

University of Bristol Ethics of Research Policy and Procedure

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 and to comply with the legitimate requirements of outside research funders and collaborators.

1. Ethics of Research Committee

The Ethics of Research Committee 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:

- ❖ put in place procedures to encourage the ethical conduct of research
- ❖ monitor the University's compliance with the *Concordat to Support Research Integrity*
- ❖ monitor and review faculty procedures
- ❖ give guidance on research ethics and integrity issues referred from faculties, taking each case on its merits
- ❖ hear appeals on decisions made by faculties and, where appropriate, make recommendations to the Research Committee for ratification by the Board of Trustees.
- ❖ report directly to the Vice-Chancellor and Chair of the Board of Trustees if it is of the view that a current or proposed research activity is unethical
- ❖ report the proceedings of meetings to the Research Committee
- ❖ be an overarching committee for all University research ethics committees (see flow diagram at Annex 3)
- ❖ be a point of referral for issues arising through other statutory ethics committees (see flow diagram at Annex 3)
- ❖ arrange for appropriate training to be provided for University, faculty and school research ethics committee members

The members of the Committee are:

- A Pro Vice Chancellor (Chair)
- The Director of Research & Enterprise Development (ex officio)
- Six members appointed by Senate from the Faculties of Arts, Engineering, Life Sciences, Health Sciences, Science and Social Sciences & Law respectively.
- The Registrar and University Secretary (or the deputy Secretary).
- Co-opted members as agreed by Senate.
- Independent lay members
- One of the Elected Postgraduate Research or Taught Faculty Representatives as agreed upon amongst themselves

2. Types of research

All research requires consideration of its ethical implications, however there are some areas of research where the ethical implications will be particularly important. The following is not an exhaustive list, however some examples of such areas of research are: where it involves human participants (particularly children and vulnerable adults); where it uses human data or human material; where there are serious health and safety implications; where animal experiments are involved; where there is a risk of damage to the environment; where the impact of the research may be emotionally damaging; where the research is politically or socially sensitive and where 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.

3. Researchers

The University expects all researchers to consider fully the current and future ethical implications of their work. This procedure 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, but is not limited to, all University staff, visiting researchers, those with honorary posts and registered students. 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.

4. Faculties

Each faculty is required to:

- ❖ draw up guidelines for the ethical conduct of all research undertaken under the auspices of the faculty, appropriate to the academic disciplines within the faculty and in accordance with recommendations made by relevant outside bodies. These guidelines should deal with those issues identified in Annex 1 in an appropriate and proportionate manner that is relevant to the nature of the research conducted by that faculty.
- ❖ ensure that staff and students in the faculty have adequate training in the ethical and appropriate conduct of research
- ❖ ensure that staff and students are aware of health and safety issues and insurance implications
- ❖ establish procedures for handling research ethics issues of all research in the faculty, through faculty or school research ethics committees or, where appropriate, through NHS or other ethics committees outside the University
- ❖ appoint a named member of staff to act as the Faculty Research Ethics Officer
- ❖ through the Faculty Research Ethics Officer, report annually to the University Ethics of Research Committee on research ethics activities and outcomes and procedures within the faculty and their operation
- ❖ refer cases to the University Ethics of Research Committee where necessary

5. Faculty Research Ethics Officers

The faculty research ethics officers shall:

- ❖ ensure that there are effective mechanisms to bring policies, guidelines and procedures to the attention of staff and students in the faculty and offer advice
- ❖ keep faculty ethics issues in research under review
- ❖ keep records of decisions made
- ❖ report as required to the University Ethics of Research Committee

6. Faculty, school or unit research ethics committees

A properly constituted research ethics committee shall have formal terms of reference, membership and standing orders and must have at least six members, including the Faculty Research Ethics Officer and one person from outside the faculty. Membership of a postgraduate research student should be encouraged. Deans shall ensure that at least one properly constituted research ethics committee is in place either at faculty or school level. This committee shall have responsibility for establishing and monitoring procedures for the approval of all appropriate student and staff research proposals in the faculty.

It is suggested that a properly constituted faculty or school research ethics committee might be able to:

- ❖ delegate authority to sub-committees to review research proposals to provide an opinion
- ❖ carry out quality control checks on a proportion of those studies reviewed by sub-committees or individuals
- ❖ confirm that research satisfies ethical requirements
- ❖ require clarification or modification of parts of a research submission
- ❖ authorise significant deviations from any approved research proposal
- ❖ defer consideration of a proposal
- ❖ reject a research proposal as a whole or in part
- ❖ revoke a favourable opinion of research if dissatisfied with the conduct of the research
- ❖ refer students or staff under the University's research misconduct or disciplinary procedures
- ❖ refer to the University Ethics of Research Committee as appropriate

The committee should give reasons for its decisions. The committee might call for reports on the conduct of research during the project and on completion. A monitoring process in line with funder requirements is in place and the committee should review any issues that might arise from the monitoring process. The committee should review significant deviations from a reviewed project proposal. All decisions must be recorded in a transparent and auditable format.

Faculties should ensure that any applicants for project review by a research ethics committee, and in the case of students, their supervisors, should not take part in decisions on their applications.

Where research is being conducted by members of staff or students in more than one faculty in the University, the research need undergo ethics review in only one faculty. Any decision should be communicated by the researcher to all faculties involved. Where research is being conducted by members of staff or students in more than one institution, the research should gain formal ethics approval in one of them. The decision on which is the most appropriate should take into account the location of the principal investigator and the formal ethics review structures in place in each institution. If ethics approval is given by another institution, this does not remove the responsibility of researchers to comply with the University's ethics policy. The Faculty Research Ethics Officer should be kept informed of the outcome of the ethics review.

All staff must comply with national statutory requirements for ethics review by a properly constituted research ethics committee set up in accordance with applicable laws (i.e. under Home Office, Department of Health, international guidelines (e.g. ICH-E6) or Human Tissue Authority regulations) [see annex3]. Any such ethical approval is normally acceptable for University purposes.

Faculties are advised not to repeat any such ethics review, but they may wish to consider additional ethical issues that are specific to the University, as appropriate.

Where research is being undertaken under the Official Secrets Act this does not negate the need for an ethics review. Faculties should consider how they would appropriately review any such work whilst complying with the terms of the Act. Faculty, school or unit research ethics committees may delegate authority to a sub-committee of staff who are also bound by the Act but who have an understanding of the faculty and University ethics policies. A senior member of the University with appropriate security clearance will provide oversight for this process.

Research undertaken under the auspices of the University should meet, as a minimum, the ethics standard required within the University, regardless of its place of conduct. Where data and /or human tissue samples are collected outside the UK, the researcher will normally be expected to have received research ethics approval from a properly constituted and independent ethics committee in the country concerned or the UK, where such a committee exists to review the type of research being proposed, before it can be considered for approval within the faculty. It is the responsibility of the researcher to check the requirements for ethics review in the country concerned or seek advice from its Foreign Office, to make the appropriate applications and to provide evidence of ethics review having been sought and given. If such review is not available or appropriate (for example under certain political regimes or for covert research), then such research and the reasoning for not obtaining local ethics approval must be agreed by the faculty or school research ethics committee.

7. Reports to the University Ethics of Research Committee

In annual reports to the University Ethics of Research Committee, faculties should report on their procedure, activity and any issues of concern. Reports are provided in the form of a presentation by the Faculty Research Ethics Officer to the University Ethics of Research Committee in February of the academic year covering the previous calendar year Annex 2

Two representatives (one lay member and one academic member) of the University Ethics of Research Committee will offer support in an informal visit to faculties where the experience and feed-back of the Faculty Research Ethics Committee can be discussed in detail. The outcome of these visits will be considered at the Committee's final meeting of the academic year.

Other annual reports to the University Ethics of Research Committee are provided by:

- The Research Governance Team (RGT) to enable the Committee to monitor the number and risk of NHS Research Ethics Committee (REC) applications and to provide an update on completed and planned activities that enhance the research ethics and integrity culture.
- The Human Tissue Working Group
- The Animal Welfare and Ethical Review Board

The Committee provides an annual report to Senate and the Board of Trustees as well as reporting on any major items as they arise.

8. Guidance by the University Ethics of Research Committee

Where particular ethical concerns are referred for advice to the University Ethics of Research Committee, the Committee will 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 members of the faculty to attend and make representations and may also seek outside advice. The guidance given shall be recorded in writing and sent to the faculty or school research ethics committee. Applicants who are applying for project review should not take part in decisions on their applications. In situations where Faculty Research Ethics Officers perceive that the University ethics infrastructure is intended to be used for implementation of processes that are not specifically about research ethics, this can be referred to the Committee for discussion.

9. Appeals to the University Ethics of Research Committee

Faculty decisions may be appealed to the University Ethics of Research Committee. The Committee will not hear appeals until faculty level processes and remedies have been exhausted. The Committee will consider the reasonableness and fairness of decisions appealed against. The Committee will not hear appeals against the decisions of external ethics committees, which should provide their own appeals procedures. However if a 'Yes' decision to proceed with research is given by an external ethics committee and this is reported (under the University's Public Interest Disclosure Policy) as contravening this University ethics policy, then the University Ethics of Research Committee can consider this as an appeal for resolution.

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 who are not members of the faculty or faculties concerned, 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, he or she may submit written observations on any issue under consideration. Where agreement cannot be reached, decisions are by a majority and in cases of equal votes, the Chair shall have the casting vote. 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.

Where the faculty does not accept the decision of the University Ethics of Research Committee, the Committee will refer the matter, by means of a written report, through the Research Committee, Senate and the Board of Trustees for final resolution.

Annex 1: Checklist of ethical research issues

The following checklist of some of the areas to consider may be helpful to researchers, faculties, schools and units in drafting their guidelines:

ADHERENCE TO REGULATIONS AND GUIDANCE

- Adherence to the University's Research Governance and Integrity Policy
- Adherence to ethics guidelines of their Faculty
- Strict adherence to legal regulations governing the conduct of research, for example NHS Ethics Committees, the Medicines for Human Use (Clinical Trials) Regulations, Home Office regulations for research involving animals, Human Tissue Act, Animal Act, Health and Safety regulations
- Adherence to discipline-specific codes and guidance and codes and guidance of outside bodies, for example the UK Policy Framework for Health & Social Care Research and Guidelines on Good Research Practice set by funding bodies
- Working in line with the University's responsibility for the Prevent Duty
- Freedom of information issues, under the Freedom of Information Act
- Awareness of the University's policy on Research Misconduct
- Awareness of the University's policy on Public Interest Disclosure
- Include dual use considerations

RESEARCH INVOLVING HUMANS

- Voluntary participation of research participants
- Whether or not incentives are appropriate/ethical to encourage participation including reimbursement of participants in line with MRC guidance
- Full information to participants, including outlining any rights to withdraw, intended publication of the results of the research, information on data use and sharing
- Ensuring appropriately recorded consent, allowing for cultural variations in practice whilst maintaining the central significance of consent of participants or those legally allowed to consent on their behalf.
- Adequate support for, or protection of, participants
- Special issues relating to children and vulnerable adults
- Risk assessment in line with Health and Safety requirements including the potential for harm, stress, anxiety etc.
- Sensitivity of the research (e.g. drug use, cultural sensitivities, mental health etc.)
- Disclosure and Barring Service (DBS).
- Feedback to participants on the research results as appropriate
- Appropriate policy and practice concerning confidentiality, anonymity or acknowledgement of research participants.
- Data Protection compliance, particularly in relation to sensitive personal data
- Anonymisation / pseudonymisation and secure storage of data
- Retention, future use, sharing or disposal of data and samples in line with consent
- Special issues relating to the Prevent Duty requirements

RESEARCH INVOLVING ANIMALS

- Implementation of the 3 R's of research involving animals: Reduction, Replacement and Refinement
- Cost benefit assessment of research involving animals
- Animal welfare
- Health and safety of staff and students

OTHER CONSIDERATIONS

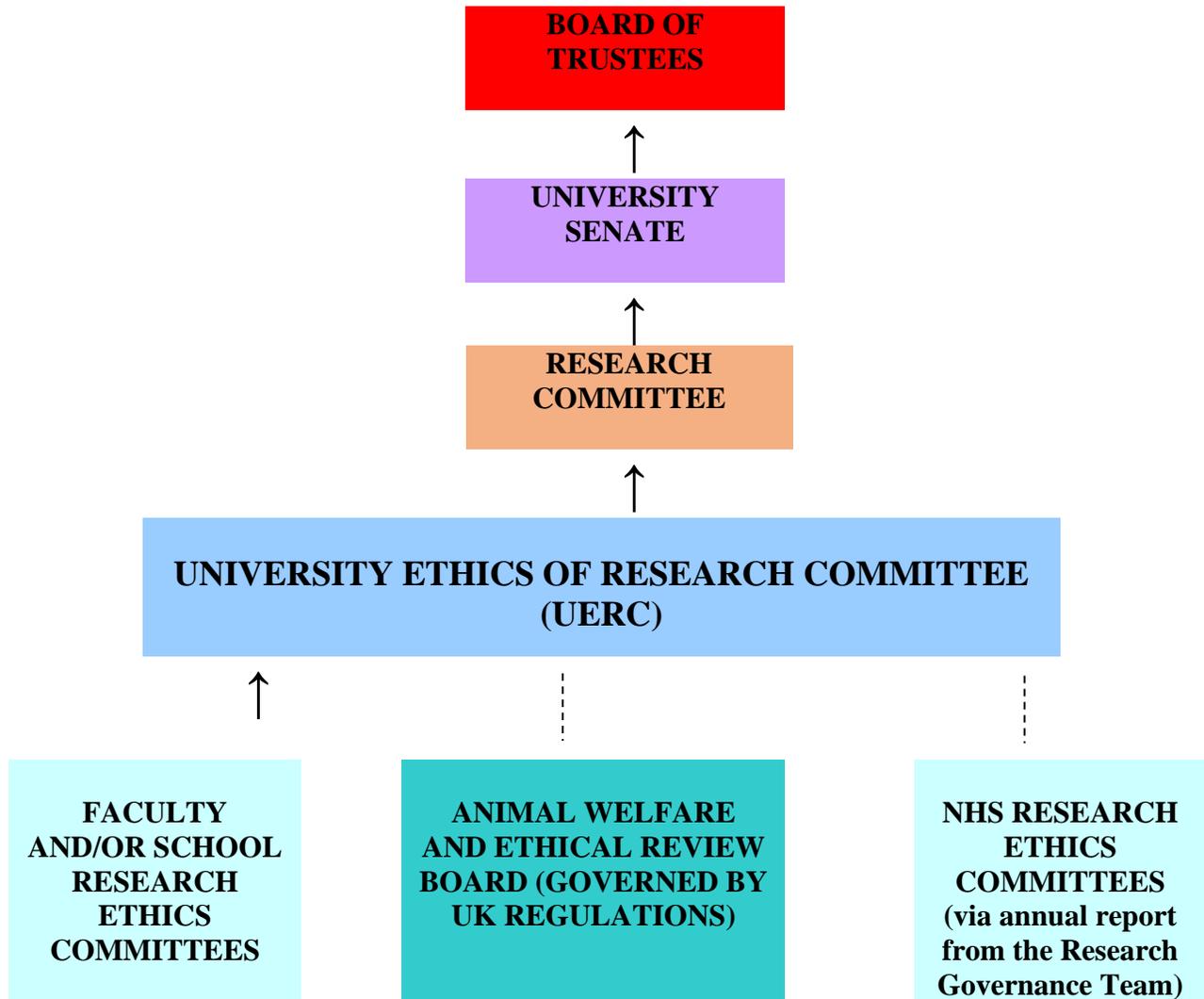
- Conflicts of interest
- Environmental issues
- Conservation issues
- Professional integrity when participating in peer review
- Publication of research results/dissemination of results
- Commercial confidentiality
- Protection and ownership of intellectual property
- Written agreements with collaborators
- Written agreements with sponsors and funders (i.e. these must not dictate research outcomes or excessively restrict publication)
- Insurance cover required
- Indemnities offered
- Risk assessments
- Value for money considerations
- Purchasing arrangements
- Financial management and issues relating to grants
- Cost : benefit analysis
- Training
- Support for students and junior staff
- Visiting researchers, honorary staff and registered students
- Safeguarding against predictable misinterpretation of results

Annex 2: Pro-forma annual report to the University Ethics of Research Committee

Annual Report Presentation Template

1. Please provide a summary of the ethics review process in the Faculty / Schools
2. Please provide a summary of the ethics review activity
3. Please provide any significant issues discussed by the faculty research ethics committee
4. Please provide suggestions that might enhance the ethics review process

Annex 3: University of Bristol Ethics Structure



_____ Reporting line

..... Information line & referral for issues specific to university ethics (UERC can override any ‘yes’ decisions but not ‘no’ decisions of these committees / units)

The Animal Welfare and Ethical Review Board will provide a report to the UERC.

For Home Office regulated research please see:

<http://www.homeoffice.gov.uk/science-research/animal-research/>

Researchers in the University who need advice on Home Office licensing matters should get in touch with the Home Office Liaison Team (HOLT). Members of the team are able to offer guidance on training, completion of license applications, and most other issues. The usual route for contacting members of HOLT is via e-mail to ASU-HOLT@bristol.ac.uk

For the University policy on working with animals, please see:

<http://www.bris.ac.uk/university/governance/policies/animal-policy.html>

For research involving the NHS, participants that might lack capacity to consent and human tissue please see:

<http://www.hra.nhs.uk/>