

BRUNEL UNIVERSITY

CODE OF RESEARCH ETHICS

Brunel University Research Ethics Committee

PREAMBLE

The contents of this document go to the heart of a vital aspect of university endeavour – ethical research in the modern environment. The main purpose of this Code is to achieve a balance between safeguarding the dignity and rights of the research participant and providing a supportive and protective ethical environment within which the university researcher can seek to further the boundaries of human knowledge.

The core themes of *autonomy, non-maleficence, beneficence and justice* as applied to research involving human participants are not, of course, new, and neither are national and international attempts to embed them. What *is* new is an increasing emphasis by the State (via legislation, research governance frameworks and codes of best practice) on accountability and supervision, at all levels and in all relevant institutions, including universities – and it is this requirement that prompts the introduction of the University Code of Research Ethics and the Research Proposal Application Form which accompanies it.

In the drafting of these documents, the University Research Ethics Committee, with membership drawn from all relevant constituencies within Brunel, has been conscious of the need to combine increased accountability with a recognition that research endeavour must be accorded the highest priority and not be compromised and strangled by bureaucracy. Inevitably, some compromise has had to be struck, and there will be those who will cavil against the requirement to complete yet another form and be answerable to an appropriate scrutiny panel. The intention, however, is to safeguard the participant and the researcher (both staff and students) by requiring rigorous and uniform consideration to be given to ethical issues at the proposal stage (hence the form), and during the implementation of the research project (hence the requirement for reporting back).

It will also be noticed that, in terms of procedure, Schools themselves have been accorded considerable freedom as to the method(s) they wish to adopt to ensure conformity with the requirements of the University, and, of course this Code will have varying degrees of relevance depending upon the school and/or research project in question. We do, however, need all schools to ‘own’ the process.

A research ethics culture should already be second nature to experienced researchers, if only because of the increasing number of external requirements for ethical appraisal. It is intended that this Code, together with its attendant procedures, will, over time, firmly embed this culture within the University.

David Anderson-Ford

PART ONE

BRUNEL UNIVERSITY CODE OF ETHICAL REQUIREMENTS FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, MATERIAL, OR THEIR DATA

Any research that involves human participation, the collection or study of their data, organs and/or tissue, and that is carried out on Brunel University premises and/or by Brunel University staff or Brunel University students under the supervision of Brunel University staff requires ethical approval.

A. Introduction

1. The Code is intended to provide a set of generic ethical requirements to be observed when designing, conducting, recording and reporting research that involves human participants. Compliance with this good practice will provide assurance that the dignity, rights, safety and well-being of research participants are of primary importance in any research study, that they are protected and that the results of the research are credible. *[Research involving human participants may include healthy volunteers, patients or clients and may include research on identifiable human material or identifiable data relating to individuals.]*
2. Progress is based on research. In many instances, such research must rest, at least in part, in part upon experimentation involving human participants. However, considerations related to the well-being of the human participant should take precedence over the interests of science and society. The advancement of knowledge and the pursuit of information are not to be considered by themselves sufficient justification for overriding other social and cultural values. Research should be an active process of supporting improvements in people's lives and services with a view to benefiting service users.
3. The primary purpose of research involving human subjects is to enhance benefit of scientific or social value, and even the best proven methods must be continuously challenged through research for their effectiveness, efficiency, accessibility and quality.
4. All research will have some degree of potential risk and benefit.

5. Research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Ethical standards should not only be considered in a protective role. The procedures should, wherever possible, be enabling and inclusive, facilitating participants to decide for themselves whether they wish to be involved. Thus, the principle of informed consent lies at the core of research endeavour. In the event that an individual is not capable of giving informed consent, permission must be obtained in accordance with applicable law.
6. The ethical implications of research should be considered at all stages of the research process, not simply at the initial stage of obtaining approval.
7. Some research populations are vulnerable and need special protection. Special attention is also required for those participants who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with professional care.
8. Research investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national, ethical or regulatory requirements should compromise any of the protections set in this Code.
9. Those undertaking research must respect the diversity of human culture and conditions and take full account of ethnicity, gender, disability, age and sexual orientation in its design, undertaking and reporting. Researchers should take account of the multi-cultural nature of society. It is particularly important that the body of research evidence available to policy makers reflects the diversity of the population.

B. Basic Ethical Principles of All Research involving Human Participants

Responsibility of researcher:

1. It is the duty of the researcher to protect the life, health, privacy and dignity of the human research participant. Research involving human participants should be conducted only by appropriately qualified persons and under the supervision of a competent person. The responsibility for the participant must always rest with the researcher and never rest on the participant, even though the participant has given consent.
2. All research on human participants must conform to generally accepted scientific principles, and be based on a thorough knowledge of the scientific literature and any other relevant sources of information. Research which

duplicates other work unnecessarily or which is not of sufficient quality to contribute anything useful to existing knowledge is itself unethical.

3. The design and performance of each experimental procedure involving human participants must be clearly formulated in an experimental protocol. This protocol must be reviewed independently to ensure that it meets ethical standards. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Code.

Risk assessment:

4. Every project involving human participants should be preceded by a careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject and/or to others. This does not preclude the participation of healthy volunteers in the research. The design of the study should be publicly available.
5. Researchers should abstain from engaging in research projects involving human participants unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Researchers should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
6. Research involving human participants should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the potential participants are healthy volunteers.

Safety:

7. Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants, and of researchers and other staff must be given priority at all times, and health and safety regulations must be strictly observed.
8. Appropriate caution must be exercised in the conduct of research using biotechnology, including genetically modified organisms. Correct level of containment must be applied for the protection of the humans and the environment.
9. Research is only justified if there is reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

Information on the research:

10. In any research using human participants, each potential participant must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The participant must be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without penalty.

Voluntary participation and informed consent:

11. The subjects must be volunteers and informed participants in the research project. Informed consent is always at the heart of ethical research. All studies must have appropriate arrangements for obtaining consent and the ethics review process must pay particular attention to these arrangements. After ensuring that the participant has understood the information, the researcher should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed. Wherever possible, participants should be involved in the design, conduct, analysis and reporting of research. Consent may, in relevant instances, need to be an ongoing and task-specific process, rather than a final consent to participate in the whole investigation. On-going support and advice may need to be considered.
12. When obtaining informed consent for the research project the researcher should be particularly cautious if the participant is in a dependent relationship with the researcher or may consent under duress. In that case, the informed consent should be obtained by a well-informed researcher who is not engaged in the investigation and who is completely independent of this relationship.
13. Whilst it is considered ethically acceptable to request an undergraduate or postgraduate student to participate in research, the student must be assured that, by declining to participate in a particular procedure, his/her assessment will in no way be adversely affected, and that undue academic pressure or financial inducement shall not be brought to bear.

Confidentiality

14. Every precaution should be taken to respect and safeguard the privacy of the subject, the confidentiality of the participant's information and to minimise the impact of the study on the participant's physical and mental integrity and personality. Personal information of any sort must be regarded as confidential. Wherever possible, participants should know how information

about them is used, and have a say in how it may be used. Normally, researchers must ensure they have each person's explicit consent to obtain, hold and use personal information. All personal information must be coded or rendered anonymous as far as is possible and consistent with the needs of the study, and as early as possible in the data processing.

Special or vulnerable groups

15. For a research participant who lacks capacity to give valid consent, the researcher must obtain informed consent from a legally authorised representative in accordance with applicable law. Such participants should not be included in research unless the research is necessary to promote the benefit of the population represented and this research cannot instead be performed on legally competent persons.
16. When a participant deemed to lack capacity is able to give consent to decisions about participation in research, the investigator should, wherever possible, obtain an assent from the participant in addition to the consent of the legally authorised representative.
17. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical or mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The scientific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the appropriate Ethics Review Committee.

Financial inducements

18. In cases where the proposal involves financial inducements to the participant, details relating to the amount and purpose of the financial inducement shall be notified at the time of the submission of the proposal.

Publication of results

19. It is an ethical requirement that research results must be published. All those pursuing research must open their work to critical review through the accepted scientific and professional channels. Once established, findings must be made available to those participating in the research and to all those who could benefit from them, through publication and/or other appropriate means.
20. Both authors and publishers have ethical obligations. In publication of the results, researchers are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise be

made publicly available. Researchers must not engage or collude in selecting methods designed to produce misleading results, or in misrepresenting findings by commission or omission. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Code should not be accepted for publication.

Retention of records

21. Data collected in the course of research must be retained for an appropriate period to allow further analysis by the original or other research teams, subject to consent, and to support monitoring of good research practice by regulatory and other authorities.

C. Additional Principles for Research Combined with Professional Care

1. The researcher may combine research with professional care only to the extent that the research is justified by its potential value. When research is combined with care, additional standards apply to protect participants who are human subjects.
2. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current method(s). This does not exclude the use of placebo, or no treatment, in studies where no proven method exists. Care should be taken in making use of a placebo-controlled trial. In general, this methodology should not be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, where, for compelling and scientifically sound methodological reasons, its use is necessary to determine the efficacy or safety of an existing method; or where an existing method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk or serious or irreversible harm. All other provisions of the Code must be adhered to, especially the need for appropriate ethical and scientific review. It is the duty of the researcher to ensure that potential research participants fully understand that they may receive a placebo rather than active treatment before their consent is obtained.
3. The researcher should fully inform the participant which aspects of the professional care are related to the research. The refusal of an individual to participate in a study must never interfere with the professional relationship with the patient or client.
4. In the treatment of a patient or client, where proven methods do not exist or have been ineffective, the professional, with the informed consent of the

patient or client, must be free to use unproven or new measures, if in the professional's judgment, it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Code should be followed.

D Special Considerations concerning Research Involving Human Tissue (including Human Embryos)

1. Research which involves the creation, storage and the use of human embryos and gametes is regulated and licensed by the Human Fertilisation and Embryology Authority. The Authority will grant licences only if it is satisfied that the use of human embryos, gametes and other genetic materials is essential for the purposes of biomedical research.
2. The validity of any such research project must first be established by peer review undertaken by appropriate academic referees chosen by the Authority.
3. Before applying for a licence, approval must be obtained by a University Ethics Committee, the composition of which is approved by the Authority.
4. Research involving the use of any human tissue must comply with regulations and guidance issued by or under the sanction of the Department of Health.

PART TWO

BRUNEL UNIVERSITY RESEARCH ETHICS COMMITTEE

“All proposed research involving human participants must be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.”

(Research Governance Framework
Department of Health, 2001)

Membership of Brunel University Research Ethics Committee

Chair

PVC for Research

Head of Health and Safety

1 representative from each School

1 representative from the Institute for the Environment

1 representative from Brunel Enterprise Centre

Up to 2 co-opted members of the University or Council, with expertise in research ethics

2 lay representatives, external to the University

Terms of Reference

1. To consider general ethical issues relating to research and enterprise activities within the University in order to uphold the good standing of the University and its staff. To articulate University-wide standards and a framework (including codes of practice where appropriate) to ensure that all research conducted within the University, particularly that involving human subjects or material derived therefrom, meet the University's ethical standards.
2. To be accountable to the Council of the University and have independent, delegated authority from Council to approve, with or without modification, or to reject proposals for research involving human subjects or material derived

therefrom, or proposals which are referred to it on ethical grounds.

3. To require reports, if appropriate, from committees or sub-groups within schools and the institute.
4. To act as a University forum and expert panel for all ethical issues in relation to research and enterprise and to ensure awareness of research ethical issues throughout the University as determined by current and relevant national and international codes of best practice.
5. To be the appropriate body to consider the ethical implications of particular research partnerships and of particular sources of research funding.
6. To provide an annual report to Council.

PART THREE

SCHOOL PROCEDURES

1. Schools vary widely in the scope and significance of the ethical issues affecting their work. Some schools regularly engage in research that requires the approval of an external research ethics review body, such as a Local Research Ethics Committee or a Multi-Centre Research Ethics Committee. Some schools routinely use students as participants in the experimental work of peers on taught programs. Some schools have significant numbers of research students whose studies involve human or other animal subjects. Some schools house research projects involving the recruitment of humans as participants for research. Some schools engage in none of these activities.
2. Each school must consider the precise nature of potential ethical issues in the conduct of its research and teaching. The following checklist is offered as guidance:
 - (a) Does the school involve “others” (humans, embryos, human tissue, etc.) as participants in research and teaching?
 - (b) If so, does it have a forum for discussing and reviewing ethical issues related to this work?
 - (c) What rights do these participants have? How are the rights preserved and protected?
 - (d) Are there especially vulnerable participants involved (e.g. children, undergraduates)? If so, do special procedures pertain?
 - (e) Do any programmes require student participation in types of group work that may have ethical implications, e.g. peer assessment?
 - (f) Is the school involved in professional training? If so, what additional ethical issues might be involved?
 - (g) Does research within the school involve sponsorship or external contracts? If so, what additional ethical issues are raised, particularly in respect of the publication of findings?
 - (h) Do any school activities raise issues of an ethical nature even if they do not raise the questions listed above?
 - (i) Generally, how are ethical principles in the conduct of research or professional life taught within the school?
 - (j) What evidence is there that they are understood and practised?
3. **All schools must have in place procedures for the consideration of ethical issues, and for ensuring that policies determined by the University Research Ethics Committee are followed, and must**

Either:

- Have in place procedures for the ethical scrutiny of research proposals involving human participants, and
- Have ongoing monitoring and supervision systems in relation to the conduct of such research;

Or:

- provide a written explanation as to why such procedures are considered to be inappropriate and/or unnecessary.

It is the responsibility of the University Research Ethics Committee to approve all school procedures and written explanations.

4. The scale of a school's procedures will be determined by the extent and frequency to which ethical issues are raised. Where a school's work rarely (if at all) raises ethical issues, a complex procedure would clearly be inappropriate and the school should state and explain this in writing. Where a school is extensively engaged in teaching and research that raise ethical issues, formal procedures are required and it may be necessary to establish an ethics committee within the school, (possibly with panels at course level if a large number of research proposals require scrutiny in batches).
5. Following a review, each school must establish an appropriate mechanism to cover all aspects of its work as revealed in its review. Formal procedures, where developed, must be consistent with best practice in the subject domain and, as a minimum, should conform to the requirements of professional bodies in that domain.
6. **Each school must appoint an officer with specific responsibility for the management of ethical issues raised by the work of the school.** Even where a school has decided that a procedure for ethical issues is unnecessary, a designated officer must be appointed to ensure that any policy of guidelines developed by the University Research Ethics Committee are followed and that school ethical issues are kept under review.
7. Cases which cannot be resolved by a school committee or panel, or cases of uncertainty must be referred to the University Ethics Committee.
8. **Ethical issues continuously evolve, change and are subject to refinement. Thus, schools, through their designated officers, must conduct an annual review of their position and report to the University Research Ethics Committee on the management of this aspect of the school's work.** Nil returns should also be submitted. It is expected that annual reports to the ethics committee will include:
 - details of any changes to the approved procedures;
 - a summary of action taken by the school ethics committee including

details of the number of cases considered (staff and student), the number of cases approved, and any particular difficulties encountered or consequent action taken;

- where appropriate, the number of cases referred to the local research ethics committees of the health authority;
- any issues for consideration by the University Research Ethics Committee.

In the case of activities which are subject to:

- statutory control
- approval by local research ethics committee of a health authority

the school's designated officer is responsible for the management and monitoring of the established procedures, for ensuring that treatment is comprehensive, for liaising with external bodies as appropriate, and for reporting back to the school as necessary. Where members of the general public are involved in the research work of a school, particular caution should be exercised to protect both the University and the public interest.

Where a school is involved in contract research or in research programmes sponsored by external bodies (other than recognised research councils) the designated officer must be satisfied prior to the commencement of the research that:

- appropriate safeguards for academic freedom are in place
- measures have been taken to ensure that findings are published as appropriate and that publication will not be compromised in the interests of the external body
- the contract or sponsorship is in the best interests of the school and the University.

The Role of the University Research Ethics Committee in relation to School Procedures

The University Committee will:

- Keep the Code under review
- Receive details of procedures and written explanations from schools
- Maintain a list of School Research Ethics Officers
- Receive annual reports from schools (including nil returns)
- Develop policy guidance and procedures as and when required in response to external constraints
- Review applications where external funding bodies require independent review by the University
- Receive applications for approval in principle where the University is joining a consortium with other universities/organisations.
- Review applications for research involving human subjects or material

derived therefrom

- Review applications for research which are referred to the Committee on ethical grounds.

Schools will:

- Have the day-to-day responsibility for the processing and approval of the majority of research proposals. *(In the case of inter-school research, responsibility is to be taken by the school in which the principal researcher is based. In cases where the principal researcher is a Head of School or a Deputy Head of School, the relevant School will need to establish an appropriately constituted review panel.)*
- Establish and maintain appropriate and relevant procedures as detailed in (3) above.
- Act in accordance with the requirements of the University Committee.

PART FOUR

SPECIFIC STANDARDS FOR RESEARCH GOVERNANCE

In addition to the generic standards relating to ethics in research detailed above, legislative requirements and the regulations of statutory and professional bodies will also apply in specific research contexts. No single document can possibly detail these specific requirements. Details of current standards, legislation and guidance are given below:

Universities and the NHS

*(extract from Department of Health Research Governance Implementation Plan)
Strengthening research governance in health and social care implies close collaboration between universities and the NHS. The NHS will rely on universities to:*

- *support the NHS in promoting a quality research culture that extends to every aspect of health and social care research*
- *participate in framework agreements that allocate research governance responsibilities to those equipped to accept them;*
- *work closely with care organisations to ensure high standards of joint supervision for research teams and for research active care teams, and maintain systems to meet those responsibilities;*
- *take part in NHS/academic groupings that can deliver collaborative programmes of R & D designed to meet the needs of health and social care;*
- *work closely with the NHS to develop information systems that support high standards of research governance and clinical governance.*

The EU Directive on Good Clinical Practice in Clinical Trials applies to work undertaken by university researchers as well as others. Universities should work with their NHS partners to develop joint quality systems.

The following guidelines are concerned with teaching and research involving human subjects. All teaching experiments and research carried out by members of Brunel University should conform with the University Code. Researchers are also required to observe the ethical guidelines established by their own appropriate Society or Professional Body, as laid down from time to time, for example:

- a. The Association of Social Anthropologists: <http://www.asa.anthropology.ac.uk>
- b. The British Sociological Association: Statement of Ethical Practice, The British Sociological Association, Unit 3F/G, Mountjoy Research Centre, Stockton Road, Durham DH1 3UR; Tel: 44(0)191 383-0839; Fax: 44(0)191 383-0782; <http://www.britsoc.org.uk>
- c. The British Psychological Society: Code of Conduct, Ethical Principles and Guidelines Address: St Andrews House, 48 Princess Road East, Leicester LE1 7DR; <http://www.bps.org.uk>
- d. The British Association of Sport and Exercise Sciences, BASES, Chelsea Close, Off Amberley Road, Armley, Leeds LS12 4HP; Tel / Fax (0113) 289 1020;

- <http://www.bases.org.uk/>
- e. The Ergonomics Society – Code of Professional Conduct; Devonshire House, Devonshire Square, Loughborough, Leicestershire LE11 3 DW; Tel: 01509 234904; Fax: 01509 235666; <http://www.ergonomics.org.uk>
 - f. Medical Research Council: Good Practice Guide/Principles; 20 Park Crescent , London W1B 1AL Tel: 020 7636 5422 <http://www.mrc.ac.uk>
 - g. The Social Research Association; Ethical Guidelines; PO Box 33660, London N16 6WE; Tel: 020 8550 5684; <http://www.the-sra.org.uk>;
 - h. The Royal College of Physicians: Guidelines; 11 St Andrews Place, Regent's Park, London NW1 4LE; Tel: 020 7935 1174; <http://www.rcplondon.ac.uk>
 - i. The Engineering Council: EC(UK), 10 Maltravers Street, London, WC2R 3ER; Tel: 020 7240 7891; Fax: 020 7379 5586; <http://www.engc.org.uk/>

N.B. A particularly useful compendium archive is provided by the Department of Health at:
<http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/fs/en>.