Brunel University London

Code of Research Ethics

Foreword

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. This Code reflects an increasing emphasis (via legislation, research governance frameworks and codes of best practice) on accountability and supervision, at all levels and in all relevant institutions, including universities, to ensure best practice in research.

In the drafting of this Code, the University Research Ethics Committee (UREC), 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 supported. The intention is to safeguard both the participant and the researcher (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.

College Research Ethics Committees adopt procedures provided by the UREC to ensure conformity with the requirements of the University. We do, however, need all Colleges to 'own' the process and. via representation on the UREC, to help the university continually improve and streamline all our processes associated with ethical research practice.

A research ethics culture will already be second nature to many experienced researchers. It is intended that this Code, together with its attendant procedures, will firmly embed this culture within all areas of the University.

This Code should not be read in isolation but should be read in parallel with the accompanying documents on the UREC IntraBrunel webpage relating to processes and procedures, and the Brunel Research Integrity Code.

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Chair, University Research Ethics Committee

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BRUNEL UNIVERSITY LONDON CODE OF RESEARCH ETHICS

REQUIREMENTS FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, MATERIAL, OR DATA

Any research that involves human participants, the collection or study of their data, and/or the use of relevant material (as defined by the Human Tissue Authority), which is undertaken by Brunel University London staff or students, requires approval from a Brunel Research Ethics Committee before the data collection can commence.

NB: Approval will also be required for:

- *Visiting researchers engaged in Brunel University London approved studies;*
- *Research partnerships where the Principal Investigator is a member of Brunel University London;*
- *Independent contractors under the auspices of an honorary contract.*

A. Introduction

- This Code is intended to provide a set of base line ethical requirements to be observed when designing, conducting, recording and reporting research that involves human participants. Compliance with this code 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, ethical approval is required for projects involving surveys, questionnaires and service evaluations.[1]

- 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.

- 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.

[1] Service evaluations are required to undergo ethical review only where they are undertaken for research purposes or student assignments; not where they relate to University operation.

- All research will have some degree of potential risk and should have some degree of benefit.

- Research is subject to ethical standards that promote respect for all human beings and protect their health and rights and freedoms. 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.

- The ethical implications of research should be considered at all stages of the research process, not simply at the initial stage of obtaining approval.

- Some research populations are potentially vulnerable and at greater risk of harm and so need special protection and additional safeguards. 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 or due to an imbalance of power, and for those for whom the research is combined with professional care.

- Research investigators have a responsibility to d be aware of the ethical, legal and regulatory requirements for research on human participants in the United Kingdom as well as applicable international requirements.

- Those undertaking research must respect the diversity of human culture and conditions and take full account of ethnicity, gender identity, 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. A failure in this area could have significant ramifications including non-compliance with the legal obligations of the Equality Act 2010 and an increased risk of the University and investigators facing legal claims for compensation.
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B. Ethical Principles of All Research involving Human Participants

Basic Principles

1. It is the duty of the researcher to protect the life, health, privacy and dignity of the dignity, rights and freedoms of any 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 where 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 involving 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 (except where this is necessary for teaching purposes, in which case the risks should be minimal).

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. Protocols which have been approved by a Research Ethics Committee (REC) must be adhered to, and changes cannot be implemented without the prior approval of the same REC. No changes in protocol are to be put into effect without formal approval, except where necessary to eliminate immediate risk of harm to participants or the researcher(s).

Risk assessment

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, to participants or to the researchers, are found to outweigh the potential benefits.

6. In designing any research project, a researcher must pay sufficient attention to any risks that may occur. These include risks to which participants, researchers or others may be exposed. In all cases it is the responsibility of the researcher to identify risks and propose mitigating actions. Some risks will fall into the category of 'health and safety' and here standard procedures laid down by the University should be followed.

7. It is important when assessing risks to consider not only the likelihood of them occurring, but their impact upon the project, researcher, participants or others. Having identified a risk, the researcher must then decide what actions have been (or will) be taken in order to lessen the likelihood that the event will occur, or to reduce the impact to a minimal level if it does. It is worth appreciating that people vary widely in their attitude to risk, and this may lead researchers in particular to accept levels of risk that are higher than desirable, either because they are highly motivated to undertake the research and will accept high personal risk factors, or sometimes just because they are less experienced. It is therefore recommended that risks are discussed within the project team, and where appropriate with the Health, Safety and Environment Team, as widely as practical. Where risks are identified that require specialist knowledge to mitigate such as privacy risks, it is the responsibility of the researcher to seek this advice **before** the research commences.

8. The Research Ethics Committee will closely examine the potential risks of a project, and may request additional information or more robust control measures. If the risks are

deemed to be too severe, either to participants or the researcher(s), ethical approval will be withheld.

9. When completing a risk assessment as part of an application for research ethics approval, researchers should outline all potential risks to participants and researchers, and others (e.g. members of the public) and state how these risks will be minimised and managed. The risks to participants should be clearly explained in the Participant Information Sheet, so that potential participants can understand any potential risks before consenting to take part in the research.

10. Consideration should be given to the procedures in place for handling unexpected disclosures by a participant in an interview or questionnaire (for example, potential harm to the participant or others, poor professional practice or commission of an offence). The REC will want to know how the researcher intends to handle such an event, and the arrangements in place for supporting the participant and the researcher. The Participant Information Sheet should set out what will happen in the event of such a disclosure.

11. Researchers should consider risks to themselves as well as the participants. This may include a variety of risks including but not limited to: loss of data in relation to legal obligations, lone working and the potential need for personal security measures, working with biological materials, geographic/location risks, psychological harm/distress, etc.

    The Social Research Association (SRA)[2] defines potential considerations as follows:

    - Risk of physical threat or abuse
    - Risk of psychological trauma, as a result of actual or threatened violence or the nature of what is disclosed during the interaction
    - Risk of being in a compromising situation, in which there might be accusations of improper behaviour
    - Increased exposure to risks of everyday life and social interaction, such as road accidents and infectious illness
    - Risk of causing psychological or physical harm to others.

    If the research involves medical intervention, additional risks must be considered.

12. If the research will take place in the field or in a laboratory for example, an appropriate Health and Safety Risk Assessment must be completed (including but not limited to a travel risk assessment, a location safety assessment). Researchers should consider any risks associated with the use of equipment, or the administration and use of drugs, if applicable. The safety of participants and of researchers and other staff must be given priority at all times.

Safety

13. Research may be undertaken in regions or environments with their own unique risks, or 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

[2] SRA Code of Practice for the Safety of Social Researchers

priority at all times, and health and safety regulations and guidance must be strictly observed.

14. Appropriate caution must be exercised in the conduct of research, particularly when undertaking biological studies including but not limited to the use of pathogenic organisms, genetically modified organisms or cells, or any biotechnological processes. Appropriate permissions and licensing must be in place, as well as the correct level of containment for the protection of humans, animals and the environment (please contact the Health, Safety & Environment Team for further advice).

Information on the research

15. 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 involved in the study, and
    - any discomfort it may entail.
    - what information will be collected about the participant
    - how the information will be used
    - if the data will be shared and who with
    - how the data is secured
    - how to exercise their information rights

    The participant must be informed of the right to abstain from participation in the study without consequence or to withdraw consent to participate at any time without penalty (or be clearly informed at which point in the study this will no longer be possible, e.g. pooled or anonymised data or samples).

Voluntary participation and informed consent

16. As a default position, participants must normally be informed volunteers and all studies must have appropriate arrangements for obtaining written consent.

17. In order for consent to be valid, it must be clear and specific what the research participant is consenting to. When providing information to the participant, this should be provided in plain English, and wherever possible, without the use of scientific language that the participant may not understand.

18. 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 such as longitudinal studies, 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.

19. 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; Such circumstances will usually be unethical and should be avoided. In cases where there is a risk of undue pressure to participate, 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. 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 reviewer. Researchers must provide convincing reasons why such research should proceed without the necessary informed consent. Moreover, where data has been obtained in such a manner, consideration should be given as to whether and how such individuals might be invited to give their consent to the use of data so obtained. Researchers must not mislead participants if it is thought that prior permission will not be obtained. Studies based on observation in natural settings must respect the privacy and psychological wellbeing of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in public situations where those observed would expect to be observed by strangers. Additionally, particular account should be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.

20. Whilst it is considered ethically acceptable for academic staff 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. It is unlawful to induce consent where such consent cannot be freely given and withdrawn without detriment.

The participants

Healthy volunteers

21. It is unlikely that healthy volunteers will benefit directly from taking part in research. They may therefore be more difficult to recruit. The following points should be noted:

    - There must be no pressure to volunteer, for example arising out of some obligation;

- Recruitment should be public, i.e. by appeal to a cohort rather than individual, private recruitment;
- The term 'healthy' requires specific definition for the purposes of the study.

Recruitment of professionals or experts

22. You may be seeking to conduct research involving participants who are members of professional groups. Members of professional groups are known in the sense that their names appear in a public register. It is the responsibility of the researcher to acknowledge the source of the name and address of such members in a covering letter which should accompany any invitation, and permission should be sought from the relevant institution or authority to seek and release information.

Patients

23. A patient is an individual who is receiving or is registered to receive medical care, and who is to be recruited due to their status as a patient. It must be noted that a patient's ability to consider the implications of involvement in the research may be impaired. Patients may be dependent upon health practitioners – a sense of obligation might therefore be present, and such a conflict of interest may need to be considered when formulating the research proposal. Research involving patients under the care of the National Health Service (NHS) will normally be subject to review by the Health Research Authority (HRA) and/or an NHS Research Ethics Committee. Research ethics applications should be submitted via BREO for review by a Brunel REC prior to submission to the HRA/NHS.

Vulnerable participants

24. Participants are deemed to be vulnerable either on the basis of capacity to consent or on a contextual basis. Vulnerability on the basis of capacity is governed by a number of separate provisions. The following are of particular importance to note:

Children

25. 'Gillick competent' children (i.e. those who, although under 16, are deemed to have a sufficient understanding to give consent in their own right) should be selected before younger children. Competence involves:

    - The ability to understand information;
    - The belief that the information applies to oneself;
    - The ability to retain, ask questions about and reflect upon the information long enough to make a decision.

Before undertaking research involving children, the investigator must ensure that:

- There is sufficient reason to involve children (meaning the research would not be equally well carried out with adults);
- The purpose of the research is to obtain knowledge relevant to the needs of children;
- A parent or guardian of each child has given permission;

- The agreement (known as assent) of each child has been obtained to the extent of the child's capabilities;
- A child's refusal to participate or continue in the research must always be respected.

Remember that unless a parent, guardian or teacher will be present at all times, a Disclosure and Barring Service (DBS) check will need to be carried out for researchers working with children. No research can commence until a DBS check has been completed.

26. For the purposes of Brunel University London policy, a child is deemed to be any individual below the age of 18. Please see University guidance on research involving participants aged between 16 to 18 years. Normally, research involving children requires the consent of an adult with parental responsibility or relevant other. That said, it is best ethical practice to involve the child in an appropriate discussion about taking part in the study, in a manner appropriately tailored to the age and understanding of the child. Written evidence of the assent of the child themselves should also normally be obtained.

27. Researchers will be required to explicitly justify why it is considered essential to conduct the proposed research using children. This justification should be included in the research ethics application.

28. Care should be taken in the drafting of appropriately designed Participant Information Sheets and Consent Forms, ensuring they are age-appropriate.

29. Any safeguarding requirements and DBS clearances should be considered at the proposal stage.

Mental Capacity Act 2005

30. 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.

31. Researchers should note that for research proposals intending to involve individuals coming within the definition of mental incapacity within the terms of the Act, research ethics approval will normally need to be obtained from a Health Research Authority authorised committee. Researchers should note that there are special statutory safeguards required in relation to the conduct of research intended to involve such individuals; see sections 30-33 of the Mental Capacity Act 2005 and appropriate guidance.

32. 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.

33. For further information on recruitment of adults unable to consent for themselves, please see additional UREC guidance.

Older people

34. Particular care should be taken if the person is living in long-stay accommodation or a residential home. Engagement with the Mental Capacity Act 2005 should be considered, and any risks associated with consent and/or safeguarding considered.

Contextual vulnerability

35. Contextual vulnerability is likely to arise where there is a perceived imbalance of power and control between the researcher and the intended participant. Indicative examples include:

    - Students (for research undertaken by academic staff or senior peers)
    - Members of the Armed Forces
    - Prisoners
    - Asylum seekers/refugees
    - Employees
    - Care home residents
    - Patients undergoing medical care
    - Participants with disabilities
    - Victims of crime

    In these cases, potential participants may feel undue pressure to participate based on the perceived status of the researcher or affiliate. This needs to be carefully mitigated.

36. 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.

Others who may be considered vulnerable

37. Some participants may be considered vulnerable for reasons unrelated to capacity or context. Members of closed or remote communities, or those who have undergone trauma, are examples of this. Researchers must consider the circumstances of their target population and take steps to protect their welfare as appropriate to their individual needs. Research ethics committee reviewers will expect to see evidence of such consideration when reviewing research proposals.

Research involving human tissue

38. It should be noted that this area of research is governed by the Human Tissue Authority and Human Tissue Act 2004. Special procedures are required for research involving 'relevant material' which includes most human tissue samples. Ethical approval will be required in all cases; please refer to the University Code of Practice on Working with Human Tissue for guidance on seeking approval for such research.

Confidentiality and anonymity

39. The use of personal information about research participants must comply with the obligations contained within the UK General Data Protection Regulation and Data Protection Act 2018. 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 privacy, physical and mental integrity and personality. Personal information of any sort must be regarded as confidential and must not be disclosed outside of the research team of for the purposes of agreed collaborative research. Unless legally exempt, participants should know how information about them is used, and be able to consent to how it may be used. Normally, and unless legally exempt, 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.

40. As a standard rule, all data provided by participants should be anonymised so that individuals cannot be identified, and their information should be kept confidential where possible. In can be argued that much of the reason we ethically scrutinise research is in order to protect the well-being and interests of those who make such research possible. This means honouring the trust that is placed in researchers by participants and being clear about how data will be used. Any data collected should only be used in the way described to participants, and for which fully informed consent has been obtained. There may be exceptions where anonymisation is not appropriate – such as personal accounts of historical events – where a participant may choose to be named in the research, but the informed choice must be theirs.

Confidentiality

41. Confidentiality relates to the protection of the data collected either verbally or in a recorded form. The researcher has a duty to make explicit what information can realistically be kept confidential and, where relevant, where the public interest in

disclosure is likely to override the duty of confidentiality. Researchers must therefore be careful not to make promises they cannot keep. A situation may arise in which a participant discloses information which gives a researcher cause for concern or the researcher may find themselves witness to an illegal or harmful activity. In such cases there may be an overriding duty to breach confidentiality in order to report something of greater importance, particularly if there is a concern that someone may be at risk of harm. If a research proposal presents a possibility of encountering these issues, researchers must ensure that measures are in place to help and support the participant(s). Where limits to confidentiality might arise, the potential participant should be informed of the nature of the limits before being asked to consent.

42. The researcher also needs to satisfy the research ethics reviewers as to precisely how security of data is to be assured, particularly in relation to the requirements of the Data Protection Act 2018 (DPA) and the General Data Protection Regulation (GDPR). This means making clear statements about how data will be stored and under what protection. Keeping participants' details together on a computer creates an immediate risk if not kept securely. Researchers must take steps to ensure data are stored securely, particularly if dealing with personal data.

    Researchers will need to show clear evidence that:

    - the personal information to be collected is needed to achieve the research purpose
    - personal information will be kept confidential;
    - data will be secured against unauthorised access;
    - no individual will be identifiable from the published result without his/her explicit consent.

    All data from which an individual is identifiable should be destroyed when no longer required. This does not apply to all research data (which should be retained in accordance with the Brunel Research Data Management Policy), but only to any information which may identify individual participants. In certain circumstances the researcher may wish/need to retain such data beyond completion (particularly for external scrutiny purposes). Here, all relevant persons (particularly the participant) must be made aware of the reasons for retention, and the circumstances where disclosure might occur. Written consent will be required.

Anonymity

43. To make data anonymous means to remove all identifying information about the contributor. Simply removing a name is not enough; participants may be concerned about being identified from many different factors of their identity, so anonymity can only be achieved by removing the name, address, job title and any other detail which may lead to identification.

    Organisations can also be identified easily if, for example, the name is removed but the location is included. As many precautions as possible should be taken to protect anonymity where required, and the researcher should think carefully about the level of anonymity they can realistically provide.

Pseudonymity

44. Pseudonymisation is similar to anonymization in that, in the possession of the holder, the information cannot reasonably be used to identify an individual. However, it differs in that the original provider of the information may retain a means of identifying individuals. This will often be achieved by attaching codes, or other unique references to information, so that the data will only be identifiable to those who have access to the key or index. Pseudonymisation allows information about the individual to be linked in a way that true anonymization does not.

Recruitment of Participants

45. Where possible, potential participants should be given the opportunity to take a positive step to participate rather than be faced with the need to decline a direct approach. If a direct approach must be used due to the circumstances of the research, then efforts must be made to notify potential participants in advance of any 'doorstep' approach.

46. Care should be taken to select methods of recruitment that are feasible, contain an appropriate risk assessment e.g. the University Policy and Field Work Policy, and conform to appropriate ethical standards and regulatory requirements where relevant. It should be noted that recruitment by use of the University global address list is contrary to the Computer Centre Acceptable Use Policy. If contact with a particular department within the University is preferred, permission will need to be obtained from the relevant Head of Department, who may give permission for a particular cohort to be contacted on the researcher's behalf.

47. If researchers intend to seek participants from outside the University, it is usually most efficient to go through a gatekeeper in the particular field. This will require an approach to a member of the relevant organisation to seek permission to contact their staff or members, or ask that they contact them on the researcher's behalf.

48. For further information on suitable recruitment methods, please see the UREC guidance.

Research integrity

49. The general principle of integrity should inform all research activities. Honesty is central to the relationship between the researcher, the participant and other interested parties.

50. Research outputs should contain acknowledgements of the work of others as appropriate. Particular care should be exercised to acknowledge the work of research students.

51. All staff and students have a responsibility to observe the highest standards of conduct. Please see the Brunel Research Integrity Code of Practice and the Universities UK concordat to support research integrity. An online training module on research integrity is available via Blackboard Learn – Brunel Graduate School Research and Teaching Courses – Research Integrity.

52. There is not always a 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.

53. 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).

54. 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 (with consultation from the Health, Safety and Environment Team as appropriate) and liaison with the University Insurance Officer to ensure that appropriate insurance is in place. Please see additional guidance on insurance for research projects.

55. Research undertaken under the auspices of the University should meet, as a minimum, the research ethics standards expected by the University, regardless of its place of conduct. Thus, where data is collected outside the UK, the research will normally be expected to have received research 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. The Brunel REC must ensure that the local customs, laws and the rights of citizens are respected at all times.

56. 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);

- ensure appropriate visas have been obtained, where relevant. The University does not sanction research outside the United Kingdom where such visas are required unless these have been obtained and can be evidenced. The University expects the relevant University Research Ethics Committee to be provided with evidence of an ethical opinion from a local Research Ethics Committee (or similar body) where possible.

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

- Ensure they are familiar with the following policies: Research Data Management, Research Misconduct, Open Access, Conflict and Declaration of Interest, Responsible Research Data and Guidance, Intellectual Property, and Data Protection.

Financial compensation

57. In cases where the proposal involves financial compensation to the participant, details relating to the amount and purpose of the financial compensation shall be notified at the

time of the submission of the proposal (see the University's Anti-Bribery Policy, incorporating the Policy and Procedures in Respect of Gifts and Hospitality). Financial inducement (i.e. a payment or reward which may influence the participant's decision or otherwise place the participant at risk, particularly if the participant may be considered vulnerable) is usually considered unethical. Any payment to be made to participants must be proportionate and not seek to induce participants to consent despite any known risks. Researchers are advised to seek guidance on this issue and make use of established frameworks for compensating research participants, particularly in health-related research; please seek advice from the UREC or the relevant College Research Office.

Publication of results

58. It is an ethical requirement that the design and results of the research must, if possible, be published (with the exception of student projects). 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 upon request and to all those who could benefit from them, through publication and/or other appropriate means.

59. 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

60. 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; see the University Research Data Management Policy.

Conflicts of interest

61. 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. Please refer to the University Conflict and Declaration of Interest Policy.

62. 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.

63. 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

64. 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.

65. 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. Draft application form and documentation will require approval from a Brunel REC via BREO prior to submission via IRAS.

66. Research involving relevant material as classified by the Human Tissue Authority must be reviewed and approved by the relevant Designated Individual, and may require review by the University Research Ethics Committee together with the Human Tissue Act Sub-Committee (please seek advice from the research ethics team via email to res-ethics@brunel.ac.uk). Please refer to the University Code of Practice on Working with Human Tissue Samples for further guidance.

67. 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.

68. Social Care research may require external review; please click here for further guidance.

69. Research commissioned by or involving the Ministry of Defence will require external review by the Ministry of Defence Research Ethics Committee. Draft application form and documentation will normally require approval from a Brunel REC via BREO prior to submission to the external REC.

70. Research involving prisoners or those engaged with Her Majesty's Prison and Probation Service will require external review by the HMPPS via IRAS. Draft application form and documentation will require approval from a Brunel REC via BREO prior to submission to the external REC.

71. All research carried out by Brunel University London staff and students must conform to the University Code. In addition, researchers are required to observe the ethical

guidelines established by the appropriate Society or professional body, as laid down from time to time.

D. Guidance on the research ethics approval process

72. All applications for research ethics approval from a Brunel REC should be made via Brunel Research Ethics Online (BREO). Please refer to your College Research Office for guidance on using the system. User guides for both applicants and reviewers provide basic instruction on using the system. Training is widely available for staff and students, and guidance is embedded within the BREO system and application form.

73. Researchers must comply with this Code (and all other relevant University policies) for the duration of an approved research project. Protocols which have been approved by a Research Ethics Committee (REC) must be adhered to throughout the life of the project, and changes cannot be implemented without the prior approval of the same REC. No changes in protocol are to be put into effect without formal approval, except where necessary to eliminate immediate risk of harm to participants or the researcher(s).

74. If the project is approved to run for a duration longer than one year, an annual progress report must be provided to the relevant REC.

75. For the University review and approval flowchart see Appendix 2.

76. For specific guidance relating to College and UREC application and review procedures, see the College Research Ethics Committees Standard Operating Procedures and the University Research Ethics Committee Standard Operating Procedures.

Appendix 1

Research Ethics Appeals

1 Introduction

Every research project conducted by members of Brunel University London, whether staff or student, which proposes to use human participants (including human data and human organs, tissue or cells), must receive ethical approval before data collection can commence. Research ethics approval is granted by either the appropriate College Research Ethics Committee (CREC), or the University Research Ethics Committee (UREC).

There may be instances where research ethics approval is not granted, for a variety of reasons, or approval may be granted subject to certain conditions. In such cases, the Principal Investigator (PI) may wish to appeal the decision of the CREC or UREC. The process to be followed is detailed in this document.

2 Grounds for appeal

A researcher whose application for research ethics approval has been rejected may appeal that decision for any one or more of the following reasons:

- The CREC or UREC has rejected the application because the proposal offends against the University's Ethical Framework, or offends against the University's Research Integrity Policy, or elements of the proposed protocol offends against the University's Code of Research Ethics, and the researcher disagrees with the decision;

- The researcher objects to the conditions that have been placed on the proposal, necessitating major amendments, and the researcher considers that:

    - The reviewer(s) have misinterpreted the provisions of the Code;

    - The amendments requested are external to the parameters of the Application Form;

- The researcher considers that the Committee has demonstrated bias, and the review was conducted unfairly, on the basis that:

    - There was a procedural irregularity;

    - The reviewer(s) failed to give reasons for not approving the proposal;

    - The competence of the researcher has been unfairly impugned;

- The reviewer(s) were not competent in the relevant area of expertise.

The decision of a CREC may be appealed to the UREC; the decision of the UREC may

be appealed to Council.

3 Procedures

3.1 Requesting an appeal

A researcher who wishes to lodge an appeal against a refusal of ethical approval must notify the appropriate person (defined below) within 28 working days of the relevant Committee's notification of its decision.

If the appeal is against a decision by a CREC, details should be sent in writing to the Chair of the University Research Ethics Committee (res-ethics@brunel.ac.uk).

If the appeal is against a decision by the UREC, details should be sent in writing to the Secretary to Council. An appeal against a decision by the UREC may be made regardless of whether the decision to refuse ethical approval was first made by a CREC. Where a decision of a CREC is appealed and upheld by the UREC, an appeal may be made to Council for a final decision.

The written communication requesting an appeal must include the grounds for the appeal.

3.2 Appeal to the University Research Ethics Committee

An appeal to the UREC shall normally be heard within 30 working days of receipt of the appeal. The appeal will be heard by the whole Committee (except as noted below), or, if this is not possible, by a quorum of the Committee, including at least one lay member.

The member or members of the Committee who represent the appellant's College will **not** be present at the hearing.

3.3 Appeal to Council

An appeal to Council will normally be heard within 60 working days of receipt of the notice of appeal. Council will appoint an Appeal Panel to hear the appeal, to consist of:

- A lay member of Council
- A member of an appropriate national body with relevant expertise (such as ARMA), who is independent of Brunel University
- Three members of academic staff who are not of the same College as the appellant
- One non-voting specialist advisor drawn from the same discipline as the appellant, who may or may not be a member of the same College as the appellant.

The Appeals Panel will choose one of its number to be Chair.

The Secretary to Council or his or her nominee shall appoint a senior member of the University's administrative staff not previously connected with the case to be Secretary to the Panel.

3.4 Representation and challenges

The Committee Chair or the Chair of the Appeal Panel may call witnesses to attend the hearing.

All parties shall have the right to be accompanied by a work colleague or trade union representative. For purposes of clarity no legal representation is permitted.

The Secretary of the Committee or Panel hearing the appeal will notify the parties in writing of the names of the Committee or Panel members.

Any party to the Appeal may object to a member of the Committee or Panel, as appropriate, including the Secretary to the Committee or Panel. The objection must be made within 5 working days of receiving notification of the names of the members of the Committee or Panel. Objections, with reasons, must be sent in writing to the appropriate Secretary, who will copy them to the other parties. The other parties may make written representations within 5 working days. The objections and representations will be considered, in the case of a challenge to a member of the Appeals Panel, by the Secretary to Council, or his or her nominee. In the case of a challenge to a member of the UREC, these will be considered by the Vice-Provost (Research) or his/her delegate. A written decision with respect to the challenge will be provided with reasons; this decision shall be final.

3.5 Documentation

The Secretary to the Committee or Panel hearing the appeal shall obtain and make available as soon as possible, and not later than 5 working days prior to the date of the hearing, to all parties and the members of the Committee or Panel, the following documents:

- A copy of the original application for research ethics approval
- A copy of the written response to the appellant from the Committee which turned down or sought amendments to the application
- A written, signed statement by the appellant, detailing the grounds for appeal and any relevant supporting evidence
- A written statement by the Chair of the Committee against which the appeal has been lodged.

4 Order of proceedings

The Committee or Panel shall examine the documents and determine if there is evidence

of a *prima facie* case. If the determination is that a case exists, then a hearing shall be held.

The Secretary of the Committee or Panel hearing the appeal shall notify the parties of the date of the hearing, not later than 10 working days prior to that date.

The Committee or Panel shall determine the order of proceedings, whether any further information is required, and whether any witnesses may be called.

The order of proceedings shall be notified to all parties not later than 2 working days before the hearing.

5 Notification of decision

The Committee or Panel shall prepare a written report of its findings and the reasons for its decision. A copy of the report shall be sent to the parties to the appeal within 10 working days of the conclusion of the hearing.

The Committee or Panel may:

- Uphold the appeal in whole or in part;
- Dismiss the appeal.

The decision shall be made available, but the report shall be confidential and shall not be disclosed or published to others except with the consent of the parties or where required by law.

Where the appeal has been heard by the Appeals Panel of Council, the decision of that Panel shall be final within the University.

6 Extension of enrolment/probation

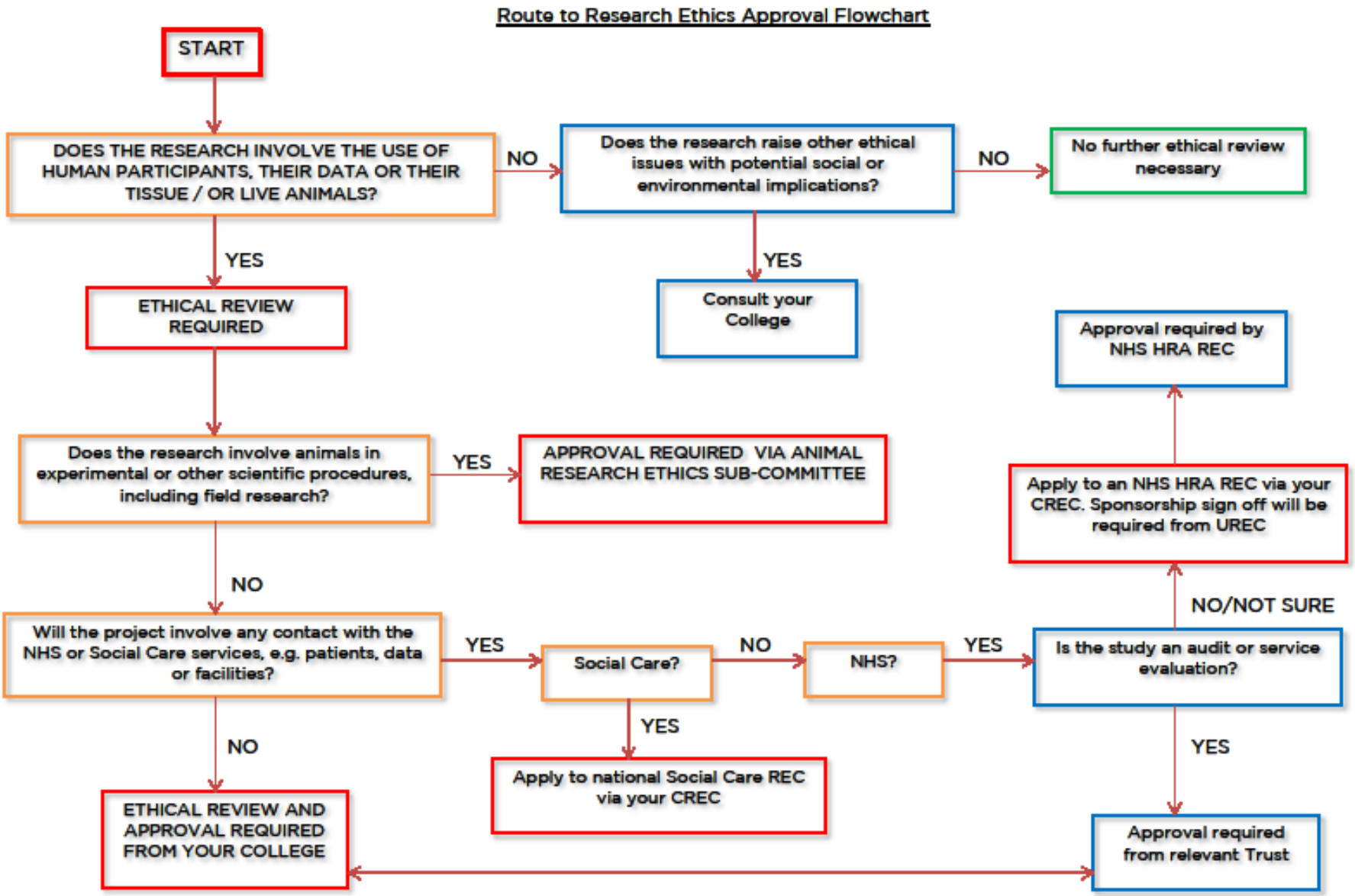
If a student appeals an ethics committee decision regarding his/her research project, and the appeal is upheld, the student's enrolment period will be appropriately extended, and the student will not incur any additional financial obligation with regard to University fees.

If a probationary member of staff appeals an ethics committee decision regarding his/her research project, and the appeal is upheld, the Committee or Panel can recommend to the College's probation panel that it consider recommending to the Committee of Academic Staff Promotions (CASP) that the person's probationary period be extended.

7 References and further information

- ESRC Research Ethics Framework
- Brunel University Statutes

APPENDIX 2


Route to Research Ethics Approval Flowchart
START
DOES THE RESEARCH INVOLVE THE USE OF HUMAN PARTICIPANTS, THEIR DATA OR THEIR TISSUE / OR LIVE ANIMALS?
NO
Does the research raise other ethical issues with potential social or environmental implications?
NO
No further ethical review necessary
YES
Consult your College
YES
ETHICAL REVIEW REQUIRED
Does the research involve animals in experimental or other scientific procedures, including field research?
YES
APPROVAL REQUIRED VIA ANIMAL RESEARCH ETHICS SUB-COMMITTEE
NO
Will the project involve any contact with the NHS or Social Care services, e.g. patients, data or facilities?
YES
Social Care?
NO
NHS?
YES
Is the study an audit or service evaluation?
NO/NOT SURE
Apply to an NHS HRA REC via your CREC. Sponsorship sign off will be required from UREC
Approval required by NHS HRA REC
YES
Apply to national Social Care REC via your CREC
NO
ETHICAL REVIEW AND APPROVAL REQUIRED FROM YOUR COLLEGE
YES
Approval required from relevant Trust