premises or facilities, have agreed in writing that this policy shall apply to them, whether or not the research is conducted on the University's premises or using the University's facilities.

The University's commitments

General

The University of Oxford is committed to ensuring that its research activities involving human participants and personal data are conducted in a way which:

☑ respects the dignity, rights, and welfare of all participants in research;

- minimises risk to participants, researchers, and third parties;
- appropriately manages personal data; and
- aims to maximise the public benefit of research.

The University requires that all those carrying out such research engage with the University's commitment to conduct research to high ethical standards and seek ethical review and approval of such research; understand the reasons for, and participate fully in, the ethical review process (whether under the University's procedures or those of authorised bodies such as the [Health Research Authority](#)); and fulfil their moral and legal responsibilities in respect of the rights and welfare of participants.

Rigour

The University is **committed** to ensuring that research involving human participants and personal data conducted on University premises or by University staff or students is carried out to high ethical standards.

The University meets this commitment by:

- requiring that research is designed and undertaken in a manner that evinces a commitment to accountability and quality;
- setting appropriate standards for the conduct of research involving human participants and personal data that are in line with current legislation and best practice;
- identifying and reviewing proportionately to the level of risk all research involving human participants and personal data, except where the ethical standards of that research are more appropriately secured by another recognised approval procedure, for example that of the National Health Service; and
- ensuring that research complies with current legislative requirements.

Respect

The University is **committed** to ensuring that all research involving human participants and personal data contributes to the public good, and that the dignity, rights and welfare of staff and students conducting research, research participants and third parties (which may include family members, carers or the wider community) are respected.

The University meets this commitment by:

- ensuring that any risk of adverse effect on people, either directly or indirectly as a result of participation in the research project, is outweighed by the benefits;
- avoiding or minimising harm to people involved in, or affected by, the research, through sound research methodology, and the early identification and considered assessment of risk;
- requiring that people are fully informed about the purpose and intended possible uses of the research, what their participation involves and details of any risks (unless the relevant ethics committee explicitly approves otherwise because, for example, the research involves the deception of participants in the research project);
- ensuring that participants formally and voluntarily register their consent to participate in such research and can choose to withdraw their participation at any time without adverse consequences; and
- observing the confidentiality of information provided by participants and, where appropriate, respecting their anonymity.

Responsibility

The University is **committed** to providing leadership in the area of ethical conduct of research and to participating openly in discussions on the direction of research, and improvements to practice, in this area.

The University meets this commitment by:

- contributing, listening and responding to the debate on issues that research involving human participants and personal data may raise for society;
- working closely with relevant peer groups and government agencies to remain abreast of developments and inform UK policy; and
- maintaining open and transparent procedures relating to the conduct and review of research.

Education and training

The University is **committed** to sustaining and encouraging ethical research conduct among staff and students through the provision of training to equip them with the skills to recognise potential risks and by raising awareness of the University's policy and procedures and the responsibilities of researchers in helping the University meet its obligations under the relevant legislation.

The University meets this commitment by:

- communicating the University's standards and policies effectively to staff and students involved in research;
- promoting awareness of best practice through education and training;
- providing appropriate training for those undertaking research involving human participants and personal data, and for those responsible for ethical review of such research, so that knowledge and skills are up-to-date; and
- fostering an environment of openness and integrity that encourages collaboration and early communication of potential risks.

Ethical review process

The University is **committed** to providing a competent, rigorous and externally-moderated process of ethical review that is proportionate to the potential risk and, where a high risk is identified, assesses that risk against the benefits to the public good.

The University meets this commitment by:

- using a procedure that distinguishes research that requires review under external procedures, such as that requiring separate review by the Health Research Authority and separates out low-risk research for 'light-touch' expedited review from those research projects requiring further scrutiny by committee;
- appointing to its ethical review committees a combination of members who are independent of the University or who are no longer involved in research, and also those who are still active in the research areas submitted to the committee for review, that reflect the interests of researchers, participants and third parties; and

- keeping under regular review the effectiveness of the ethical review process, including the composition of its review committees.

University staff and students as participants in research

The University extends to its staff and students the same protection as to all other participants. Staff and students may be invited to participate in research carried out in the University but their participation must be entirely voluntary, they may withdraw at any time, and their participation or decision not to participate will not affect their employment or academic assessment in any way. It is normally acceptable for students to be invited to take part in teaching exercises, one of the main aims of which is to train them to make their own observations.

Responsibilities

Registrar

The Registrar, reporting to the Vice-Chancellor, is the University's chief administrative officer and, as such, has overall responsibility for ethical conduct in the University and for the University's compliance with government policy and legislation.

Research and Innovation Committee

It is the responsibility of Research and Innovation Committee to keep under regular review policies which promote the responsible conduct of research and meet the relevant regulatory requirements, including University policy relating to the ethical conduct of research involving human participants and personal data.

Pro-Vice-Chancellor (Research)

The Pro-Vice-Chancellor (Research) is appointed by Council to provide leadership in all matters relating to research. Specific duties include co-ordination of the activities of bodies concerned with research ethics and an audit role in ensuring that compliance is being achieved in this area. The Pro-Vice-Chancellor chairs the Research and Innovation Committee (to which the Central University Research Ethics Committee reports) and consults with the Registrar on ethical matters and compliance issues of wider concern to the University.

Heads of division

Heads of division provide senior academic leadership within the University, an important element of which is to promote the highest ethical standards in the design, conduct and reporting of research.

Heads of department

Heads of department as senior academic leaders within the University should promote the highest ethical standards in the design, conduct and reporting of research.

As one component of this, heads of departments are responsible to heads of division for ensuring their staff and students observe this policy and for the effective local review and approval of departmental research applications before submission to one of the Central University Research Ethics Committee (CUREC)'s subcommittees for ethical review.

Ethical review committees

The Central University Research Ethics Committee (CUREC), which reports to Research and Innovation Committee, has overall responsibility for the University's ethical review process and makes recommendations to Research and Innovation Committee on changes to this policy, its remit as set out in the University's regulations and the composition of its membership and that of its subcommittees.

Research Services

Research Services is responsible for promoting the responsible conduct of research and compliance with regulatory and research funder requirements through information and advice, training, policy development, clinical trials and research governance support. Through its Clinical Trials and Research Governance Team, it facilitates compliance, on an individual and institutional level, with all regulations governing clinical research involving human participants. Through its Research Ethics and Integrity Team, it supports CUREC's three subcommittees (and provides advice to departmental research ethics committees), which consider applications for ethical review and approval by the University, ensuring that applications assessed to be more than minimal risk are considered by the appropriate sub-committee. Research Services' officers work closely with CUREC.

Staff and students

This policy applies to all those involved in research involving human participants or personal data, whether as staff or students. The University expects them to take personal responsibility for familiarising themselves with the policy, with professional frameworks, standards and obligations that apply to their research, with their statutory responsibilities and for keeping such knowledge up-to-date .

Research involving human participants and personal data requires ethical review and must not be undertaken unless and until that review has been sought and approval provided. Research supervisors should assist their students to become familiar with this and other University policies and procedures relevant to the conduct of the student's project, and provide specific advice and guidance.

Sanctions

The University regards any breach of this policy or any breach of the approved terms of a project, as a very serious matter, which may result in disciplinary action, which may include dismissal for staff and expulsion for students. In appropriate circumstances, the Central University Research Ethics Committee subcommittees have the power under the regulations to withhold, suspend or withdraw approval of research, whether as part of disciplinary proceedings or otherwise.

Appeals and complaints

Appeals

Staff or students may appeal the decision of a University ethical review committee to withhold, suspend or withdraw ethical approval of research involving human participants or personal data by contacting the [Chair of the Central University Research Ethics Committee](#).

Complaints

Suspected breaches of this policy should be reported to the [Chair of the Central University Research Ethics Committee](#).

Suspected misconduct in research should be considered and reported as set out in the University's [Academic Integrity in Research: Code of Practice and Procedure](#).

Updated and approved by the Central University Research Ethics Committee: 4 June 2019

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