

Ethics of Research Policy

Summary

This policy sets out the University's expectations regarding the ethical and regulatory oversight of research involving human participants. It describes the applicable oversight processes for various types of research; the structure of and process for review by University Research Ethics Committees; and the structure and role of the University Ethics of Research Committee.

Control information:	Control detail:
Owner	Pro Vice-Chancellor - Research and Innovation, Senior Team
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Sponsor	Chair of the University Ethics of Research Committee
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Reporting requirements	Concerns relating to health and social care research should be addressed to research-governance@bristol.ac.uk Concerns relating to other human participant research, or other research ethics concerns should be addressed to research-ethics@bristol.ac.uk Concerns or allegations relating to potential Research Misconduct should be addressed to research-misconduct@bristol.ac.uk
Applicable statutory, legal or best practice requirements	Concordat to Support Research Integrity, Higher Education (Freedom of Speech) Act 2024, Human Tissue Act 2004, Medicines for Human Use (Clinical Trials) Regulations 2004, UK Policy Framework for Health & Social Care Research
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Related information	Research involving animals, Official Secrets Act 1989, Public Interest Disclosure Policy, Research involving the NHS, Research Misconduct

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1. Updates to this policy

- 1.1. This policy has been updated to reflect current practices in research ethics and to align to the new University of Bristol policy management framework.
- 1.2. It has been revised and re-ordered, to more clearly present the University's priorities and responsibilities relating to the ethical review of research projects.
- 1.3. The described structures of ethical review and oversight committees has been significantly revised to reflect the recently restructured committees, and to clearly describe the application process.
- 1.4. Required references to the Higher Education (Freedom of Speech) Act 2024 have been included.
- 1.5. The policy has been streamlined by removing obsolete annexes and by reducing overlap with the Research Governance and Integrity Policy.

2. Introduction

- 2.1. The University is concerned to protect the rights, dignity, health, safety and privacy of research participants, the welfare of animals and the integrity of the environment. The University is also concerned to protect the health, safety, rights and academic freedom of researchers and the reputation of the University as a centre for properly conducted, high quality research. This document is written to further those ends, to the extent allowable by the Higher Education (Freedom of Speech) Act 2024, and to comply with the legitimate requirements of outside research funders and collaborators.

3. Scope

- 3.1. The University expects all researchers to consider fully the current and future ethical implications of their work. This policy applies to everyone carrying out research under the auspices of the University, whether their current place of work is within or outside University premises. This includes academics, research staff, persons with honorary and substantive positions, undergraduate students, postgraduate students and anyone else conducting or supporting research under the University's auspices (hereinafter referred to as 'Researchers'). It is the responsibility of the principal investigator of a project to ensure that all researchers

involved in the project (including external & international collaborators) are aware of and comply with the policies of the University.

- 3.2. Research undertaken under the auspices of the University should meet, as a minimum, the ethics standards required by the University, regardless of its place of conduct.

4. Definitions

- 4.1. See [Research Governance Glossary](#).

5. Responsibilities

- 5.1. **Researchers:** Consider the ethical implications of all research that they undertake or are involved in. Understand when Research Ethics Committee review is required and seek review prior to the conduct of any applicable research.
- 5.2. **University Ethics of Research Committee members:** Provide oversight and guidance to the Research Ethics Committees. Drive or support policies and processes that promote high standards of research ethics and integrity. Provide consultation and arbitration as required.
- 5.3. **Research Ethics Committee members:** Review research proposals in accordance with this policy, accepted ethical standards and committee terms of reference.
- 5.4. **Faculty Research Ethics Officers (FREOs):** Ensure the representation of Ethics of Research concerns and processes at a Faculty level. Act as a conduit for information, best practice and concerns between UERC and Faculty and between UERC and School Research Officers within their Faculty.
- 5.5. **School Research Ethics Officers:** Ensure the representation of Ethics of Research concerns and processes at a Faculty level. Provide training and information where required and disseminate policies and best practice - as advised by FREOs. Escalate School level concerns to FREOs.

6. University Ethics of Research Committee

- 6.1. The University Ethics of Research Committee (UERC) is an advisory committee to the Research Committee, the Senate and the Board of Trustees, charged with

sustaining a University-wide awareness of research ethics and integrity issues. The Committee aims to assist faculties with ethical issues in research and in doing so will:

- a. Oversee the administration and oversight of the Research Ethics Committee (REC) review structure, as conducted by Research Governance.
- b. Accept, discuss and advise on concerns or queries raised by review committees.
- c. Put in place procedures to encourage the ethical conduct of research.
- d. Monitor the University's compliance with the Concordat to Support Research Integrity.
- e. Give guidance on research ethics and integrity issues referred from review committees, taking each case on its merits.
- f. Hear appeals on decisions made by review committees and, where appropriate, make recommendations relating to individual cases, and update guidance for review committees and/or researcher, where appropriate.
- g. Report directly to the Vice-Chancellor and Chair of the Board of Trustees any appeals to unfavourable reviews which cannot be resolved to the satisfaction of both the committee and the researcher(s).
- h. Report the proceedings of meetings to the University Research Committee (URC).
- i. Arrange for appropriate training to be provided for University, faculty and school research ethics committee members.

6.2. The members of the Committee are:

- a. The Chair will be a University of Bristol member of staff with experience of human participant research. The position of Chair will confer a seat on the University Research Committee and on Senate.

- b. Two members from each of the Faculties of Arts, Social Sciences and Law, Science & Engineering, and Health and Life Sciences appointed by their Dean and ratified by the University Research Committee (URC).
- c. The Chair of the Animal Welfare and Ethical Review Body (AWERB) (or a delegated member).
- d. The Head of Research Governance.
- e. The Research Ethics and Integrity Manager.
- f. The Head of Legal Services (or delegate).
- g. Any co-opted members as agreed by Senate, including an academic member who sits upon the Board of Trustees.
- h. At least two Independent Members, in line with UKRI best practice on Research Ethics.
- i. One of the Elected Postgraduate Research or Taught Faculty Representatives as agreed upon amongst themselves.

7. Types of research

- 7.1. All research requires consideration of its ethical implications, in the first instance this is the responsibility of researchers undertaking that work, and academic supervisors, in the case of student research.
- 7.2. Research that involves human participants or their data (including anonymised data*) must receive a favourable review from a REC before commencing.
- 7.3. Research that involves any of the following may require review by an NHS REC instead of a University REC:
 - a. The NHS (including GPs)
 - b. Social Care services or facilities
 - c. Human Tissue

d. Healthcare data¹

e. Access to Healthcare Records

- 7.4. It may also require review by the Health Research Authority. Further information can be found here: <https://www.bristol.ac.uk/research-enterprise-innovation/research-governance/ethics/>. Such reviews are managed in accordance with the Research Governance and Integrity Policy: <https://www.bristol.ac.uk/media-library/sites/red/documents/research-governance/research-governance-and-integrity-policy.pdf>
- 7.5. Any research team, school or faculty may propose that their project, which does not meet any of the above requirements, requires an ethical review, for example because there are serious health and safety implications; there is a risk of damage to the environment; the impact of the research may be emotionally damaging; the research is politically or socially sensitive; the nature of a project, partner or source of funding could be a risk to the University's reputation or position as a publicly funded charitable body; or is otherwise highly novel or high-risk.

8. REC applications

- 8.1. All applications for ethical review by a University REC will be made via the Online Research Ethics Management System (OREMS), managed by Research Governance.
- 8.2. Based on initial filter questions – and clarification by Research Governance staff, if necessary – applications will be sorted into one of the following four workstreams:

Workstream 1

- 8.3. All staff and PGR research requiring University REC review, which does not fall under workstreams 3 or 4.

Workstream 2

- 8.4. All undergraduate and PGT research requiring University REC review, which does not fall under workstreams 3 or 4.

¹ Data from a formally established Research Database or biobank, which has current NHS REC approval for the sharing of that data for research purposes is exempt from this requirement.

Workstream 3

- a. Research relating to the Avon Longitudinal Study of Parents and Children (ALSPAC) project, which will be reviewed by the ALSPAC Law and Ethics Committee (ALEC).
- b. Research which, due to the requirements of funders or providers of data, requires review by a US registered Institutional Review Board.
- c. Research involving large, extant data sets.

Workstream 4

- 8.5. Research which requires more extensive, or ongoing ethical oversight. These will be exceptional cases and will have been agreed with Research Governance in advance.

9. REC reviews

Workstream 1 (Staff & PGR)

- 9.1. Applications processed via this route will be reviewed by one of the workstream 1 RECs.
- 9.2. A review committee will be composed of at least six members. This will include a chair, one member who is nominated as a deputy chair, and one Independent Member. Each of the University's three faculties should be represented on each REC. Membership of a postgraduate research student is encouraged. A minimum of 4 members should participate in a Discussion Review. 3 members will be asked to conduct a Virtual Review.
- 9.3. The RECs will meet regularly, on a rotating schedule – calibrated according to observed peaks and troughs in application numbers over time.

Workstream 2 (UG & PGT)

- 9.4. Applications processed via this route will be reviewed by an appropriate School or Faculty REC, composed according to School / Faculty policies.
- 9.5. The REC will meet according to their agreed schedule.

- 9.6. Note: This approach is subject to change and is expected to be replaced with a system analogous to Workstream 1 by the end of the 2026/27 academic year, at the latest.

Workstream 3

- 9.7. Applications processed via this route will be reviewed by ALEC or potentially (for non-ALSPAC projects) another IRB-certified REC.
- 9.8. ALEC / the REC will meet according to their agreed schedule.

Workstreams 1-3

- 9.9. An application will be considered within the scheduled review period by a quorum of the committee (as defined in the appropriate committee's terms of reference, which will include any variances according to the nature of the application) with comments shared in writing via OREMS, or verbally at a remote or in-person meeting.
- 9.10. The committee will return an opinion, via Research Governance, which will be one of the following:
- a. **Favourable opinion:** The committee have no concerns or comments, the project can proceed as planned.
 - b. **Favourable opinion with conditions:** The committee have specific concerns or comments which must be addressed prior to the project commencing. The nature and cause of these concerns, the actions required to address them, and the evidence of actions required prior to the study proceeding will be communicated in the response. The project can proceed, without a further application, once these conditions have been met.
 - c. **Unfavourable opinion:** The committee have broad or significant concerns regarding the proposed project. It must not proceed as currently proposed. The committee will clearly define the nature and cause of their concerns, and suggest remedies where appropriate. If the study is to proceed, it must be revised and a further application submitted.

Workstream 4

- 9.11. For each application processed via this route, a committee will be convened – from a pre-defined pool of experts, in research ethics and other applicable subjects – to meet the particular needs of the project.
- 9.12. Their approach and responsibilities will be defined per project but will include, at a minimum, the review process described for workstreams 1-3.

Amendments

- 9.13. If, during the conduct of a study, there is a need to vary the procedures or intent of the project, such that the summary of intent previously reviewed by the REC is no longer reflective of intended practice, and/or changes are to be made to any participant-facing documents, an amendment application must be submitted via OREMS, and approved in accordance with the relevant terms of reference, prior to those changes being implemented. (In the unlikely situation that changes are required urgently, in order to prevent harm to participants and/or researchers, the researchers should contact research-ethics@bristol.ac.uk, marking the correspondence as 'Urgent', for a rapid assessment.)

External Reviews

- 9.14. Wherever possible, it is preferable that any given study only undergoes a single ethical review. (Note, a study is a discrete set of investigations with a defined protocol. A research project, as may be covered by a single funding arrangement, might involve multiple studies.)
- 9.15. If a study involves multiple academic organisations, REC review should be conducted by the substantive employer of the principal investigator, with the following exceptions:
- 9.16. If a study will involve data collection in a non-UK location, REC review should be conducted by an appropriately constituted local body, where practical. Researchers should check the requirements for ethics review in the country concerned, seeking advice from its Foreign Office if necessary.

- 9.17. In either of the above cases, Research Governance will file copies of the application and REC opinion, these should be made available prior to the conduct of the study.
- 9.18. In either of the above cases, if the preferred review process is not practicable, it may be appropriate instead to submit an application via OREMS, for UoB REC review. This should be discussed with Research Governance.

Appeals

- 9.19. REC decisions may be appealed to the University Ethics of Research Committee. The Committee will not hear appeals until REC level processes and remedies have been exhausted.
- 9.20. Appeals may be made on any grounds, including concerns that decisions have been made on grounds which are not within the purview of the committee or are unlawful.
- 9.21. The Committee will consider the reasonableness and fairness of decisions appealed against.
- 9.22. The Committee will not hear appeals against the decisions of external ethics committees, which should provide their own appeals procedures. However if a favourable opinion is given by an external ethics committee and a concern is raised that this may contravene this policy, then the University Ethics of Research Committee can consider this as an appeal for resolution.
- 9.23. In exceptional circumstances when, for good reason, issues need rapid consideration, the Chair may act after consultation with no fewer than two members of the Committee, one of whom must be a lay member. The Committee shall be informed promptly of decisions made on this basis. If a member of the Committee is not able to attend the meeting, they may submit written observations on any issue under consideration.
- 9.24. Where agreement cannot be reached, decisions are by a majority and in cases of equal votes, the Chair shall have the casting vote.
- 9.25. The Committee and the Chair are empowered to take advice from senior University officers, lawyers, or any person in or outside the University with

specialist knowledge on the issues in question. The Committee shall be permitted to co-opt specialists to advise its members, when required.

10. School / Faculty Research Ethics Officers (SREOs / FREOs)

- 10.1. Each school and faculty shall appoint, according to their own processes (with the support of the Research Ethics and Integrity Manager, if required) a Research Ethics Officer.
- 10.2. This individual will represent the principles of ethical research and the interests of UERC within their school / faculty. It is expected that they will be members of, or routinely invited to, research-related committees and working groups within their school / faculty.
- 10.3. They will provide guidance, training and information relating to research ethics within their school / faculty and will, from time to time, contribute to the development of local and/or university-wide guidance and procedures.
- 10.4. FREOs will routinely meet with the SREOs whose schools are within their faculty; to discuss updated policies and guidance; to provide information about relevant training or events; to elicit questions and concerns – which they may be able to address individually, or which may require escalation to UERC; and to provide a forum for the sharing of experiences and practice.
- 10.5. FREOs will be members of UERC, will routinely attend meetings of the committee and will represent the interests of their faculty and their faculty's SREOs.

11. Official Secrets Act

- 11.1. Where research being undertaken in accordance with the Official Secrets Act would require REC review, as per section 3, this will be conducted by a specially convened REC, comprised of individuals with the appropriate clearance to review such work. An individual will be delegated to report annually to UERC on the number of cases reviewed in this manner and to raise any questions or concerns from the committee members (in a manner which does not breach the requirements of the act).

12. Guidance by the University Ethics of Research Committee

- 12.1. Where particular ethical concerns are referred for advice to the University Ethics of Research Committee, the Committee may request a written statement of the issues, supported by relevant documentation and a summary of the reasons for doubt or disagreement. The Committee may, as it deems appropriate, invite interested parties to attend and make representations and may also seek outside advice. The guidance given shall be recorded in writing and sent to all those involved. Applicants who are applying for project review should not take part in discussions on their applications.