The University of Oxford

Central University Research Ethics Committee (CUREC)

Research Ethics Policy

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Related Statutes, Ordinances, Regulations, Policies and Guidance	The University of Oxford's Code of practice and procedure on academic integrity in research University Research Ethics Guidance Website Integrity and ethics training
Version control	
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Amendment history

Version No.	Date	Summary of amendments	**Author**
4.0	HT 2026	- Introduction of section and page numbering. - Clarified scope, including who eligible for submitting an application for review and focus on ethics review. - Removal of reassertion of responsibilities under the Concordat to Support Research Integrity - Inclusion of core ethical principles in line with global standards to be upheld in human research. - Inclusion of section on Informed Consent - Inclusion of certain high-level research ethics considerations in Social, Biomedical and International proposals, noting that researchers should observe all of the relevant considerations to their given work. - Additional provision for agreements with external ethics committees to perform primary ethics reviews. - Addition of signposting to AWERB - Revision of Responsibilities and Implementation sections - Integration of Worktribe online ethics review platform and related revised processes - Strengthening section on consequences of breach of this policy and ethics in general – signposting to research misconduct	CUREC/ RGEA

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/ Research Ethics and Integrity Team (REIT)

1.0 Introduction

The University of Oxford ('the University'), conducts research across a breadth of academic disciplines, often interdisciplinary in nature, striving to generate new knowledge, address real-world challenges and to advance the public good. The University also aims to identify new areas of study and research for development and enhancement, responding to contemporary developments in both the intellectual and social environment. The University is committed to ensuring research is conducted responsibly to the highest standards of research integrity, in accordance with recognised national and international principles of research ethics, including the protection of human dignity, rights and welfare of participants, communities, staff, students, third parties and other stakeholders.

The University achieves this by:

1.1 Providing an infrastructure to support researchers in meeting their responsibilities under ethical, legal, regulatory and professional frameworks, including statutory authorities, funders and international collaborators.

1.2 Operating a proportionate, risk-based ethics review system that ensures that research is scrutinised at a level appropriate to potential foreseeable risks.

1.3 Fostering a culture of research excellence that embraces the University's commitments to integrity, transparency and accountability.

1.4 Ensuring that all our research is subject to ongoing, active, and appropriate consideration of ethical issues

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

University staff and students are expected to read this policy in conjunction with the University of Oxford's Code of practice and procedure on academic integrity in research and with the UK Committee on Research Integrity's (UKCORI) Concordat to Support Research Integrity. Researchers should recognise their responsibility to seek training, advice and guidance *proactively* to ensure ethical and compliant conduct in all aspects of their research activity.

2.0 Scope

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), regardless of whether 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, collaborating on research or on University premises) are expected to adhere to the University's ethical standards of research conduct.

Research (and development) is defined in the Frascati Manual[1] 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." This includes basic research, applied research and experimental development.

This policy does not apply to:

- activities that do not fall under the above definition of research, including:
  - *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 records and sources that are already in the public domain such as historical, literary, and theoretical research. Noting local laws, policies and good practice relating to archives must be followed;
  - activities undertaken to inform business and operational matters within the University or its service providers.

2.1 Please also note that researchers and departments are responsible for managing their research data appropriately, and in accordance with University of Oxford Research Data Policy[2]. Researchers must ensure that their proposal has been planned in alignment with the current data policies *before* submission for ethics review. This policy does not seek to replace any provision in the University's Research Data policy. Ethics review will focus primarily on *ethics* issues and not specific data management arrangements; unless these arrangements clearly impact the ethics of the proposed research (e.g. relevant data arrangements are not transparently or appropriately communicated in participant facing materials)

2.2 The University ethics subcommittees provide *ethics* review and *ethics* oversight for research conducted under this University's auspices. They do not normally review and/or offer opinions on research led by external organisations where University staff or students may be performing limited or specific sub-awarded or contracted tasks for research developed by another University, non-governmental organisation, private company, spin-out organisation, or other HEI.

3.0 Core Ethical Principles

All research conducted under the auspices of the University involving humans, their data, modification of their lived environments, or human tissue must align with the following core ethical principles. These have been compiled from the Belmont Report (National Commission, 1979), The Declaration of Helsinki (WMA, 2024), and the work of Beauchamp & Childress (2019). The below principles must be considered and adhered to regardless of the CUREC subcommittee the applicant will be applying to.

3.1 **Respect for Participants** – Ensuring a voluntary, informed, and comprehensible consent process; respecting the participant's autonomy and right to withdraw from the research without penalty; and providing appropriate additional safeguards for vulnerable participants.

3.2 **Minimising Harm (Non-Maleficence)** – Taking careful consideration to minimise risks of harm, including physical, psychological, social, reputational and/or digital harms.

3.3 **Maximising Benefits (Beneficence)** – Maximising the benefits of research and its contribution to knowledge, health and social welfare. This includes considering the utility of research, in that researchers must aim to balance benefits and drawbacks to produce the best overall results.

[1] Frascati Manual 2015: Guidelines for collecting and reporting data on research and experimental development

[2] University of Oxford Research Data Policy

3.4 **Fairness and inclusion (Justice)** – Ensuring equitable inclusion and fair distribution of research burdens and benefits, avoiding exploitation of individuals and/or communities.

3.5 **Scientific and Social Value** – Research must have clear aims, valid methods, the potential for discovery, and societal or cultural benefit.

3.6 **Transparency and Accountability** – Committing to Openness in design, conduct, reporting, public-facing registration of research (where required), and clear management of actual or potential conflicts of interest.

3.7 **Independent Ethics Review and Oversight** – A commitment to subject human research proposals to risk-proportionate review under processes and oversight of appropriate independent ethics committee(s). This includes submission to university ethics subcommittees, appropriate UK national and/or other in-country/local ethics committees as appropriate.

These principles are further supported and/or informed by sector standards including the Concordat to Support Research Integrity (UKCORI, 2025), UKRIO guidance (UK Research Integrity Office, 2023), and Governance arrangements for Research Ethics Committees (GAfREC, Health Research Authority, 2021).

4.0 Specific Ethics Considerations

Expanding the core principles listed above, below are related relevant ethical concepts, considerations and norms that are generally expected to be followed for specific research activities. In practice, research that spans across research areas, (i.e., multi-disciplinary research) should ensure familiarity with all applicable considerations below and ensure appropriate ethics-related protections are in place.

4.1 Informed Consent

4.1.1 Participants (or their recognised representatives) must benefit from a well-designed consent process, responsive to any limitations and level of understanding, which allows them to ask questions, deliberate and exercise free choice to participate or not participate in the research, having been made aware of foreseeable risks and benefits of taking part.

4.1.2 Researchers need to take care to ensure the informed consent/assent process is voluntary, comprehensible to potential participants and treated as an *ongoing process* (not a one-time transaction). Consent documents and processes must be designed to be clear, concise and appropriately adaptive (e.g., via multimedia, using comprehension checks, or appropriately documented verbal consent where written consent is impracticable), consistent with a risk-proportionate approach.

4.1.3 Consent documents (and/or other media) must be updated, and re-consent must be sought (after amendment/modification) if, and when, the risk-profile of research notably changes for a given participant. The participant should be made aware of any relevant new information related to their ongoing participation as soon as possible.

4.1.4 When involving people who cannot legally consent, but can express a view (e.g., most children or some adults with impaired capacity), effort should be made to obtain their voluntary assent in addition to consent from a parent or recognised/legally authorised representative.

4.1.5 Ethnographic and participant-observation research must rely on negotiated and iterative consent. Covert or deceptive methods are permissible only with compelling

justification, proportionate risk-benefit rationale, and after robust Research Ethics Committee (REC) favorable opinion (ASA, 2021; BSA, 2021).

4.2 Social and Human Considerations in Research

Research involving human participants and/or their data may encounter complex social, cultural and personal circumstances. The considerations below further support the Core Ethical Principles above (Section 3.0) and provide high-level considerations which may be relevant while planning and conducting research across various disciplines, including the social sciences, humanities, biomedical, clinical and overseas research.

4.2.1 Abide by the University's code of practice on Academic integrity in research and other ethical and professional standards[3] relevant to their work. All researchers, including students, are expected to act with integrity, honesty, respect and care in their dealings with participants, communities, collaborators and data. They must treat participant's rights, dignity, welfare and safety as central to their decision-making, not as secondary to personal, scientific, educational or institutional goals.

4.2.2 In all research, non-physical harms such as reputational damage, social stigma, employment risks, or digital harassment must be considered alongside physical and psychological harms. Researchers must design safeguards accordingly.

4.2.3 Research involving children and other minors in schools, youth groups or similar settings must address inherent power asymmetries, prioritise safeguarding and ensure that access is approved by the host organisation, and that participation is genuinely voluntary and informed. Consent procedures, including the use of opt-in or (for low-risk studies) opt-out arrangements, should be proportionate to risk and sensitivity and compliant with local applicable norms, institutional and legal requirements. Recruitment methods of minors in these settings, including online approaches, similarly must not bypass parents or guardians and must use age-appropriate, inclusive and trauma-informed[4] materials (BERA, 2024; NSPCC, 2022; ERIC, 2013).

4.2.4 When conducting internet and digital research, researchers must assess participants' reasonable expectations of privacy and potential for harm. Use of direct quotes, screenshots, or identifiers from online sources must be justified, and anonymisation, paraphrase, or aggregation should be applied by default (AoIR, 2019).

4.2.5 Where research relies on archival, historical, or documentary sources, researchers must comply with access conditions, donor or deposit agreements, copyrights/licences, and citation norms set by the holding archive or repository.

4.2.6 Personal data of deceased persons is not covered by UK data protection law; however, consideration of confidentiality, cultural respect, and avoidance of foreseeable harm to living relatives or communities still must be reasonable. Researchers should consider whether disclosure could reasonably cause distress, stigma, or risk to others.

4.2.7 When foreseeable, researchers must also consider and control for risks of inadvertent self-incrimination or self-compromise (sometimes described as

[3] Some discipline-specific codes of practice include but are not limited to: the Academy of Social Sciences (2023), British Psychological Society (2021), British Educational Research Association (2024), British Sociological Association (2021), Association of Social Anthropologists (2021), Association of Internet Researchers (AoIR, 2019), Social Research Association (2021), and resources such as ERIC (2013) and NSPCC (2022).

[4] "Trauma-informed materials" are participant-facing documents and communications that are written to minimise the risk of distress or re-traumatisation, give clear warnings and choices, use non-judgmental language, and signpost appropriate support, recognising that some children and young people may have prior experiences of harm or adversity.

researcher endangerment or accidental self-disclosure). In qualitative or ethnographic contexts, researchers should be careful not to unintentionally reveal sensitive personal information, political positions, past crimes or affiliations that could compromise their safety, impartiality, or the integrity of the research.

4.3 Additional Considerations in Biomedical Research

Research involving biological or medical investigations should, in addition to the considerations above, take special care to align their research with these considerations:

4.3.1 Appropriate efforts should be made to promote equity in research participants from groups in biomedical research. For example, including people from groups who may be under-represented in biomedical/clinical research whenever feasible, especially when findings will likely directly apply to members of those groups.

4.3.2 Researchers must ensure participant safety through careful design and monitoring, maintaining a favourable balance between potential risks and expected benefits.

4.3.3 Substantial protocol amendments/modifications affecting participants must be reviewed and approved following the responsible committee's standing orders before implementation, **except** where Urgent Safety Measures are required to safeguard participants - when prompt notification will suffice, where the priority must be to protect the wellbeing of the participant(s). (see Section 7.2 for more on management of non-substantial amendments)

4.3.4 Serious adverse events (unless exceptions in the protocol), protocol violations, or emerging safety concerns must be reported promptly to the approving ethics committee(s) and other applicable oversight bodies.

4.3.5 Identifiable health-related data is often, by its nature, highly sensitive. Careful consideration of data minimisation is needed (only gathering the data required for the research at hand). Researcher access to, processing, and security of this data should be carefully considered and safeguarded in the research at each stage.

4.3.6 There are important ethical and regulatory frameworks for collecting and/or using stored human tissue. Researchers working with human tissue in the UK must be appropriately trained and familiar with their legal responsibilities when it comes to the Human Tissue Act 2004 (UK Public General Act, 2004 c. 30). Researchers should refer to, and abide by, the relevant guidance available on the University's intranet on Human Tissue Governance.

4.4 Additional Considerations in International Research

Studies where participants residing outside of the UK are involved are considered Overseas/International Research. These studies may include Clinical Trials, research funded by US NIH/other US federal funding agencies, as well other biomedical or Social Sciences and Humanities research taking place in whole or in part overseas. Researchers aiming to conduct such research should consider all the relevant principles above as well as align their research with the following:

4.4.1 Research taking place overseas must comply with **both** Oxford/UK ethical standards and host-country requirements. When differences arise, the consideration to provide a favourable opinion must carefully consider local context and alignment with our core principles (Section 3.0).

4.4.2 Researchers must aim to work in true collaboration with the studied communities and participants – respecting local context. To provide appropriate protections for vulnerable populations in low-resource settings, emphasising fairness, respect, care, honesty and avoidance of conducting research abroad that would not be permitted in the UK and exploits the local setting. This includes, for example, neglecting pragmatic safety measures or standards, bypassing or eroding informed consent protections, or performing high-risk studies in settings where participants may have reduced capacity to refuse participation without transparent justification and appropriate mitigatory steps.

4.4.3 Interventional, health-related clinical studies (e.g., Clinical Trials) ideally should be prospectively registered in a publicly accessible trial registry before enrolment of the first participant.

4.4.4 Where called-for and feasible, proposals must set out suitable plans for appropriate community engagement.

4.4.5 Where feasible, proposals must consider post-study access to research findings and/or beneficial interventions and feedback of results to participants and host communities.

4.4.6 All overseas research involving humans, their tissue, data, and/or modification of their lived environments, must receive favorable opinion from both the relevant CUREC subcommittee **and** an acceptable in-country local Research Ethics Committee – in multi-country studies additional favorable opinions must be obtained from relevant RECs in each country at minimum.

The following cases are excepted:

4.4.6.1 Where no such acceptable local review body exists the relevant CUREC subcommittee may issue a favourable opinion alone, but the committee must be clearly informed of the absence of local review to factor this into their deliberations and consider if additional safeguards are proportionate to this risk.

4.4.6.2 Where the local country, region or facility has an experienced, robust and comparable Research Ethics Committee (REC) or Institutional Review Board (IRB). The relevant CUREC subcommittee may put in place a process to assess and acknowledge the appropriate local ethics review body as meeting an acceptable review standard for the proposed research and, at their discretion, accept the ethics review from the local review body as sufficient; this arrangement must be clearly documented. The relevant CUREC subcommittee must retain accountability to CUREC and maintain the right to be promptly informed of serious ethical concerns, protocol violations and/or serious breaches at minimum, and reserve the right to withdraw favourable opinion/support from research studies if deemed appropriate by the subcommittee chair, and inform the Research Governance, Ethics and Assurance (RGEA) team.

4.4.7 Any serious adverse events not precluded in the approved protocol, protocol violations, serious breaches or significant ethical concerns arising in overseas research must be reported promptly to the approving committee, the relevant local ethics committees/authorities and the Sponsor (where appropriate).

4.4.8 For Clinical Trials of Investigational Medicinal Products (CTIMPs) the University expects the current version of the ICH-GCP Guidelines to be understood and

practised by research teams in conjunction with any in-country guidance and in line with all relevant statutory and regulatory requirements in-country.

4.4.9 In emergency situations, where consent cannot be obtained prior to research participation, consent should be obtained from the participant or their legally acceptable representative as soon as possible in accordance with the applicable regulatory requirements and processes approved by the REC.

5.0 Animal Research

Research involving animals must comply with the University's current Policy on the Use of Animals in Scientific Research. All such research must be guided by the 3Rs principle: Replacement (using alternatives to animals wherever possible), Reduction (minimising the number of animals used), and Refinement (enhancing animal welfare). Oversight and ethics review are provided by the Animal Welfare and Ethical Review Body (AWERB), which has statutory responsibilities under the Animals [Scientific Procedures] Act 1986.

Opinion on animal research is *not adjudicated* by CUREC or our subcommittees. Applicants whose proposed research involves both humans and animals must seek both human and animal (AWERB) ethics opinion and must follow all statutory and regulatory provisions.

6.0 Responsibilities

All members of the University's research community are individually responsible for ensuring that their work is conducted in accordance with the Concordat to Support Research Integrity and continuous compliance with all policies that form part of the terms and conditions of employment and study.

Failure to comply with this policy may lead to serious consequences including, but not limited to, failure of assessed work; the premature suspension or termination of research, and/or funding from research sponsors/funders; deletion of data/records collected without a favourable ethics opinion letter (ethics approval) and/or the inability to publish or otherwise present findings.

Work conducted in deliberate/known contravention of the decisions of an ethics review committee (aside from Urgent Safety Measures) or with deliberate disregard for the ethics review process, or in breach of regulatory requirements, would not be covered by the University's indemnity arrangements and may be subject to research misconduct investigation, which could result in further consequences. (See section 7.7 below)

6.1 Registrar

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

6.2 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. The RIC Committee also approve the annual report of the Central University Research Ethics Committee (CUREC) and changes to the University's policies and procedures on research involving human participants and personal data as recommended to the committee by CUREC; they make

appointments to CUREC and CUREC's sub-committees as set out in Part 13 of Council Regulations 15 of 2002.

6.3 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.

6.4 Heads of Academic Division

The Heads of Division are accountable 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.

6.5 CUREC and University Research Ethics Subcommittees

Under Council Regulations 15 of 2002, Part 13: The Central University Research Ethics Committee (CUREC) is accountable for developing, promoting, periodically reviewing and implementing the University's policies on research involving human participants, including establishing and maintaining procedures for consideration and ethics approval of research involving human participants or personal data. This function is in service of the University's requirement that all such research shall be subject to ethics review [Section 1.4 (1-2)].

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 has the responsibility for satisfying itself that the University meets the required ethical standards through appropriate review and oversight, and provision of advice, training and guidance, via its subcommittees.

CUREC's subcommittees are responsible for arranging or performing the independent committee-based reviews of researchers' applications where these applications do not require statutory ethics review by external committees such as, for example, the NHS Research Ethics Service or the Ministry of Defence Research Ethics Committee (MoDREC).

CUREC subcommittees are responsible for maintaining suitable levels of review expertise, review capacity and engagement to ensure ethics reviews are performed expertly, robustly and in a timely fashion to permit research to proceed without undue delay. The designated subcommittees and technical advisory panel are as follows:

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

6.6 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 accountable 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. When concerns are raised in regard to non-compliance with this policy, or poor ethical standards have been identified, the Heads of Department have a responsibility to engage with responsible persons within the University to ensure the matter is resolved satisfactorily, transparently and without bias.

6.7 Research Governance, Ethics and Assurance (RGEA), 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.

RGEA advises CUREC on best practices for ethics governance of human research at the University. The RGEA team includes staff who act as the ethics secretariat, they coordinate and support CUREC subcommittee business and provide direct support and training to researchers and reviewers on the application of this ethics policy and use of the related application system (Worktribe), they facilitate risk-proportionate ethics reviews and provide favourable opinion letters as required.

RGEA maintains version-controlled templates, Approved Procedures, Best Practice Guidance and other supportive documents, which may be updated and shared to support researchers, plus the Research Governance and Ethics FAQ page on the Intranet. The RGEA ethics secretariat may also provide quality control and crosschecking on ethics operations on behalf of the University and the subcommittees.

RGEA may collect and present operational data and periodic reports on the University ethics function as required to RS and/or CUREC to support their oversight and a robust research ecosystem.

6.8 Staff and Students

The University expects all those involved in research involving human participants (directly or indirectly), their personal data and/or tissue, whether as staff or students, to take personal responsibility for familiarising themselves with the policies, professional 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 research, and provide, or direct the student to, specific advice, training, and guidance.

7.0 Implementation

7.1 Applications

The University requires all 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, including engaging in research ethics review, as appropriate. (See section 1. c. of the Academic Integrity in Research Policy[5])

The following research must be submitted to, and a favourable opinion obtained from, an ethics committee before research is conducted:

- research involving living human participants;
- research involving the personal data of living human participants;
- research involving modification of human's lived environments
- research involving human tissue;
- research requiring approval or authority from other bodies.

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 University's intranet.

The University's online ethics application system (Worktribe ethics) supports the preparation, submission and review of applications to the CUREC subcommittees. More information on the University's Research Ethics Committee application process, user guides and video training can be accessed via the Online Ethics Application System page on the intranet. If there is uncertainty as to whether activity requires research ethics review, or which ethics review process should be followed, researchers are advised to contact the Research Governance, Ethics and Assurance team for advice when developing their proposal.

Once a completed application is received via Worktribe, administrative checks are performed within the RGEA Ethics Secretariat to ensure completeness and acceptable levels of quality. On satisfactory completion of administrative checks, the application will be sent for review by the relevant subcommittee in line with their standing orders. Comments and revisions are made until the application is viewed as favourable by the subcommittee, and a letter is issued to this effect.

Where favourable ethics opinion is required but the University of Oxford is not the lead institution, the Department should ensure their researcher can demonstrate that the research has an appropriate favourable ethics opinion letter from the lead institution before undertaking the research.

7.2 Amendments/Modifications

During the research life cycle, changes may need to be made to the study after receiving ethics committee favourable opinion (e.g. revised study design, protocol, third party involvement, participant-facing materials, etc.). These changes may be due to operational, scientific or new safety considerations and are referred to as amendments or modifications. A *substantial* amendment/modification is any change that materially impacts the risks, burdens, benefits, consent process, participant population, research procedures or the scientific validity of the research.

Amendments/modifications must be submitted for review by the relevant ethics committee prior to implementation. The level of review of the amendment/modification will be contingent on the complexity and impact of the proposed changes to the research participants and the integrity of the data.

No substantial changes can be implemented as approved research, without further review and favourable opinion of the relevant committee, except for Urgent Safety Measures required to protect participants health or wellbeing in the immediacy (see section 4.3.3 above).

[5] Academic Integrity in Research Policy

Non-substantial amendments/modifications (minor amendments) must also be submitted to the relevant committee and, in the case of CUREC sub-committees, will be processed in line with the relevant subcommittee's standing orders.

7.3 Appeals

A procedure[6] is available for appealing a decision made by the CUREC sub-committees to withhold, suspend or withdraw favourable opinion of research.

7.4 Complaints

If a research participant wishes to complain they should be free to do so, information about how to do this should be provided and be readily available on the Participant Information Sheet. In the first instance, the complainant should be advised to contact the Principal Investigator (PI) or Research Supervisor. If the PI or supervisor cannot resolve the complaint, the complainant does not wish to speak with the PI or researcher, or the participant remains unhappy and wishes to lodge a formal complaint they may do so.

CUREC maintains a procedure for confidential handling of complaints received by CUREC and its subcommittees. This document explains the process for dealing with complaints made about research approved by one of the subcommittees of CUREC, and complaints made about CUREC itself or a subcommittee.

All complaints received by CUREC, its subcommittees and/or the secretariat should be forwarded and/or copied to rgea.complaints@admin.ox.ac.uk who will support the complaint handling process to document and resolve complaints.

7.5 Reporting

The approving university subcommittee, has the discretion to request annual reports, end-of-study reports, or other documentation/information related to the approved research to permit oversight. This reporting will follow a risk-proportionate approach and be defined by the given subcommittee**.**

If research is prematurely stopped/paused/closed for any reason the relevant subcommittee must be informed.

If research is unlikely to complete within the expected end date, this should be reported and an extension sought with a clear justification, via submission of an amendment/modification.

Any study that has passed the end date of the ethics favourable opinion letter and is still actively performing research involving humans and has not been granted an extension, will be deemed in breach of the conditions of the ethics approval, and thus invalidate their indemnity coverage.

7.6 Retrospective reviews of applications and substantive amendments

Retrospective ethics reviews will not be performed by the subcommittees for research already conducted.

Research conducted, or being conducted, without appropriate ethics review or favourable opinion will be considered as a serious breach of ethical conduct (see Section 7.7 below). If this has been identified, staff and students of the University have a responsibility to refer this to RGEA, the relevant Head of Department and/or other appropriate officers of the University. The

[6] CUREC: Appeal Procedure

appropriate ethics committee will be notified, and in consultation with RGEA and other officers of the University, will determine the appropriate procedure to follow.

7.7 Ethics Breaches, Misconduct and Research Stoppage

The University regards as a serious matter any breach of this policy. Failure to follow accepted procedures, legal or ethical requirements (such as those laid out in this policy), or to exercise due care in carrying out responsibilities for avoiding unreasonable harm or risk to humans or the environment is considered research misconduct.

If Research Misconduct is alleged, the case may be referred as set out in the University's Academic Integrity in Research: Code of Practice and Procedure[7]. Formal research misconduct allegations and subsequent investigation may result in serious consequences. The CUREC subcommittees and ethics secretariat will cooperate fully and openly with any such investigation, providing relevant submitted review documentation, communications, etc. as requested.

Additionally, the CUREC subcommittees have the power to withhold, suspend or withdraw ethics favourable opinion of research, whether as part of misconduct investigations, disciplinary proceedings or otherwise.

If suspending research or part of a study is deemed necessary, relevant stakeholders will be informed including the Head of Department and other responsible officers of the University, to ensure a collaborative, pragmatic approach is taken to protect participants and to ensure reporting requirements to stakeholders are met (e.g. to funders and Sponsors).

8.0 Public Sector Equality Duty

As a public body, the University has an active duty to consider the impact on equality in all decision making. In exercising its functions, CUREC and its subcommittees commit to operate within the framework of the Equality Act 2010 and the University's duties under the Public Sector Equality Duty, including the requirement to have due regard to eliminating discrimination, advancing equality of opportunity and fostering good relations.

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

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