



BRUNEL UNIVERSITY LONDON

CODE OF RESEARCH ETHICS

*Brunel University London 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; hence the need for the University Code of Research Ethics.

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, and during the implementation of the research project (hence the requirement for reporting back).

It will also be noticed that, in terms of procedure, Colleges 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 College and/or research project in question. We do, however, need all Colleges 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.

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## BRUNEL UNIVERSITY LONDON CODE OF ETHICS REQUIREMENTS FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, MATERIAL, OR THEIR DATA

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

### A. Introduction

1. This 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, clients and 'people in everyday life' (e.g., ethnographic studies). This may include research on identifiable human material or data relating to individuals. For the removal of doubt, ethics review and approval is required for projects involving surveys, questionnaires and service evaluations.
2. Progress is based on research. In many instances, such research must rest, at least 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.
3. The primary purpose of research involving human participants is to enable enhancements 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/or 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, allowing participants to decide for themselves whether they wish to be involved.
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 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 participants in the United Kingdom as well as applicable international requirements.
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**

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/or under the supervision of a competent person. The responsibility for the participant must always rest with the researcher and never with the participant, even though the participant has given consent.
2. Research using human participants is only justified if there is a reasonable likelihood that the populations within which the research is carried out stand to benefit from the results of the research. This may not necessarily mean that the participants themselves will benefit directly from taking part in a study. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current method(s). If no proven method exists, this does not preclude the undertaking of such research, provided that suitable safeguards are in place.
3. All research on human participants must conform to generally accepted scientific principles, and be based on a thorough knowledge of the 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.
4. The design and performance of each study involving human participants must be clearly formulated in a research protocol. The research protocol must always contain a statement of the ethical considerations involved and must indicate that there is compliance with the principles enunciated in this Code.

### Risk assessment

5. Every project involving human participants should be preceded by a careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the participant and/or to others.
6. 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.

## Safety

7. Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants and of researchers and others 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. The correct level of containment must be applied for the protection of humans and the environment.

## Information on the research

9. Unless otherwise justified, in any research involving 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
  - any 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

10. As a default position, participants must normally be informed volunteers. All studies must have appropriate arrangements for obtaining consent and the research ethics review process will pay particular attention to these arrangements. After ensuring that the participant has understood the information, the researcher should then obtain the participant's freely-given informed consent, normally in writing. If the consent cannot be obtained in writing, the researcher must provide evidence that the potential participant has been appropriately informed. 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.
11. 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 person who is not engaged in the investigation and who is independent of this relationship.

12. Where the nature of the research is such that informing participants before the study is carried out might render the results invalid, for example within aspects of the cognitive and social sciences, there must be appropriate explanations provided to the research ethics committee. Researchers must provide convincing reasons why such research should proceed without the necessary informed consent. Researchers must not mislead participants if it is thought that prior permission will not be obtained.
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.

#### Consent relating to human tissue

14. The principles of consent as described elsewhere in this document apply equally to situations where a researcher wishes to use human tissue in a research project. However, there are additional provisions which are required for compliance with the Human Tissue Act 2004 (HT Act), and are set out by the Human Tissue Authority (HTA).

#### *General provisions*

15. Consent under the HT Act relates to the **purpose(s)** for which material might be stored or used. As research is a **scheduled purpose** under the HT Act, the requirements of the HT Act apply. For consent to be valid it must be given voluntarily by an appropriately informed person (who could be a child) who has the capacity to agree to the activity in question.
16. Consent can be **general**, that is, it is possible to ask for consent to store and use tissue for an unspecified number of research projects. If there is any possibility that a researcher may wish to use tissue originally obtained for one project in another project, then that possibility should be included on the original consent form. If consent is withdrawn **after** the sample(s) has been used for research, it is *not necessary to withdraw the data related to that sample from the project*.
17. If material is obtained from a UK-based source, then the researcher must ensure that consent was properly obtained. Proof of consent should be supplied with the material, and retained centrally within the College/Research Institute.
18. Tissue which has been obtained from a **non-UK source** does not require consent. However, it is good practice to see if there is any information available from the source which indicates that consent has been obtained in an appropriate manner.

#### *Consent from children and persons lacking capacity*

19. Under the HT Act, a child is defined as a person under the age of 18. If a child is considered to be competent to give valid consent, then the consent for removal, storage and/or use of the tissue should be given by the child. It is important to make sure the child has consented *voluntarily* and has not been

unduly influenced by anyone else. For removal, storage and use of tissue from persons lacking capacity to consent (for the purpose of research), the researcher must refer to sections 30 – 34 of the Mental Capacity Act 2005.

#### *Use of tissue from deceased persons*

20. Consent is **required** for the removal, storage and use of tissue from a deceased person for any scheduled purpose. The University's license from the HTA covers research, and education or training relating to human health. Consent must be obtained for either of those purposes. If a person has given consent for the use of tissue to take place *after their death*, then that consent is considered sufficient. If consent was not obtained prior to the person's death, then it must be obtained from a nominated representative or a person in a "qualifying relationship". Detailed information regarding how to obtain consent for removal, storage and/or use of tissue from a deceased person is available from the HTA's Code of Practice 1 (Consent) ([http://www.hta.gov.uk/\\_db/\\_documents/Code\\_of\\_practice\\_1\\_-\\_Consent.pdf](http://www.hta.gov.uk/_db/_documents/Code_of_practice_1_-_Consent.pdf)).

#### *Use of tissue from living persons*

21. Consent from the living is required if the tissue is to be stored and used specifically for **research purposes**. Consent is *not* required if the tissue is being stored and used for education or training relating to human health. **Fetal tissue** is regarded as the mother's tissue.
22. The HTA's Code of Practice 1 (Consent), referenced above, includes several useful charts in the appendices as a guide to consent requirements.
23. It should be noted that the University Research Ethics Committee **is not** a "recognised research ethics committee" as referenced in the HT Act or any HTA document. Where relevant, application for research ethics approval may need to be made to a HRA Research Ethics Committee.

#### *Research involving human embryos*

24. 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.
25. The validity of any such research project must first be established by peer review undertaken by appropriate academic referees chosen by the Authority.
26. Before applying for a licence, approval must be obtained by a University Ethics Committee, the composition of which is approved by the Authority.
27. 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.



### Special or vulnerable groups

28. For a research participant who lacks capacity to give valid consent, the researcher must act in accordance with the provisions of the Mental Capacity Act 2005. The Act applies to all decisions taken on behalf of people who permanently or temporarily lack capacity to make decisions for themselves, including decisions to involve such individuals in research. All researchers working with participants who lack, or may lack, capacity need to be aware of its underlying principles and the statutory provisions relating to research.
29. When a participant deemed to lack capacity is able to give consent to decisions about participation in research, the researcher should, wherever possible, obtain an assent from the participant in addition to the consent of the legally authorised representative. Recognition of, for instance, a child's involvement in a particular study where consent cannot be obtained because of lack of capacity might be attained through the process of assent.
30. 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 participants with a condition that renders them unable to give informed consent must be stated for consideration and approval by the appropriate Research Ethics Committee.
31. Vulnerability is not to be confined to matters relating to capacity. The giving, or withholding, of fully informed consent is potentially liable to be compromised in varying degrees in a wide variety of interactions between the research and the potential research participant, where there is a potential power imbalance allowing for an inference of undue influence. In such circumstances, there is a heightened responsibility to ensure that extra care is taken in the provision of information about the research, and promoting the individual's autonomy when seeking consent. (*See also: Conflict of interest, paragraph 46.*)

### Confidentiality

32. Every precaution must be taken to respect and safeguard the privacy of the participant, the confidentiality of the participant's data 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.
33. It should be noted that in exceptional circumstances, the public interest may override the protection of a participant's confidentiality. Particular examples relate to child protection, and dangerous professional practice. Where limits to confidentiality might arise, the potential participant should be informed of the nature of the limits.

## Research integrity

34. The general principle of integrity should inform all research activities. Honesty should be central to the relationship between the researcher, the participant and other interested parties.
35. Research outputs should contain acknowledgements of the work of others as appropriate. Particular care should be exercised to acknowledge the work of research students.
36. All staff and students shall have a responsibility to observe the highest standards of conduct. Please see the Research Integrity Code of Practice ([http://www.brunel.ac.uk/\\_\\_data/assets/pdf\\_file/0007/384235/research-integrity-code.pdf](http://www.brunel.ac.uk/__data/assets/pdf_file/0007/384235/research-integrity-code.pdf)) and the Universities UK concordat on research integrity (<http://www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx>).
37. There is no legal obligation for a researcher to report a crime if one is observed during the conduct of research. However, each project where this might occur must be risk-assessed and considered by the Research Ethics Committee on a case-by-case basis.
38. Brunel University London policy and procedures require that there be strict adherence to legal regulations governing the conduct of research, together with adherence to good research practice (this to include proper and appropriate conduct of research, together with professional integrity and honesty).
39. All offsite research undertaken outside the United Kingdom must comply with standards current in the UK and with the regulatory requirements of the country in which it takes place, and must include a thorough risk assessment and liaison with the University Insurance Officer to ensure that appropriate insurance is in place.
40. 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. Thus, where data are collected outside the UK, the research will normally be expected to have received ethics approval from a properly constituted and independent ethics committee in the country concerned, where such a committee exists to review the type of research being proposed, before final approval can be provided by the University.
41. It is the responsibility of the researcher to:
  - check the requirements for the conduct of the proposed research, and for ethics review in the country concerned (including the seeking of advice from the proper authorities of the country in question);
  - The University does not sanction research where the appropriate visas have not been obtained. It also expects the University Research Ethics Committee to be provided with evidence of ethics approval having been sought and given.

- If there is a lack of clarity about the relevant legal and regulatory requirements then further advice must be sought from the Secretary to Council and University Secretary.

#### Financial inducements

42. 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

43. It is an ethical requirement that the design and results of the research 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.

44. 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 research not in accordance with the principles laid down in this Code should not be submitted for publication.

#### Retention of records

45. 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.

#### Conflicts of interest

46. Conflict of interest arises where a researcher's private interests diverge from and compete with his or her ethical responsibilities in the research endeavour, such that it might be reasonable to infer that the researcher's behaviour or judgement is likely to be motivated by such private, competing interests. Although a competing interest does not, of itself, imply wrongdoing, declaration and appropriate management of the issue is required where such an interest might reasonably be foreseen to unduly influence the researcher's overall ethical responsibilities.

47. 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 human participants.

48. 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.

## C. 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. Links to a selection of other standards, legislation and guidance are given below.

Within the context of research involving NHS patients and/or persons lacking capacity within the meaning of the Mental Capacity Act 2005, the university researcher is required to make an application to the Integrated Research Application System (IRAS) using the electronic form available on their website. Careful attention should also be paid to the Guidance provided by IRAS on the same website (<http://www.myresearchproject.org.uk>).

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. See <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/index.htm>.

All research carried out by Brunel University London staff and students must conform to the University Code. Researchers are also required to observe the ethical guidelines established by the appropriate Society or professional body, as laid down from time to time.

The University has signed up to the provisions of the Universities UK concordat on research integrity (<http://www.universitiesuk.ac.uk/Publications/Pages/concordattosupportresearchintegrity.aspx>).