The University of Oxford

Central University Research Ethics Committee

Research Ethics Policy

Owner and key contact(s)	Owner: CUREC Chair Key contact: Dr Karen Melham, Sponsorship and Ethics Lead, Research Governance, Ethics & Assurance Team
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Approving body/ bodies	Research and Innovation Committee, **RC(22)43**; Central University Research Ethics Committee, **(REM(22)16)**
Related Statutes, Ordinances, Regulations, Policies and Guidance	The University of Oxford's Code of practice and procedure on academic integrity in research Application process Guidance for researchers Integrity and ethics training
Version control	
Current version number	**3.0**
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Date of next review	Trinity Term 2025
Amendment history	

Version No.	Date	Summary of amendments	Author
3.0	TT 2022	Reformatted to structure recommended by the Council Secretariat for University policies; Research Services updated in keeping with its reorganisation; description of non-CUREC research ethics approval mechanisms added.	CUREC/ RGEA
2.1	TT 2019	Clarification of the responsibilities of individual researchers following the revisions to the Concordat to Support Research Integrity and the role of RIC in approving changes to this policy.	CUREC/ REIT

Introduction

The University of Oxford seeks to protect the dignity, rights and welfare of all those involved in research (whether they are participants, third parties, staff or 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 ethics 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.

The aim of this policy is to set out the responsibilities and requirements for ethics review of University of Oxford research.

This policy should be read in conjunction with the University of Oxford's Code of practice and procedure on academic integrity in research and reflects the principles and commitments outlined in the funder-endorsed Concordat to Support Research Integrity.

The University's commitments

Rigour: The University is committed to ensuring that research conducted on University premises or by University staff or students is carried out to high ethical standards.

Respect: The University is committed to ensuring that all research 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.

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.

Education and training: The University is committed to cultivating and sustaining ethical research conduct among staff and students through the provision of training to equip them with the skills to recognise potential risks and by informing of the University's relevant policies and procedures, and the responsibilities of researchers in helping ensure the University meet its obligations under the relevant legislation.

Ethics review process: The University is committed to providing a competent, rigorous and externally-moderated process of ethics 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.

More information about how these commitments are met is provided in **Annex 1**.

Scope and Definitions

This policy applies to all staff and students of the University of Oxford who conduct research (including those with visiting or honorary contracts and students on placements), whether or not the research is conducted on the University's premises or using the University's facilities. Third parties (for example staff of other institutions working with University of Oxford students or on University premises) are expected to adhere to the University's ethical standards of research conduct.

Research is defined in the Concordat to support research integrity as 'a process of investigation leading to new insights, effectively shared…'. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction'. [1]

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[1] https://www.universitiesuk.ac.uk/sites/default/files/field/downloads/2021-08/Updated%20FINAL-the-concordat-to-support-research-integrity.pdf Annex E

This definition of research would not normally include:

- routine audit and evaluation, such as the routine evaluation of teaching;
- the development of teaching and other materials that do not involve original research;
- purely documentary research on sources that are already in the public domain such as historical, literary, and theoretical research. Local laws, policies and good practice relating to archives must be followed.

Responsibilities

All members of the University are individually responsible for ensuring that their work is conducted in accordance with the research commitments[2] set out in the University's Strategic Plan (2018-2024), the Concordat to Support Research Integrity[3], and with all policies that form part of the terms and conditions of employment and study.

Failure to comply with this policy may lead to the failure of assessed work; the suspension of study, research projects, and/ or funding from research sponsors; or to the inability to publish. Work conducted in deliberate contravention of the decisions of an ethics review committee, or with deliberate disregard for the ethics review process, would not be covered by the University's indemnity arrangements.

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

The Research and Innovation Committee is responsible for University policies that promote responsible conduct of research and for meeting relevant regulatory requirements[4].

Research Ethics Committees

The Central University Research Ethics Committee (CUREC) has overall responsibility for the University's ethics review process. CUREC reports to Research and Innovation Committee and recommends 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.

CUREC's subcommittees are responsible for the review of researchers' applications for ethics approval where these do not require ethics review by external committees such as, for example, the NHS Research Ethics Service.

- MS IDREC (Medical Sciences Interdivisional Research Ethics Committee)
- OxTREC (Oxford Tropical Research Ethics Committee)
- SSH IDREC (Social Sciences and Humanities Interdivisional Research Ethics Committee)
- DRECs (Departmental Research Ethics Committees) have delegated authority from the SSH IDREC

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[2] https://www.ox.ac.uk/about/organisation/strategic-plan-2018-23/research

[3] https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity

[4] https://governance.admin.ox.ac.uk/legislation/part-6-research-and-innovation-committee

Pro-Vice-Chancellor (Research)

The Pro-Vice-Chancellor (Research) is appointed by Council to provide leadership in all matters relating to research and works closely with Oxford colleagues to create an environment conducive to world leading applied and curiosity-driven research. 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 and compliance issues of wider concern to the University.

Heads of Academic Division

The Heads of Division are responsible to the Vice-Chancellor for the management and academic leadership of their Division, including taking forward research policies.

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, are responsible for promoting 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 oversight of departmental research activity, including endorsement of applications submitted to one of the Central University Research Ethics Committee (CUREC)'s subcommittees for ethics review.

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, and research governance support. Through its Research Governance, Ethics and Assurance (RGEA) team, it facilitates compliance, on an individual and institutional level, with all regulations governing research involving human participants, human samples, and personal data. RGEA provides advice, guidance and training in this respect, as well as research governance oversight. It also supports the work of CUREC and its subcommittees. The Managers of the CUREC subcommittees have delegated authority to review and approve research with relatively straightforward ethical issues. The Manager of the SSH IDREC is responsible for managing the network of Departmental Research Ethics Committees.
RGEA also acts as sponsor representative for clinical research subject to the UK Policy Framework for Health and Social Care Research 2017[5], and where there is a requirement for review by NHS Research Ethics Committee.[6]

Staff and Students

The University expects all those involved in research involving human participants, personal data and /or regulated material and procedures, whether as staff or students, to take personal responsibility for familiarising themselves with the policies, professional

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[5] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research

[6] https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/GAfREC_Final_v2.1_July_2021_Final.pdf

frameworks, standards, obligations, and relevant legislation that apply to their research, and for keeping such knowledge current.

Research supervisors should assist their students in becoming familiar with this and other University policies and procedures relevant to the conduct of the student's project, and provide, or direct the student to, specific advice, training, and guidance.

Implementation

The University requires all its staff and students to observe the highest standards of ethics and integrity in the conduct of their research as set out in its [Code of practice and procedure on academic integrity in research](#),[7] including engaging in research ethics review, as appropriate.

The following research must be reviewed through the appropriate research ethics committee and formally approved before it is conducted:

- research involving living human participants;
- research involving the personal data of living human participants;
- research involving human samples;
- research requiring approval or authority from other bodies.

Information about the University of Oxford's research ethics committee application process is available on the Research Support [website](#)[8].

If there is uncertainty as to whether activity requires research ethics review, researchers are advised to contact a member of the Research Governance, Ethics and Assurance Team for advice before the research is undertaken.

Information about the process for University sponsorship of clinical and other research required to be reviewed by the NHS Research Ethics Service is available on the Research Support [website](#)[9].

Activity that may raise other significant ethical issues or pose a reputational risk to researchers or the University of Oxford and is not reviewed by another regulatory body may be referred for advice and/ or review by a subcommittee of CUREC, for example if there are ethical issues other than the involvement of human participants or personal data.

Where ethics approval is required but the University of Oxford is not the lead institution, the researchers from the University of Oxford must provide the relevant CUREC subcommittee with details of the ethics application, including all documents, the ethics application form that was submitted to the lead institution, and their approval notice. This will be reviewed to ensure that the approval already obtained is in accordance with the requirements of the University's Research Ethics Policy[10].

The University regards as a very serious matter any breach of this policy or any breach of the approved terms of a project. These 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 has the power under the regulations to withhold, suspend or withdraw approval of research, whether as part of disciplinary

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[7] https://hr.admin.ox.ac.uk/academic-integrity-in-research

[8] https://researchsupport.admin.ox.ac.uk/governance/ethics

[9] https://researchsupport.admin.ox.ac.uk/clinical-trials-research-governance

[10] https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/faqs#collapse3147431

proceedings or otherwise. Similarly, the sponsor representative may withhold, suspend or withdraw sponsorship of research subject to the UK Policy Framework for Health and Social Care Research.

Appeals

A procedure[11] is available for appealing a decision to withhold, suspend or withdraw approval of research.

Complaints

The Procedure for handling complaints received by CUREC and its subcommittees[12] explains the process for dealing with complaints made about research approved by one of the subcommittees of the Central University Research Ethics Committee (CUREC), and complaints made about a CUREC subcommittee.

University Core Standard Operating Procedure 9[13] explains the process for managing complaints arising from clinical research.

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[14].

Public Sector Equality Duty

As a public body, the University has an active duty to consider the impact on equality in all decision making.

Negative Equality impact

It is considered unlikely that this item will have a negative equality impact by creating or contributing to a risk of discrimination, harassment, victimisation or other prohibited conduct.

Positive Equality impact

This item could have positive impact on equality by eliminating unlawful discrimination, harassment or victimisation, advancing quality of opportunity between people who share protected characteristics and those who do not, fostering good relations between people who share a protected characteristic and those who do not.

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[11] https://researchsupport.admin.ox.ac.uk/governance/ethics/apply

[12] https://researchsupport.admin.ox.ac.uk/files/curecsubcommitteecomplaintsprocedurepdf

[13] https://researchsupport.admin.ox.ac.uk/files/universitycoresop9managingcomplaintsarisingfromclinicalresearchpdf

[14] https://hr.admin.ox.ac.uk/academic-integrity-in-research

Annex 1: The University's commitments

General

The University of Oxford is committed to ensuring that its research activities involving human participants, personal data, and /or regulated material and procedures 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 ethics review and approval of such research; understand the reasons for, and participate fully in, the ethics 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 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 demonstrates accountability and quality;
- setting appropriate standards for the conduct of research that are in line with current legislation and best practice;
- identifying and reviewing, proportionately to the level of risk, all research involving human participants, personal data, and / or regulated material and procedures, 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;
- ensuring that research complies with current legislative requirements; and
- promoting research transparency through: encouraging registration of research, expecting researchers to seek to publish their results in accordance with current best practice and funders' terms and conditions[15] and by expecting researchers to be as transparent as possible when sharing research findings with others, e.g. making it clear whether the findings have been peer reviewed.

Respect

The University is committed to ensuring that all research 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:

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[15] https://researchsupport.admin.ox.ac.uk/governance/integrity/publication

- 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 expected 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 and burdens (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
- safeguarding the confidentiality of information provided by participants and, where appropriate, 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:

- facilitating and participating in examination of issues that research may raise for society;
- working closely with relevant peer groups and government agencies to remain abreast of developments and contribute to UK policy and standards of good practice; and
- maintaining open and transparent procedures relating to the conduct and review of research.

Education and training

The University is committed to cultivating and sustaining ethical research conduct among staff and students through the provision of training to equip them with the skills to recognise potential risks and by informing of the University's relevant policies and procedures, and the responsibilities of researchers in helping ensure 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, personal data, and / or regulated material, and for those responsible for ethics review of such research, so that knowledge and skills are current; and
- fostering an environment of openness and integrity that encourages collaboration and early communication of potential risks or issues.

Ethics review process

The University is committed to providing a competent, rigorous and externally-moderated process of ethics 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:

- distinguishing research that requires external review, such as by the Health Research Authority and separating out low-risk research for 'light-touch' expedited review from those research projects requiring further scrutiny by committee, and providing researchers guidance and support through the relevant review process;
- appointing to its ethics 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 ethics review process, including the composition of its review committees.